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Title 3—

The President

Executive Order 13703 of July 30, 2015

Implementing the National HIV/AIDS Strategy for the United States for 2015–2020

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to ensure improved health outcomes for Americans at risk for or living with HIV/AIDS and achieve greater coordination across the Federal Government, I hereby order as follows:

Section 1. *Policy.* My Administration has made substantial progress in addressing the domestic HIV epidemic since the National HIV/AIDS Strategy for the United States (Strategy), the first of its kind, was released in July 2010. The Strategy has served as a blueprint for executive departments and agencies (agencies) as well as for community partners in the private and nonprofit sectors. This effort has led to increased coordination and collaboration among agencies and fostered the use of evidence-based policy approaches for improving HIV prevention and care.

Federal, State, and local agencies have contributed to significant improvements in health outcomes through their enhanced focus on the HIV care continuum—the sequential stages of care from being diagnosed to achieving viral suppression. Our partners across all levels of government and all sectors of society have also worked to ensure that all Americans living with HIV/AIDS receive our full support at every stage of their illness.

Further, my Administration has been committed to reducing the HIV-related disparities experienced by certain populations, including gay and bisexual men of all races and ethnicities, Black women and men, Latino women and men, people who inject drugs, youth aged 13–24, people in the Southern United States, and transgender women. Addressing the intersection between HIV/AIDS, violence against women and girls, and gender-related health disparities has also been a priority. The Working Group on the Intersection of HIV/AIDS, Violence Against Women and Girls, and Gender-related Health Disparities established in my memorandum of March 30, 2012, has focused its efforts on increasing screenings for HIV and intimate partner violence, addressing violence and trauma when supporting women in HIV care, and expanding public education efforts across all levels of government regarding HIV and violence against women and girls.

Today, I am releasing the National HIV/AIDS Strategy for the United States: Updated to 2020 (Updated Strategy) to build on this progress. The Updated Strategy integrates the recommendations of the HIV Care Continuum Working Group, established in Executive Order 13649 of July 15, 2013 (HIV Care Continuum Initiative), and the recommendations of the Working Group on the Intersection of HIV/AIDS, Violence Against Women and Girls, and Gender-related Health Disparities, so that their work can inform the Nation's response to the domestic HIV/AIDS epidemic. The Updated Strategy also takes into account recent research advancements in our understanding of HIV/AIDS, and builds on the historic successes of the Affordable Care Act, which is helping millions of Americans, including those who are living with HIV, access affordable, quality health care.

This order is designed to ensure successful implementation of the Updated Strategy by requiring coordination and collaboration by, and accountability of, the Federal Government; fostering enhanced and innovative partnerships with State, tribal, and local governments; and encouraging the commitment

of all parts of society. The duties and authorities this order assigns are in addition to those assigned by my memorandum of July 13, 2010 (Implementation of the National HIV/AIDS Strategy). In light of recent progress and continuing challenges, we must continue to improve our national effort to reduce new HIV infections, increase access to care for people living with HIV, reduce HIV-related disparities and health inequities, and achieve greater coordination across all levels of government.

Sec. 2. *Role of the White House Office of National AIDS Policy (ONAP).* (a) The Director of ONAP, in consultation with the Director of the Office of Management and Budget (OMB), shall be responsible for monitoring the implementation of the Updated Strategy.

(b) The Director of ONAP shall annually report to the President on the implementation of the Updated Strategy, including progress in meeting key targets and taking key actions identified in the Updated Strategy and the Federal Action Plan, an annual guidepost developed by ONAP in conjunction with agencies, designed to implement new efforts to address the domestic HIV/AIDS epidemic.

Sec. 3. *Lead Agency Responsibilities.* While the Updated Strategy will require a Government-wide effort in order to succeed fully, certain agencies have primary responsibilities and competencies in implementing the Updated Strategy.

(a) *Designation of Lead Agencies.* Lead agencies for implementing the Updated Strategy shall be:

(i) the Department of Defense;

(ii) the Department of Justice;

(iii) the Department of the Interior;

(iv) the Department of Labor;

(v) the Department of Health and Human Services;

(vi) the Department of Housing and Urban Development;

(vii) the Department of Education;

(viii) the Department of Veterans Affairs;

(ix) the Department of Homeland Security; and

(x) the Social Security Administration.

(b) *Lead Agency Action Plans.* Within 100 days of the date of this order, the head of each lead agency shall submit a report to ONAP and OMB on the agency's action plan for implementing the Updated Strategy. The plans shall assign responsibilities to agency officials, designate reporting structures for actions identified in the Federal Action Plan, and identify other appropriate actions to advance the Updated Strategy. The plans shall also include steps to strengthen coordination in planning, budgeting for, and evaluating domestic HIV/AIDS programs within and across agencies. Lead agencies are encouraged to consider, and reflect in their plans, steps to streamline grantee reporting requirements and funding announcements related to HIV/AIDS programs and activities.

(c) *Ongoing Responsibilities of Lead Agencies.* The head of each lead agency shall:

(i) designate an official responsible for coordinating the agency's ongoing efforts to implement the Updated Strategy;

(ii) develop and support a process for sharing progress reports, including status updates on achieving specific quantitative targets established by the Updated Strategy, with relevant agencies and ONAP on an annual basis, or at such other times as ONAP requests; and

(iii) in consultation with OMB, use the budget development process to prioritize programs and activities most critical to meeting the goals of the Updated Strategy.

Sec. 4. *Other Agency Responsibilities.* All agencies that support HIV/AIDS programs and activities shall ensure that, to the extent permitted by law, they are meeting the goals of the Updated Strategy.

(a) *Department of State.* Within 100 days of the date of this order, the Secretary of State shall submit to ONAP and OMB recommendations for improving the Government-wide response to the domestic HIV/AIDS epidemic, based on lessons learned in implementing the President's Emergency Plan for AIDS Relief program.

(b) *Equal Employment Opportunity Commission (Commission).* Within 100 days of the date of this order, the Chair of the Commission shall submit to ONAP and OMB recommendations for increasing employment opportunities for people living with HIV and a plan for addressing employment-related discrimination against people living with HIV, consistent with the Commission's authorities and other applicable law.

Sec. 5. *Role of the Presidential Advisory Council on HIV/AIDS (PACHA).* The PACHA, which was established by Executive Order 12963 of June 14, 1995 (Presidential Advisory Council on HIV/AIDS), as amended, shall monitor the implementation of the Updated Strategy and make recommendations to the Secretary of Health and Human Services (Secretary) and to the Director of ONAP, as appropriate, concerning implementation and progress in achieving the Updated Strategy's goals.

Sec. 6. *National HIV/AIDS Strategy Federal Interagency Working Group.* There is established the National HIV/AIDS Strategy Federal Interagency Working Group (Federal Interagency Working Group) to support the implementation of the Updated Strategy.

(a) *Membership.* The Federal Interagency Working Group shall be co-chaired by the Director of ONAP and the Secretary or their designees. In addition to the Co-Chairs, the Federal Interagency Working Group shall consist of representatives from each lead agency, OMB, and any other agency or office designated by the Co-Chairs.

(b) *Consultation.* The Federal Interagency Working Group shall consult with the PACHA, as appropriate.

(c) *Outreach.* The Federal Interagency Working Group shall hold regular meetings and conduct outreach with representatives of private and nonprofit organizations, State, tribal, and local governments and agencies, elected officials, and other interested persons to assist the Federal Interagency Working Group in its efforts.

(d) *Functions.* As part of its efforts, the Federal Interagency Working Group shall:

(i) request and review information from agencies describing their efforts to implement the Updated Strategy;

(ii) share and disseminate best practices to combat the HIV epidemic among agencies and other stakeholders;

(iii) integrate new HIV-related research results into the overall implementation of the Updated Strategy;

(iv) obtain input from community partners, scientific and technical experts, and stakeholders in State, tribal, and local governments to inform implementation of the Updated Strategy;

(v) increase government and public awareness of HIV-related issues;

(vi) specify how to better align and coordinate Federal efforts, both within and across agencies, to improve health outcomes for Americans at risk for or living with HIV; and

(vii) integrate the Working Group on the Intersection of HIV/AIDS, Violence Against Women and Girls, and Gender-related Health Disparities into the implementation of the Updated Strategy.

(e) *Reporting.*

(i) Within 100 days of the date of this order, the Federal Interagency Working Group shall provide recommendations to the President on actions that agencies should take to implement the Updated Strategy through 2020.

(ii) The Director of ONAP shall include, as part of the Director's annual report to the President, a report prepared by the Federal Interagency Working Group concerning Government-wide progress in implementing the Updated Strategy.

Sec. 7. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department, agency, or the head thereof; or

(ii) the functions of the Director of OMB relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

THE WHITE HOUSE,
July 30, 2015.

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Rules and Regulations

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DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 6

Adjustment of Appendices to the Dairy Tariff-Rate Import Quota Licensing Regulation for the 2015 Tariff-Rate Quota Year

AGENCY: Office of the Secretary, USDA.

ACTION: Final rule.

SUMMARY: This document sets forth the revised appendices to the Dairy Tariff-Rate Import Quota Licensing Regulation for the 2015 quota year reflecting the cumulative annual transfers from Appendix 1 to Appendix 2 for certain dairy product import licenses permanently surrendered by licensees or revoked by the Licensing Authority.

DATES: *Effective:* August 4, 2015.

FOR FURTHER INFORMATION CONTACT: Abdelsalam El-Farra, Dairy Import Licensing Program, Import Policies and Export Reporting Division, U.S. Department of Agriculture, at (202) 720–9439; or by email at: *abdelsalam.el-farra@fas.usda.gov.*

SUPPLEMENTARY INFORMATION: The Foreign Agricultural Service, under a delegation of authority from the Secretary of Agriculture, administers the Dairy Tariff-Rate Import Quota Licensing Regulation codified at 7 CFR 6.20–6.37 that provides for the issuance of licenses to import certain dairy articles under tariff-rate quotas (TRQs) as set forth in the Harmonized Tariff Schedule of the United States. These dairy articles may only be entered into the United States at the low-tier tariff by or for the account of a person or firm to whom such licenses have been issued and only in accordance with the terms and conditions of the regulation.

Licenses are issued on a calendar year basis, and each license authorizes the license holder to import a specified quantity and type of dairy article from a specified country of origin. The Import Policies and Export Reporting Division, Foreign Agricultural Service, U.S. Department of Agriculture, issues these licenses and, in conjunction with U.S. Customs and Border Protection, U.S. Department of Homeland Security, monitors their use.

The regulation at 7 CFR 6.34(a) states: ''Whenever a historical license (Appendix 1) is not issued to an applicant pursuant to the provisions of 6.23, is permanently surrendered or is revoked by the Licensing Authority, the amount of such license will be transferred to Appendix 2.'' Section 6.34(b) provides that the cumulative annual transfers will be published in the **Federal Register**. Accordingly, this document sets forth the revised Appendices for the 2015 tariff-rate quota year.

List of Subjects in 7 CFR Part 6

Agricultural commodities, Cheese, Dairy products, Imports, Reporting and recordkeeping requirements.

Issued at Washington, DC, the 16th day of July, 2015.

Ronald Lord,

Licensing Authority.

Accordingly, 7 CFR part 6 is amended as follows:

PART 6—IMPORT QUOTAS AND FEES

■ 1. The authority citation for Part 6, Subpart—Dairy Tariff-Rate Import Quota Licensing continues to read as follows:

Authority: Additional U.S. Notes 6, 7, 8, 12, 14, 16–23 and 25 to Chapter 4 and General Note 15 of the Harmonized Tariff Schedule of the United States (19 U.S.C. 1202), Pub. L. 97–258, 96 Stat. 1051, as amended (31 U.S.C. 9701), and secs. 103 and 404, Pub. L. 103–465, 108 Stat. 4819 (19 U.S.C. 3513 and 3601).

■ 2. Appendices 1, 2 and 3 to Subpart—Dairy Tariff-Rate Import Quota Licensing are revised to read as follows:

ARTICLES SUBJECT TO: APPENDIX 1, HISTORICAL LICENSES; APPENDIX 2 NON-HISTORICAL LICENSES; AND APPENDIX 3, DESIGNATED IMPORTERS LICENSES FOR QUOTA YEAR 2015

[Quantities in kilograms]

Non-cheese articles	Appendix 1	Appendix 2	Sum of appendix 1 & 2	Appendix 3		Grand total	HTS
				Tokyo R.	Uruguay R.		Chapter 4/2014
BUTTER (NOTE 6)	4,545,013	2,431,987	6,977,000			6,977,000	6,977,000
EU–27	62,599	33,562	96,161				
New Zealand	88,264	62,329	150,593				
Other Countries	39,173	34,762	73,935				
Any Country	4,354,977	2,301,334	6,656,311				
DRIED SKIM MILK (NOTE 7)		5,261,000	5,261,000			5,261,000	5,261,000
Australia	0	600,076	600,076				
Canada	0	219,565	219,565				
Any Country	0	4,441,359	4,441,359				
DRIED WHOLE MILK (NOTE 8)	0	3,321,300	3,321,300			3,321,300	3,321,300
New Zealand	0	3,175	3,175				
Any Country	0	3,318,125	3,318,125				
DRIED BUTTERMILK/ WHEY (NOTE 12)	0	224,981	224,981			224,981	224,981

ARTICLES SUBJECT TO: APPENDIX 1, HISTORICAL LICENSES; APPENDIX 2 NON-HISTORICAL LICENSES; AND APPENDIX 3, DESIGNATED IMPORTERS LICENSES FOR QUOTA YEAR 2015—Continued

[Quantities in kilograms]

Non-cheese articles	Appendix 1	Appendix 2	Sum of appendix 1 & 2	Appendix 3		Grand total	HTS
				Tokyo R.	Uruguay R.		Chapter 4/2014
Canada	0	161,161	161,161				
New Zealand	0	63,820	63,820				
BUTTER SUBSTITUTES CONTAINING OVER 45 PERCENT OF BUTTERFAT AND/OR BUTTER OIL (NOTE 14)	0	6,080,500	6,080,500			6,080,500	6,080,500
Any Country	0	6,080,500	6,080,500				
TOTAL: NON-CHEESE ARTICLES	4,545,013	17,319,768	21,864,781			21,864,781	21,864,781
Cheese articles	**Appendix 1**	**Appendix 2**	**Sum of appendix 1 & 2**	**Tokyo R.**	**Uruguay R.**	**Grand total**	**Chapter 4/2010**
CHEESE AND SUBSTITUTES FOR CHEESE (NOTE 16)	18,385,959	13,083,772	31,469,731	9,661,128	7,496,000	48,626,859	48,626,859
Argentina	0	7,690	7,690	92,310		100,000	100,000
Australia	535,628	5,542	541,170	758,830	1,750,000	3,050,000	3,050,000
Canada	977,439	163,561	1,141,000			1,141,000	1,141,000
Costa Rica	0	0	0		1,550,000	1,550,000	1,550,000
EU–27	14,342,806	8,924,850	23,267,656	1,132,568	3,446,000	27,846,224	27,493,224
Of which Portugal is:	65,838	63,471	129,309	223,691		353,000	353,000
Israel	79,696	0	79,696	593,304		673,000	673,000
Iceland	29,054	264,946	294,000	29,000		323,000	323,000
New Zealand	1,595,012	3,220,460	4,815,472	6,506,528		11,322,000	11,322,000
Norway	122,860	27,140	150,000			150,000	150,000
Switzerland	536,720	134,692	671,412	548,588	500,000	1,720,000	1,720,000
Uruguay	0	0	0		250,000	250,000	250,000
Other Countries	100,906	100,729	201,635			201,635	201,635
Any Country	0	300,000	300,000			300,000	300,000
BLUE-MOLD CHEESE (NOTE 17)	1,947,512	533,489	2,481,001		430,000	2,911,001	2,911,001
Argentina	2,000	0	2,000			2,000	2,000
EU–27	1,945,512	533,488	2,479,000		350,000	2,829,000	2,829,000
Chile	0	0	0		80,000	80,000	80,000
Other Countries	0	1	1			1	1
CHEDDAR CHEESE (NOTE 18)	2,344,177	1,939,679	4,283,856	519,033	7,620,000	12,422,889	12,422,889
Australia	897,786	86,713	984,499	215,501	1,250,000	2,450,000	2,450,000
Chile	0	0	0		220,000	220,000	220,000
EU–27	52,404	210,596	263,000		1,050,000	1,313,000	1,313,000
New Zealand	1,292,374	1,504,094	2,796,468	303,532	5,100,000	8,200,000	8,200,000
Other Countries	101,613	38,276	139,889			139,889	139,889
Any Country	0	100,000	100,000			100,000	100,000
AMERICAN-TYPE CHEESE (NOTE 19)	1,248,043	1,917,510	3,165,553	357,003	0	3,522,556	3,522,556
Australia	761,890	119,108	880,998	119,002		1,000,000	1,000,000
EU–27	140,611	213,389	354,000			354,000	354,000
New Zealand	217,680	1,544,319	1,761,999	238,001		2,000,000	2,000,000
Other Countries	127,862	40,694	168,556			168,556	168,556
EDAM AND GOUDA CHEESE (NOTE 20)	4,335,725	1,270,677	5,606,402	0	1,210,000	6,816,402	6,816,402
Argentina	105,418	19,582	125,000		110,000	235,000	235,000
EU–27	4,114,499	1,174,501	5,289,000		1,100,000	6,389,000	6,389,000
Norway	111,046	55,954	167,000			167,000	167,000
Other Countries	4,762	20,640	25,402			25,402	25,402
ITALIAN-TYPE CHEESES (NOTE 21)	6,179,155	1,341,392	7,520,547	795,517	5,165,000	13,481,064	13,481,064
Argentina	3,762,028	363,455	4,125,483	367,517	1,890,000	6,383,000	6,383,000

Cheese articles	Appendix 1	Appendix 2	Sum of appendix 1 & 2	Tokyo R.	Uruguay R.	Grand total	Chapter 4/2010
EU–27	2,417,127	964,873	3,382,000		2,025,000	5,407,000	5,407,000
Romania	0	0	0		500,000	500,000	500,000
Uruguay	0	0	0	428,000	750,000	1,178,000	1,178,000
Other Countries	0	13,064	13,064			13,064	13,064
SWISS OR EMMENTHALER CHEESE (NOTE 22)	5,182,610	1,468,704	6,651,314	823,519	380,000	7,854,833	7,854,833
EU–27	3,918,461	1,233,533	5,151,994	393,006	380,000	5,925,000	5,925,000
Switzerland	1,230,651	188,836	1,419,487	430,513		1,850,000	1,850,000
Other Countries	33,498	46,335	79,833			79,833	79,833
CHEESE AND SUBSTITUTES FOR CHEESE (NOTE 23)	1,837,206	2,587,702	4,424,908	1,050,000	0	5,474,908	5,474,908
EU–27	1,837,206	2,587,701	4,424,907			4,424,907	4,424,907
Israel	0	0	0	50,000		50,000	50,000
New Zealand	0	0	0	1,000,000		1,000,000	1,000,000
Other Countries	0	1	1			1	1
SWISS OR EMMENTHALER CHEESE WITH EYE FORMATION (NOTE 25)	13,609,024	8,688,307	22,297,331	9,557,945	2,620,000	34,475,276	34,475,276
Argentina	0	9,115	9,115	70,885		80,000	80,000
Australia	209,698	0	209,698	290,302		500,000	500,000
Canada	0	0	0	70,000		70,000	70,000
EU–27	10,081,002	6,395,826	16,476,828	4,003,172	2,420,000	22,900,000	22,900,000
Iceland	0	149,999	149,999	150,001		300,000	300,000
Israel	27,000	0	27,000			27,000	27,000
Norway	2,480,021	1,175,289	3,655,310	3,227,690		6,883,000	6,883,000
Switzerland	763,050	921,055	1,684,105	1,745,895	200,000	3,630,000	3,630,000
Other Countries	48,253	37,023	85,276			85,276	85,276
TOTAL: CHEESE ARTICLES	55,069,411	32,831,232	87,900,643	22,764,145	24,921,000	135,585,788	135,585,788
TOTAL: CHEESE & NON-CHEESE	59,614,424	50,151,000	109,765,424	22,764,145	24,921,000	157,450,569	157,450,569

[FR Doc. 2015–19083 Filed 8–3–15; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–3139; Directorate Identifier 2012–NM–139–AD; Amendment 39–18224; AD 2015–15–14]

RIN 2120–AA64

Airworthiness Directives; BAE Systems (Operations) Limited Airplanes

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

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for all BAE Systems (Operations) Limited Model ATP airplanes. This AD requires a one-time inspection for solder deposited on the frangible plug of certain engine and auxiliary power unit (APU) fire extinguishers. This AD was prompted by reports of a fire extinguisher that failed to discharge due to solder deposited on the frangible plug of the fire extinguisher. We are issuing this AD to detect and correct solder deposited on the frangible plug of the fire extinguisher, which could result in failure of the fire extinguisher to discharge, and consequent inability to put out a fire in an engine or in the APU.

DATES: This AD becomes effective August 19, 2015.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of August 19, 2015.

We must receive comments on this AD by September 18, 2015.

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

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

For BAE Systems (Operations) Limited service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom;

telephone: +44 1292 675207; fax: +44 1292 675704; email: *RApublications@baesystems.com*; Internet *http://www.baesystems.com/Businesses/RegionalAircraft/index.htm*.

For Kidde Graviner service information identified in this AD, contact Kidde Graviner Limited, Mathisen Way, Colnbrook, Slough, Berkshire, SL3 0HB, United Kingdom; telephone: +44 (0)1753 683245, fax: +44 (0)1753 685040.

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. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3139.

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–2015–3139; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone: 425–227–1175; fax: 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2012–0127R1, dated September 10, 2012 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all BAE Systems (Operations) Limited Model ATP airplanes. The MCAI states:

> A fire handle on a BAe 146 aeroplane was operated on the ground as a precautionary measure after the throttle cable on the affected engine failed, due to corrosion. The extinguisher failed to discharge.
>
> Investigation results revealed that excess solder, which had been deposited during overhaul on the frangible plug of the extinguisher, prevented the release of the extinguishant. Prompted by this report, Kidde Graviner, the fire extinguisher manufacturer, identified four further extinguishers of similar design that had the same issue. The ATP aeroplane extinguisher is one of those of a similar design.
>
> This condition, if not detected and corrected, could result in the failure of a fire bottle to discharge, which reduces the ability of the fire protection system to extinguish fires in the engine or Auxiliary Power Unit (APU) fire zones, possibly resulting in damage to the aeroplane and injury to the occupants.
>
> For the reasons described above, EASA issued AD 2012–0127 [dated July 10, 2012, *http://ad.easa.europa.eu/ad/2012-0127R1*] to require a one-time inspection of the affected Part Number (P/N) 57183 engine and APU fire extinguishers. In addition, this [EASA] AD prohibited installation of a fire extinguisher, unless it has passed the inspection as required by AD 2012–0127.
>
> Revision 1 of this [EASA] AD is issued to clarify that new extinguishers P/N 57183 may be fitted with no additional inspection required by this [EASA] AD.

You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3139.

Related Service Information Under 1 CFR Part 51

BAE Systems (Operations) Limited and Kidde Graviner have issued the following service information.

- BAE Systems (Operations) Limited Service Bulletin ATP–26–016, dated October 4, 2011. The service information describes procedures for an inspection for solder deposited on the frangible plug of certain engine and APU fire extinguishers.
- Kidde Graviner Service Bulletin 26–080, Revision 1, dated July 27, 2011. The service information describes procedures for an inspection for solder deposited on the frangible plug of certain engine and APU fire extinguishers.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this AD.

FAA's Determination and Requirements of This AD

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

FAA's Determination of the Effective Date

Since there are currently no domestic operators of this product, notice and opportunity for public comment before issuing this AD are unnecessary.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–3139; Directorate Identifier 2012–NM–139–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD based on those comments.

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

Costs of Compliance

Currently, there are no affected airplanes on the U.S. Register. However, if an affected airplane is imported and placed on the U.S. Register in the future, the required actions will take about 1 work-hour, at an average labor rate of $85 per work-hour. Based on these figures, we estimate the cost of this AD to be $85 per airplane.

In addition, we estimate that any necessary follow-on actions will take about 1 work-hour and require parts costing $7,042, for a cost of $7,127 per product.

Authority for This Rulemaking

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

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

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

Regulatory Findings

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

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

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

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):

2015–15–14 BAE Systems (Operations) Limited: Amendment 39–18224. Docket No. FAA–2015–3139; Directorate Identifier 2012–NM–139–AD.

(a) Effective Date

This AD becomes effective August 19, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all BAE Systems (Operations) Limited Model ATP airplanes, certificated in any category, all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 26, Fire Protection.

(e) Reason

This AD was prompted by reports of a fire extinguisher that failed to discharge due to solder deposited on the frangible plug of the fire extinguisher. We are issuing this AD to detect and correct solder deposited on the frangible plug of the fire extinguisher, which could result in failure of the fire extinguisher to discharge, and consequent inability to put out a fire in an engine or in the APU.

(f) Compliance

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

(g) Inspection of Fire Extinguishers

(1) For airplanes equipped with Kidde Graviner fire extinguishers having part number (P/N) 57183 (all dash numbers): Within 12 months after the effective date of this AD, inspect each affected fire extinguisher for solder deposited on the frangible plug of the fire extinguisher, in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Service Bulletin ATP–26–016, dated October 4, 2011, and Kidde Graviner Service Bulletin 26–080, Revision 1, dated July 27, 2011. If any solder deposit is detected, replace the fire extinguisher with a serviceable fire extinguisher before further flight, in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Service Bulletin ATP–26–016, dated October 4, 2011.

(2) Fire extinguishers that meet any condition identified in paragraph (g)(2)(i), (g)(2)(ii), or (g)(2)(iii) of this AD are compliant with the requirements of paragraph (g)(1) of this AD.

(i) Fire extinguishers that have been overhauled by Kidde Graviner or Hugen.

(ii) Fire extinguishers that have been overhauled as specified in Kidde Graviner Service Information Letter (SIL) 01–10, dated July 29, 2010.

(iii) Fire extinguishers that have been overhauled as specified in Kidde Graviner Component Maintenance Manual with Illustrated Parts List 26–21–52, Automatic Extinguishers with Steel Containers Part Numbers 57133, 57135, 57145, and 57183 Series, Revision 17, dated June 13, 2012.

(h) Definition of ''Overhaul''

For the purpose of this AD, an overhaul is considered to include replacement of the operating head. Replacement of the pressure relief plug assembly only is not considered an overhaul.

(i) Parts Installation Limitations

As of the effective date of this AD, do not install a Kidde Graviner fire extinguisher having P/N 57183 (all dash numbers) on any airplane, unless the fire extinguisher meets any condition specified in paragraph (i)(1), (i)(2), (i)(3), (i)(4), or (i)(5) of this AD.

(1) The fire extinguisher is new.

(2) The fire extinguisher has passed the inspection as specified in the instructions of Kidde Graviner Service Bulletin 26–080, Revision 1, dated July 27, 2011.

(3) The fire extinguisher has been overhauled by Kidde Graviner or Hugen.

(4) The fire extinguisher has been overhauled as specified in the instructions of Kidde Graviner SIL 01–10, dated July 29, 2010.

(5) The fire extinguisher has been overhauled in accordance with Kidde Graviner Component Maintenance Manual with Illustrated Parts List 26–21–52, Automatic Extinguishers with Steel Containers Part Numbers 57133, 57135, 57145, and 57183 Series, Revision 17, dated June 13, 2012.

(j) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraphs (g)(2)(iii) and (i)(5) of this AD, if those actions were performed before the effective date of this AD in accordance with the service information identified in paragraph (j)(1), (j)(2), (j)(3), or (j)(4) of this AD. These documents are not incorporated by reference in this AD.

(1) Kidde Graviner Component Maintenance Manual with Illustrated Parts List 26–21–52, Automatic Extinguishers with Steel Containers Part Numbers 57133, 57135, 57145, and 57183 Series, Revision 13, dated August 9, 2010.

(2) Kidde Graviner Component Maintenance Manual with Illustrated Parts List 26–21–52, Automatic Extinguishers with Steel Containers Part Numbers 57133, 57135, 57145, and 57183 Series, Revision 14, dated August 8, 2011.

(3) Kidde Graviner Component Maintenance Manual with Illustrated Parts List 26–21–52, Automatic Extinguishers with Steel Containers Part Numbers 57133, 57135, 57145, and 57183 Series, Revision 15, dated January 16, 2012.

(4) Kidde Graviner Component Maintenance Manual with Illustrated Parts List 26–21–52, Automatic Extinguishers with Steel Containers Part Numbers 57133, 57135, 57145, and 57183 Series, Revision 16, dated May 21, 2012.

(k) 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: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1175; 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: 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 BAE Systems (Operations) Limited's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2012–0127R1, dated September 10, 2012, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3139.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (m)(4), (m)(5), and (m)(6) of this AD.

(m) 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) BAE Systems (Operations) Limited Service Bulletin ATP–26–016, dated October 4, 2011.

(ii) Kidde Graviner Service Bulletin 26–080, Revision 1, dated July 27, 2011.

(3) For BAE Systems (Operations) Limited service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com*; Internet *http://www.baesystems.com/Businesses/RegionalAircraft/index.htm*.

(4) For Kidde Graviner service information identified in this AD, contact Kidde Graviner Limited, Mathisen Way, Colnbrook, Slough, Berkshire, SL3 0HB, United Kingdom; Telephone: +44 (0)1753 683245, Fax: +44 (0)1753 685040.

(5) 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.

(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 July 23, 2015.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–18710 Filed 8–3–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket Nos. FDA–2014–C–1616 and FDA–2015–C–0245]

Listing of Color Additives Exempt From Certification; Mica-Based Pearlescent Pigments; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of July 9, 2015, for the final rule that appeared in the **Federal Register** of June 8, 2015, and that amended the color additive regulations to expand the permitted uses of mica-based pearlescent pigments prepared from titanium dioxide and mica as color additives in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, non-alcoholic cocktail mixers and mixes, and in egg decorating kits for coloring shell eggs.

DATES: Effective date of final rule published in the **Federal Register** of June 8, 2015 (80 FR 32303), confirmed: July 9, 2015.

FOR FURTHER INFORMATION CONTACT: Ellen Anderson, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1309.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 8, 2015 (80 FR 32303), we amended the color additive regulations in § 73.350 *Mica-based pearlescent pigments* (21 CFR 73.350) to expand the permitted uses of mica-based pearlescent pigments prepared from titanium dioxide and mica as color additives in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, non-alcoholic cocktail mixers and mixes, and in egg decorating kits for coloring shell eggs.

We gave interested persons until July 8, 2015, to file objections or requests for a hearing. We received no objections or requests for a hearing on the final rule. Therefore, we find that the effective date of the final rule that published in the **Federal Register** of June 8, 2015, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Office of Food Additive Safety, we are giving notice that no objections or requests for a hearing were filed in response to the June 8, 2015, final rule. Accordingly, the amendments issued thereby became effective July 9, 2015.

Dated: July 29, 2015.

Susan Bernard,

Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

[FR Doc. 2015–18996 Filed 8–3–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2015–N–2526]

Medical Devices; Immunology and Microbiology Devices; Classification of *Trichomonas Vaginalis* Nucleic Acid Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying a *Trichomonas vaginalis* nucleic acid assay into class II (special controls). The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective August 4, 2015. The classification was applicable April 19, 2011.

FOR FURTHER INFORMATION CONTACT: Himani Bisht, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5565, Silver Spring, MD 20993–0002, 301–796–6189.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on April 12, 2011, automatically classifying the APTIMA *Trichomonas vaginalis* Assay in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On April 13, 2011, Gen-Probe Incorporated, submitted a request for de novo classification of the APTIMA *Trichomonas vaginalis* Assay under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request for de novo classification in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 19, 2011, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 866.3860.

Following the effective date of this final classification administrative order, any firm submitting a premarket notification (510(k)) for a *Trichomonas vaginalis* nucleic acid assay will need to comply with the special controls named in the final administrative order.

The device is assigned the generic name *Trichomonas vaginalis* nucleic acid assay, and it is identified as a device that consists of primers, probes, enzymes, and controls for the amplification and detection of trichomonas nucleic acids in endocervical swabs, vaginal swabs, and female urine specimens, from women symptomatic for vaginitis, cervicitis, or urethritis and/or to aid in the diagnosis of trichomoniasis in asymptomatic women. The detection of trichomonas nucleic acids, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of trichomoniasis caused by *Trichomonas vaginalis.*

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks:

TABLE 1—IDENTIFIED RISKS AND REQUIRED MITIGATIONS

Identified risks	Required mitigations
A false positive test result may lead to inappropriate use of antibiotics for treatment.	The FDA document entitled ''Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas vaginalis*'', which addresses this risk through: Specific device description requirements, performance studies, and labeling.
A false negative test result for an individual may lead to a potential delay in treatment.	The FDA document entitled ''Class II Special Controls Guideline: *Trichomonas vaginalis* Nucleic Acid Amplification Test System'', which addresses this risk through: Specific device description requirements, performance studies, and labeling.
Failure of the test to perform properly.	The FDA document entitled ''Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas Vaginalis*'', which addresses this risk through: Labeling.
Failure to properly interpret the test results.	The FDA document entitled ''Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas Vaginalis*'', which addresses this risk through: Labeling

FDA believes that the measures set forth in the special controls guideline entitled ''Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas vaginalis*'' are necessary, in addition to general controls, to mitigate the risks to health described in table 1.

A *Trichomonas vaginalis* nucleic acid assay is a prescription device. Section

510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the *Trichomonas vaginalis* nucleic acid assay they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 866.3860 to subpart D to read as follows:

§ 866.3860 Trichomonas vaginalis nucleic acid assay.

(a) *Identification.* A *Trichomonas vaginalis* nucleic acid assay is a device that consists of primers, probes, enzymes, and controls for the amplification and detection of trichomonas nucleic acids in endocervical swabs, vaginal swabs, and female urine specimens, from women symptomatic for vaginitis, cervicitis, or urethritis and/or to aid in the diagnosis of trichomoniasis in asymptomatic women. The detection of trichomonas nucleic acids, in conjunction with other laboratory tests, aids in the clinical laboratory diagnosis of trichomoniasis caused by *Trichomonas vaginalis*.

(b) *Classification.* Class II (special controls). The special controls are set forth in FDA's guideline document entitled: ''Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas vaginalis;* Guideline for Industry and Food and Drug Administration Staff.'' See § 866.1(e) for information on obtaining this document.

Dated: July 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–19072 Filed 8–3–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. FDA–2015–N–2525]

Medical Devices; Ear, Nose, and Throat Devices; Classification of the External Upper Esophageal Sphincter Compression Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the external upper esophageal sphincter (UES) compression device into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the external UES compression device's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective August 4, 2015. The classification was applicable on March 6, 2015.

FOR FURTHER INFORMATION CONTACT: Sunny Park, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2432, Silver Spring, MD, 20993–0002, 301–796–7059, *sunny.park@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2) of the FD&C Act. Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act.

If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device. On November 22, 2013, Somna Therapeutics, LLC, submitted a request for classification of the REZA BAND UES Assist Device under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 6, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 874.5900.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an external UES compression device will need to comply with the special controls named in this final order. The device is assigned the generic name external UES compression device, and it is identified as a prescription device used to apply external pressure on the cricoid cartilage for the purpose of reducing the symptoms of laryngopharyngeal reflux disease.

FDA has identified the following risks to health associated specifically with this type of device, as well as the mitigation measures required to mitigate these risks, in table 1.

TABLE 1—EXTERNAL UES COMPRESSION DEVICE RISKS AND MITIGATION MEASURES

Identified risk	Mitigation method
Adverse tissue reaction.	Biocompatibility assessment.
Risk of over-compression.	Clinical study. Labeling. Technical specifications.
Device misuse/incorrect fitting/malfunctions.	Technical specifications. Clinical study. Labeling. Performance testing (mechanical integrity and shelf life testing).

FDA believes that the following special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness:

1. The patient contacting components must be demonstrated to be biocompatible.

2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:

a. Mechanical integrity testing (*e.g.,* tensile strength testing, fatigue testing) and

b. shelf life testing

3. The technical specifications must include pressure measurement accuracy to characterize device performance.

4. Clinical performance testing must document any adverse events observed during clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

5. Labeling must include the following:

a. Appropriate warnings and precautions.

b. A detailed summary of the clinical testing pertinent to use of the device including a detailed summary of the device-related complications or adverse events.

c. Detailed instructions on how to fit the device to the patient.

d. Instructions for reprocessing of any reusable components.

6. Patient labeling must be provided and must include:

a. Relevant warnings, precautions, and adverse effects/complications.

b. Information on how to correctly wear the device.

c. The potential risks and benefits associated with the use of the device.

d. Alternative treatments.

e. Reprocessing instructions.

The external UES compression device is a prescription device restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see 21 CFR 801.109 (*Prescription devices*).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the external UES compression device they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov*.

1. DEN130046: De Novo Request per 513(f)(2) from Somna Therapeutics, LLC, dated November 11, 2013.

List of Subjects in 21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 874 is amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

■ 1. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 874.5900 to subpart F to read as follows:

§ 874.5900 External upper esophageal sphincter compression device.

(a) *Identification.* An external upper esophageal sphincter compression device is a prescription device used to apply external pressure on the cricoid cartilage for the purpose of reducing the symptoms of laryngopharyngeal reflux disease.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient contacting components must be demonstrated to be biocompatible.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:

(i) Mechanical integrity testing (*e.g.,* tensile strength testing, fatigue testing) and

(ii) Shelf life testing.

(3) The technical specifications must include pressure measurement accuracy to characterize device performance.

(4) Clinical performance testing must document any adverse events observed during clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

(5) Labeling must include the following:

(i) Appropriate warnings and precautions,

(ii) A detailed summary of the clinical testing pertinent to use of the device including a detailed summary of the device-related complications or adverse events,

(iii) Detailed instructions on how to fit the device to the patient, and

(iv) Instructions for reprocessing of any reusable components.

(6) Patient labeling must be provided and must include:

(i) Relevant warnings, precautions, and adverse effects/complications,

(ii) Information on how to correctly wear the device,

(iii) The potential risks and benefits associated with the use of the device,

(iv) Alternative treatments, and

(v) Reprocessing instructions.

Dated: July 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–19074 Filed 8–3–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2015–0543]

RIN 1625–AA00; 1625–AA11

Safety Zones and Regulated Navigation Area; Shell Arctic Drilling/Exploration Vessel and Associated Voluntary First Amendment Area, Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary safety zones around Royal Dutch Shell's (Shell) contracted vessel FENNICA, which is participating in Shell's planned Arctic oil drilling and exploration operations, while it is located in the U.S. Territorial and Internal Waters of the Sector Columbia River Captain of the Port Zone. In addition, the Coast Guard is establishing a regulated navigation area to designate a Voluntary First Amendment Area for individuals that desire to exercise their First Amendment free speech rights with regards to Shell's operations. The safety zones and regulated navigation area created by this rule are necessary to ensure the mutual safety of all waterways users including the FENNICA and those individuals that desire to exercise their First Amendment rights.

DATES: This rule is effective without actual notice from August 4, 2015 until August 22, 2015. For the purposes of enforcement, actual notice will be used from July 22, 2015 until August 4, 2015.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2015–0543 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 Lieutenant Commander Laura Springer, Waterways Management Division, Coast Guard Marine Safety Unit Portland; telephone (503) 240–2594, email *Laura.M.Springer@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

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

A. 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 because publishing an NPRM would be impracticable since the regulation is immediately necessary to help ensure the safety of all waterway users including the Shell contracted vessel FENNICA and those individuals that desire to exercise their First Amendment rights regarding Shell's activities and holding a notice and comment period at this time would delay regulatory implementation beyond the arrival of the FENNICA and expected start of First Amendment activities regarding Shell's operations, thereby increasing the safety risk to all waterways users.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. For reasons identical to those described above, delaying the effective

date until 30 days after publication would be impracticable since the regulation is immediately necessary to help ensure the safety of all waterway users.

B. Basis and Purpose

The legal basis for this rule is the Coast Guard's authority to establish limited access areas: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

Shell is planning Arctic oil drilling and exploration operations for the summer of 2015. One of the Shell contracted vessels related to these operations, FENNICA, has been damaged and will be returning to Portland, Oregon for repairs. Over the last several months there has been significant waterborne First Amendment activity related to Shell's operations, particularly in the Puget Sound region, and the Coast Guard believes there will be similar activity in the greater Portland area related to FENNICA's presence there. The First Amendment activity previously observed includes unauthorized boardings of Shell contracted vessels and the formation of a ''kayak flotilla'' designed to protest as well as attempt to block Shell contracted vessels from departing for the Arctic.

Draft restrictions, vessel maneuvering characteristics, and geographic/environmental conditions may constrain the ability of large commercial vessels such as FENNICA to maneuver in close quarters with other vessels, particularly small craft piloted by recreational operators. Intentional close-in interaction of these vessels will create an increased risk of collision, grounding, or personal injury for all parties. Furthermore, while moored, at anchor, and in drydock the FENNICA will have ongoing operations occurring onboard, some of which could pose a safety risk to other maritime traffic. The myriad of potential safety risks to all parties and the port itself is best addressed by mandating a minimum zone of separation. For these reasons, the Coast Guard believes that a safety zone around the FENNICA is necessary to ensure the safety of all waterways users.

Additionally, the Coast Guard believes that given the nature of the First Amendment activity expected and the likely type of vessels used by individuals desiring to express their First Amendment rights, namely kayaks and other small vessels, a regulated navigation area designating a Voluntary First Amendment Area is necessary to ensure the safety of those vessels and persons. The regulated navigation area encompassing the Voluntary First Amendment Area would do so by establishing it as a ''no wake'' area, which is particularly important for small boats such as kayaks, to better enable persons and vessels to congregate and exercise their First Amendment rights safely and without interference from or interfering with other maritime traffic.

C. Discussion of the Final Rule

In this rule, the Coast Guard is establishing safety zones around the FENNICA, a Shell contracted vessel involved in the company's Arctic oil drilling and exploration operations, and a regulated navigation area for a Voluntary Free Speech Area that will allow individuals a meaningful opportunity to be heard in exercising their First Amendment rights while not compromising the safety of maritime traffic or the individuals exercising their First Amendment rights.

The safety zones are established in subsection (a) of this temporary regulation. Per subsection (a)(1)(i), while transiting, the safety zone around FENNICA will encompass all waters within a rectangle measuring 500 yards in front and 100 yards to the port, starboard, and astern of that vessel and any other vessel actively engaged in towing or escorting it. Per subsection (a)(1)(ii), while moored, anchored, or in drydock, the safety zone around FENNICA will encompass all waters within 100 yards of the vessel in all directions. Persons and/or vessels that desire to enter these safety zones must request permission to do so from the Captain of the Port, Columbia River by contacting the Coast Guard Sector Columbia River Command Center at 866–284–6958 or 503–861–6211, or the on-scene Law Enforcement patrol craft, if any, via VHF–FM CH 16.

The Coast Guard is also establishing a regulated navigation area to ensure the safety of individuals that desire to exercise their First Amendment rights related to Shell's activities in subsection (b) of this regulation. The Voluntary First Amendment Area is being established in an area where we believe individuals will be able to effectively communicate their message, without posing an undue risk to maritime safety, after analyzing maritime traffic patterns and other environmental factors. The regulated navigation area encompassing the Voluntary First Amendment Area will ensure the safety of small boats by establishing it as a ''no wake'' area for persons and/or vessels to congregate and exercise their First Amendment rights safely and without interference from or interfering with other maritime traffic. The ''no wake'' provisions will ensure all interactions between vessels within the area occur at a low rate of speed, thereby reducing risk of collision and personal injury. Likewise, the designation of a Voluntary First Amendment Area will help to ensure that a large congregation of vessels does not impede or endanger other commercial and recreational users who are not associated with Shell's arctic drilling and exploration operations or the associated First Amendment activity.

These provisions are particularly vital given the expected presence of a ''kayak flotilla'' described above. Persons or vessels desiring to exercise their First Amendment rights to free speech regarding Shell's Arctic drilling and exploration operations may enter the regulated navigation area at any time. All other persons or vessels are advised to avoid the regulated navigation area. When inside the regulated navigation area, all vessels must proceed at ''no wake'' speed and with due regard for all other persons and/or vessels inside the regulated navigation area.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes and 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 rule is not a significant regulatory action as the safety zones and regulated navigation area are limited in both size and duration and any person and/or vessel needing to transit through the safety zones or regulated navigation area may be allowed to do so in accordance with the regulatory provisions.

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 term

''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit the affected waterways when the safety zones and regulated navigation area are in effect. The safety zones and regulated navigation area will not have a significant economic impact on a substantial number of small entities, however, because the safety zones and regulated navigation area are limited in both size and duration and any person and/or vessel needing to transit through the safety zones or regulated navigation area may be allowed to do so in accordance with the regulatory provisions.

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. First Amendment Activities

The Coast Guard respects the First Amendment rights of all individuals. This regulation establishes a regulated navigation area to create a Voluntary First Amendment Area so that persons and vessels can congregate and exercise their First Amendment free speech rights safely and without interference from or interfering with other maritime traffic. Of particular note, large vessels operating in restricted waters cannot maneuver freely, nor can they stop immediately. As such, any First Amendment activity taking place in immediate proximity to such vessels can quickly result in extremis. The Voluntary First Amendment Area has been located to allow individuals a meaningful opportunity to be heard. Individuals that desire to exercise their First Amendment rights are asked utilize the designated area to the extent possible, however, its use is voluntary. Individuals that desire to exercise their First Amendment rights outside the designated area are requested to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate their activities so that their message can be heard, 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 the establishment of temporary safety zones and a regulated navigation area to deal with an emergency situation that is one week or longer in duration. 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**.

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; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T13–292 to read as follows:

§ 165.T13–292 Safety Zones and Regulated Navigation Area; Shell Arctic Drilling/Exploration Vessel and Associated Voluntary First Amendment Area, Portland, OR.

(a) *Safety Zones*—(1) *Location.* The following areas are designated as safety zones:

(i) All waters within a rectangle measuring 500 yards in front and 100 yards to the port, starboard, and astern of the vessel FENNICA and any other vessel actively engaged in towing or escorting it while transiting within the U.S. Territorial or Internal Waters of the Sector Columbia River Captain of the Port Zone as defined in 33 CFR 3.65–15.

(ii) All waters within 100 yards of the vessel FENNICA while moored, anchored, or in drydock within the U.S. Territorial or Internal Waters of the Sector Columbia River Captain of the Port Zone as defined in 33 CFR 3.65–15.

(2) *Regulations.* In accordance with the general regulations in 33 CFR part 165 Subpart C, no persons or vessels may enter these safety zones unless authorized by the Captain of the Port, Columbia River or his designated representative. To request permission to enter one of these safety zones contact the Coast Guard Sector Columbia River Command Center at 866–284–6958 or 503–861–6211, or the on-scene Law Enforcement patrol craft, if any, via VHF–FM CH 16. If permission for entry into one of these safety zones is granted, vessels must proceed at a minimum speed for safe navigation.

(b) *Regulated Navigation Area*—(1) *Location.* The following area is designated as a regulated navigation area: All waters of Swan Island Basin south east from a line connecting the following points: 45°34′04″ N, 122°42′57″ W and 45°34′00″ N, 122°43′03″ W.

(2) *Regulations.* In accordance with the general regulations in 33 CFR part 165 Subpart B, persons or vessels desiring to exercise their First Amendment right to free speech regarding Royal Dutch Shell's Arctic drilling and exploration operations may enter the regulated navigation area at any time. All other persons or vessels are advised to avoid the regulated navigation area. When inside the regulated navigation area, all vessels must proceed at no wake speed and with due regard for all other persons and/or vessels inside the regulated navigation area.

(c) *Dates.* This rule will be enforced from July 22, 2015 through August 22, 2015.

Dated: July 22, 2015.

D.L. Cottrell,

Captain, U.S. Coast Guard, Acting Commander, Thirteenth Coast Guard District.

[FR Doc. 2015–19120 Filed 8–3–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AP21

Vet Centers

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its medical regulation that governs Vet Center services. The National Defense Authorization Act for Fiscal Year 2013 (the 2013 Act) requires Vet Centers to provide readjustment counseling services to broader groups of veterans, members of the Armed Forces, including a member of a reserve component of the Armed Forces, and family members of such veterans and members. This interim final rule amends regulatory criteria to conform to the 2013 Act, to include new and revised definitions.

DATES: *Effective date:* This rule is effective on August 4, 2015.

Comment date: Comments must be received by VA on or before October 5, 2015.

ADDRESSES: Written comments may be submitted through *www.Regulations.gov;* by mail or hand-delivery to Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to ''RIN 2900–AP21—Vet Centers.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Michael Fisher, Readjustment Counseling Service (10RCS), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420; (202) 461–6525. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On September 17, 2013, VA promulgated 38 CFR 17.2000, which implemented VA's authority to provide readjustment counseling services through Vet Centers based on 38 U.S.C. 1712A, as amended by the Caregivers and Veterans Omnibus Health Services Act of 2010 (the 2010 Act), Public Law 111–163, sec. 304, 401(a) and (b). The 2010 Act amended section 1712A to require VA to provide readjustment counseling services to certain servicemembers and veterans who served on active duty in specific theaters of combat operations, or in certain areas in which hostilities occurred. The 2010 Act also mandated that VA provide readjustment counseling to veterans and servicemembers of Operation Enduring Freedom and Operation Iraqi Freedom, and the family members of such veterans and servicemembers after the veterans and servicemembers return from deployment. Although not expressly stated in the 2010 Act, VA also considered veterans, servicemembers, and the family members of such veterans and servicemembers who participated in Operation New Dawn as eligible for readjustment counseling. In promulgating § 17.2000, VA implemented the mandates in the 2010 Act, as well as interpreted section 1712A to permit VA to provide readjustment counseling to family members of all veterans that were themselves eligible for readjustment counseling. See 77 FR 14707 and 78 FR 57067. The term ''servicemembers'' as used in § 17.2000 means a member of the Armed Forces, including a member of a reserve component of the Armed Forces. We note, however, that the terms servicemembers and member of the Armed Forces, including a member

of a reserve component of the Armed Forces, are not used consistently in § 17.2000. We are, therefore, amending § 17.2000 to reflect the statutory language, which is member of the Armed Forces, including a member of a reserve component of the Armed Forces. This change in term will not affect or otherwise change the types of individuals who are eligible to receive care in Vet Centers.

On January 2, 2013, Congress enacted the National Defense Authorization Act for Fiscal Year 2013, Public Law 112–239 (Jan. 2, 2013) (the 2013 Act), section 727 of the 2013 Act amended section 1712A to broaden the groups of individuals who are eligible to receive readjustment counseling from VA. Section 17.2000 is revised to conform to these amendments. Section 1712A(a)(1)(C)(i) requires VA to provide readjustment counseling to veterans and members of the Armed Forces, including a member of a reserve component of the Armed Forces, who served on active duty in a theater of combat operations or an area at a time during which hostilities occurred in that area, without restricting eligibility to any specific theater during combat operations, or any specific area of hostilities. Paragraph (a) of § 17.2000 is revised to restate this statutory eligibility in new § 17.2000(a)(1)(i). We note that § 17.2000(a)(1)(i), as revised by this rulemaking, encompasses the categories of eligible veterans and members of the Armed Forces, including a member of a reserve component of the Armed Forces, that are listed in current § 17.2000(a)(1) through (a)(4). The revisions made by this rulemaking merely restate and reorganize the existing language to clarify that the listed individuals have been and will continue to be eligible for readjustment counseling. Section 1712A(a)(1)(C)(ii) requires that VA provide readjustment counseling to a veteran or member of the Armed Forces, including a member of a reserve component of the Armed Forces, who provided direct emergency medical or mental health care, or mortuary services to the casualties of combat operations or hostilities, but who at the time was located outside the theater of combat operations or area of hostilities. Paragraph (a) of § 17.2000 is revised to restate this statutory eligibility in new § 17.2000(a)(1)(ii). Section 1712A(a)(C)(1)(iii) states that VA shall provide readjustment counseling to a veteran or member of the Armed Forces, including a member of a reserve component of the Armed Forces, who engaged in combat with an enemy of the United States or against an opposing military force in a theater of combat operations or an area at a time during which hostilities occurred in that area by remotely controlling an unmanned aerial vehicle, notwithstanding whether the physical location of such veteran or member during such combat was within such theater of combat operations or area. Paragraph (a) of § 17.2000 is revised to restate this statutory eligibility in new § 17.2000(a)(1)(iii).

VA consulted with the Department of Defense (DoD) to clarify the individuals who are considered as remotely controlling an unmanned aerial vehicle. DoD indicated that individuals who remotely control unmanned aerial vehicles includes, but is not limited to, individuals who pilot the unmanned aerial vehicle as well as individuals who are crew members of the unmanned aerial vehicle and participate in combat related missions. The crew members could include, but are not limited to, intelligence analysts or weapons specialists who control the cameras, engage the weapon systems, as well as those individuals who are directly responsible for the mission of the unmanned aerial vehicle. We defer to DoD's expertise in classifying the individuals who remotely control an unmanned aerial vehicle because they are the ultimate subject matter experts in this field. We are not restricting who VA considers to control an unmanned aerial vehicle, we are merely clarifying who is eligible for readjustment counseling services. This clarifying language is included in paragraph (a)(1)(iii).

Section 1712A(1)(C)(iv) requires that VA provide readjustment counseling to any individual who received counseling under this section before the date of the enactment of the National Defense Authorization Act for Fiscal Year 2013. We are revising § 17.2000(a) to include these individuals as eligible to receive readjustment counseling under new § 17.2000(a)(2). New paragraph (a)(2) is added to clearly state that VA will continue to provide readjustment counseling to individuals who had been receiving such counseling prior to the 2013 Act.

Section 1712A(a)(1)(C)(v)(I) requires that readjustment counseling shall be provided to the family members of a member of the Armed Forces, including a member of a reserve component of the Armed Forces, who is serving on active duty in a theater of combat operations or in an area at a time during which hostilities are occurring in that area. Readjustment counseling shall also be provided to family members of veterans and members of the Armed Forces, including a member of a reserve component of the Armed Forces, who are eligible to receive readjustment counseling under section 1712A, namely those previously listed in this rulemaking. See 38 U.S.C. 1712A(a)(1)(C)(v)(II). Paragraph (a) of § 17.2000 is revised to restate this statutory eligibility in new § 17.2000(a)(3), which uses the broader language in section 1712A (a)(1)(C)(v)(II), because it encompasses the eligibility in (a)(1)(C)(v)(I). Current § 17.2000(a)(5) already provides readjustment counseling broadly to all family members, and new § 17.2000(a)(3) is merely a renumbering of current § 17.2000(a)(5).

Section 1712A provides a definition of the term ''family member'' that is substantively identical to the definition of ''family member'' in current § 17.2000(a)(5), and this definition will be restated in new § 17.2000(a)(3).

Current paragraph (d) of § 17.2000 contains a list of the readjustment counseling services provided by the Vet Centers, defines a ''psychosocial assessment,'' and generally states that readjustment counseling may be provided to eligible veterans and servicemembers, and to their family members when such services would aid in the readjustment of a veteran or servicemember. Section 1712A(a)(1)(B) of 38 U.S.C. uses the term ''comprehensive individual assessment'' with a definition identical to ''psychosocial assessment'' as it is currently used in § 17.2000. We will continue to use the term ''psychosocial assessment'' because it is the term most widely used in VA. We do not interpret the term ''psychosocial assessment'' to have a different meaning than the statutory term ''comprehensive individual assessment.'' We are adding paragraphs (d)(1) through (d)(3) to § 17.2000(d) to better explain when readjustment counseling is provided to veterans, members of the Armed Forces, including a member of a reserve component of the Armed Forces, and their family members, consistent with subsections (a)(1)(B)(i) and (a)(1)(B)(ii) of section 1712A. New § 17.2000(d)(1) states that readjustment counseling is provided for the readjustment of veterans and members of the Armed Forces, including a member of a reserve component of the Armed Forces, to civilian life or readjustment to continued military service following participation in or in support of operations in a combat theater or area of hostility. New § 17.2000(d)(2) states that readjustment counseling is provided for the readjustment of a family member of a member of the Armed Forces,

including a member of a reserve component of the Armed Forces, to aid the family member in coping with such member's deployment. We had previously stated in a proposed rulemaking that readjustment counseling was provided to the veteran's or servicemember's family to assist such veteran in readjusting to civilian life, and further that the readjustment counseling provided to the family members is only to the extent that such readjustment relates to the veteran's or servicemember's military experience. 77 FR 14707, Mar. 13, 2012. The 2013 Act also states that readjustment counseling is provided to such individuals to assist the individual in coping with the veteran's or member's of the Armed Forces, including a member of a reserve component of the Armed Forces, deployment, to assist in the readjustment of the veteran or member to civilian life. We are amending § 17.2000 by adding a new paragraph (d)(3) to conform with the 2013 Act and current VA policy by stating that readjustment counseling is provided to a family member of a veteran or member of the Armed Forces, including a member of a reserve component of the Armed Forces, to aid in a veteran's or member's readjustment to civilian or continued military service following participation in or in support of operations in a combat theater or area of hostility, only as it relates to the veteran's or member's military experience.

Section 1712A(h)(1) defines the term ''Vet Center.'' We add a substantively identical definition of ''Vet Center'' as the last sentence in § 17.2000(e), to mean ''a facility that is operated by VA for the provision of services under this section and that is situated apart from a VA general health care facility.'' Section 17.2000(e) deals with the confidentiality of Vet Center records and this definition will reassure the individuals who receive readjustment counseling that VA maintains the confidentiality of records associated with readjustment counseling.

The authority citation at the end of § 17.2000 is currently 38 U.S.C. 501, 1712A, 1782, and 1783; Pub. L. 111–163, sec. 304, 401, and 402. Because the 2013 Act supersedes the 2010 Act, we amend the authority citation at the end of § 17.2000 to simply state 38 U.S.C. 501, 1712A, 1782, and 1783.

Administrative Procedure Act

In accordance with U.S.C. 553(b)(B) and (d)(3), the Secretary of Veterans Affairs concluded that there was good cause to publish this rule without prior opportunity for public comment and to publish this rule with an immediate effective date. This interim final rule incorporates a specific program requirement mandated by Congress in Public Law 112–239. The Secretary finds that it is impracticable and contrary to the public interest to delay this rule for the purpose of soliciting advance public comment or to have a delayed effective date. This rule will increase the pool of individuals who are eligible to receive mental health care at Vet Centers. This rule will also increase access to much needed mental health care services in Vet Centers. For the above reason, the Secretary issues this rule as an interim final rule. VA will consider and address comments that are received within 60 days of the date this interim final rule is published in the **Federal Register**.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this interim final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Paperwork Reduction Act

Although this action contains provisions constituting collections of information, at 38 CFR 17.2000, under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), no new or proposed revised collections of information are associated with this final rule. The information collection requirements for § 17.2000 are currently approved by the Office of Management and Budget (OMB) and have been assigned OMB control number 2900–0787.

Regulatory Flexibility Act

The Secretary hereby certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This interim final rule directly affects only individuals and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action'' requiring review by OMB, unless OMB waives such review, as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at *http://www.va.gov/orpm/,* by following the link for VA Regulations Published from Fiscal Year 2004 to Fiscal Year to Date.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more

(adjusted annually for inflation) in any one year. This interim final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are as follows: 64.009, Veterans Medical Care Benefits; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; and 64.024, VA Homeless Providers Grant and Per Diem Program.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Nabors, II, Chief of Staff, approved this document on July 29, 2015, for publication.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Drug abuse, Health care, Health facilities, Homeless, Mental health programs, Veterans.

Dated: July 29, 2015.

William F. Russo,

Acting Director, Office of Regulation Policy & Management, US Department of Veterans Affairs.

For the reasons set forth in the preamble, the Department of Veterans Affairs amends 38 CFR part 17 as follows:

PART 17—MEDICAL

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

Authority: 38 U.S.C. 501, and as noted in specific sections.

■ 2. Amend § 17.2000 by:
■ a. Revising paragraph (a).
■ b. In paragraph (b) introductory text, removing the term ''servicemember's'' and adding in its place ''member's of the Armed Forces, including a member of a reserve component of the Armed Forces,''.
■ b. Revising paragraph (d).
■ c. Revising paragraph (e).
■ d. Revising the authority citation at the end of the section.

The revisions read as follows:

§ 17.2000 Vet Center services.

(a) *Eligibility for readjustment counseling.* Upon request, VA will provide readjustment counseling to any individual who:

(1) Is a veteran or member of the Armed Forces, including a member of a reserve component of the Armed Forces, who:

(i) Served on active duty in a theater of combat operations or an area of hostilities (*i.e.,* an area at a time during which hostilities occurred in that area); or

(ii) Provided direct emergency medical or mental health care, or mortuary services, to the causalities of combat operations or hostilities, but who at the time was located outside the theater of combat operations or area of hostilities; or

(iii) Engaged in combat with an enemy of the United States or against an opposing military force in a theater of combat operations or an area at a time during which hostilities occurred in that area by remotely controlling an unmanned aerial vehicle operations, notwithstanding whether the physical location of such veteran or member during such combat was within such theater of combat operations or area. Individuals who remotely control unmanned aerial vehicles includes, but is not limited to, individuals who pilot the unmanned aerial vehicle as well as individuals who are crew members of the unmanned aerial vehicle and participate in combat related missions. The crew members include, but are not limited to, intelligence analysts or weapons specialists who control the cameras, engage the weapon systems, as well as those individuals who are directly responsible for the mission of the unmanned aerial vehicle.

(2) Received counseling under this section before January 2, 2013.

(3) Is a family member of a veteran or member of the Armed Forces, including a member of a reserve component of the Armed Forces, who is eligible for readjustment counseling under paragraphs (a)(1) or (a)(2) of this section. For purposes of this section, family member includes, but is not limited to, the spouse, parent, child, step-family member, extended family member, and any individual who lives with the veteran or member of the Armed Forces, including a member of a reserve component of the Armed Forces, but is not a member of the veteran's or member's family.

* * * * *

(d) *Readjustment counseling defined.* For the purposes of this section, readjustment counseling includes, but is not limited to: Psychosocial assessment, individual counseling, group counseling, marital and family counseling for military-related readjustment issues, substance abuse assessments, medical referrals, referral for additional VA benefits, employment assessment and referral, military sexual trauma counseling and referral, bereavement counseling, and outreach. A ''psychosocial assessment'' under this paragraph means the holistic assessing of an individual's psychological, social, and functional capacities as it relates to their readjustment from combat theaters. Readjustment counseling is provided to:

(1) Veterans and members of the Armed Forces, including a member of a reserve component of the Armed Forces, for the purpose of readjusting to civilian life or readjustment to continued military service following participation in or in support of operations in a combat theater or area of hostility.

(2) A family member of a member of the Armed Forces, including a member of a reserve component of the Armed Forces, for the purpose of coping with such member's deployment.

(3) A family member of a veteran or member of the Armed Forces, including a member of a reserve component of the Armed Forces, to aid in a veteran's or member's readjustment to civilian or continued military service following participation in or in support of operations in a combat theater or area of hostility, only as it relates to the veteran's or member's military experience.

* * * * *

(e) *Confidentiality.* Benefits under this section are furnished solely by VA Vet Centers, which maintain confidential records independent from any other VA or Department of Defense medical records and which will not disclose such records without either the veteran's or member's of the Armed Forces, including a member of a reserve component of the Armed Forces, voluntary, signed authorization, or a specific exception permitting their release. For more information, see 5 U.S.C. 552a, 38 U.S.C. 5701 and 7332, 45 CFR parts 160 and 164, and VA's System of Records 64VA15, ''Readjustment Counseling Service Vet Center Program.'' The term Vet Center means a facility that is operated by VA for the provision of services under this section and that is situated apart from a VA general health care facility.

(Authority: 38 U.S.C. 501, 1712A, 1782, and 1783)

(The Office of Management and Budget has approved the information collection requirement in this section under control number 2900–0787.)

[FR Doc. 2015–18988 Filed 8–3–15; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2014–0816; FRL–9931–29–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Consumer and Commercial Products and Mobile Equipment Repair and Refinishing Operations

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 Virginia. This revision consists of amendments to Virginia's regulation for consumer and commercial products in order to apply provisions pertaining to portable fuel containers, consumer and commercial products, architectural and industrial maintenance coatings, adhesives, adhesive primers, sealants, and sealant primers to the Richmond volatile organic compound (VOC) Emissions Control Area. The revision also consists of amendments to Virginia's regulation for existing stationary sources to apply provisions pertaining to mobile equipment repair and refinishing operations in the Richmond VOC Emissions Control Area. EPA is approving these revisions to the Virginia SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on September 3, 2015.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2014–0816. 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 State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

FOR FURTHER INFORMATION CONTACT: Leslie Jones Doherty, (215) 814–3409 or by email at *jones.leslie@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 16, 2015 (80 FR 13510), EPA published a notice of proposed rulemaking (NPR) for the Commonwealth of Virginia. In the NPR, EPA proposed approval of revisions to Virginia's consumer and commercial products and mobile equipment repair and refinishing operations regulations. The formal SIP revision was submitted by the Commonwealth of Virginia on April 10, 2014.

II. Summary of SIP Revision

The SIP revision consists of amendments to 9VAC5 Chapter 45—Consumer and Commercial Products in order to apply provisions pertaining to portable fuel containers, consumer and commercial products, architectural and industrial maintenance coatings, adhesives, adhesive primers, sealants, and sealant primers to the Richmond VOC Emissions Control Area. This revision also amends Article 48 of 9VAC5 Chapter 40—Existing Stationary Sources to apply provisions pertaining to mobile equipment repair and refinishing operations in the Richmond VOC Emissions Control Area. Also, the SIP revision includes revised compliance dates for Chapters 40 and 45 and retains in Chapter 45 a temporary exemption for the manufacture and distribution of single-ply roof membrane adhesives and sealants. Other specific requirements and the rationale for EPA's proposed action are explained in the NPR and will not be restated here. No public comments were received on the NPR.

III. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) ''privilege'' for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information that: (1) Are generated or developed before the commencement of a voluntary environmental assessment; (2) are prepared independently of the assessment process; (3) demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information ''required by law,'' including documents and information ''required by Federal law to maintain program delegation, authorization or approval,'' since Virginia must ''enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts. . . .'' The opinion concludes that ''[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval.''

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that ''[t]o the extent consistent with requirements imposed by Federal law,'' any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since ''no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity.''

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its

program consistent with the Federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, EPA may at any time invoke its authority under the CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the CAA is likewise unaffected by this, or any, state audit privilege or immunity law.

IV. Final Action

EPA is approving the amendments to Virginia's regulations for consumer and commercial products and mobile equipment repair and refinishing operations as a revision to the Virginia SIP.

V. Incorporation by Reference

In this rulemaking action, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the Virginia Department of Environmental Quality (VADEQ) Regulations described in amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

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 October 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 Virginia's control of VOC emissions from commercial and consumer products and mobile equipment repair and refinishing operations 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, Ozone, Volatile organic compounds.

Dated: July 9, 2015.

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 VV—Virginia

■ 2. In § 52.2420, the table in paragraph (c) is amended by:

■ A. In the entries for Chapter 40, Part II, Article 48, revise Sections 5–40–6970 and 5–40–7050 and add 5–40–6975 in numerical order.

■ B. In entries for Chapter 45, Part II, Article 1, revise Sections 5–45–70 and 5–45–90; Article 2 Sections 5–45–160, 5–45–170 and 5–45–240; Article 3 Section 5–45–310; Article 4 Sections 5–45–400, 5–45–420, 5–45–430 and 5–45–480; Article 5 Sections 5–45–520, 5–45–530 and 5–45–580; and Article 6 Sections 5–45–620, 5–45–630, 5–45–650 and 5–45–700.

The revisions and additions read as follows:

§ 52.2420 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES

State citation	Title/subject	State effective date	EPA approval date	Explanation [former SIP citation]
*	*	*	*	*
9 VAC 5, Chapter 40 Existing Stationary Sources (Part IV)				
*	*	*	*	*
Part II Emission Standards				
Article 48 Emission Standards for Mobile Equipment Repair and Refinishing (Rule 4–48)				
*	*	*	*	*
5–40–6970	Applicability and designation of affected facility.	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Revision extends the applicability to include the Richmond VOC Emissions Control Area.
*	*	*	*	*
5–40–6975	Exemptions	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Added.
*	*	*	*	*
5–40–7050	Compliance schedules	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Amended.
*	*	*	*	*
9 VAC 5, Chapter 45 Consumer and Commercial Products				
*	*	*	*	*
Part II Emission Standards				
Article 1 Emission Standards For Portable Fuel Containers And Spouts Manufactured Before August 1, 2010				
*	*	*	*	*
5–45–70	Exemptions	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Amended.
*	*	*	*	*
5–45–90	Standard for volatile organic compounds.	*10/01/13*	08/04/15	Amended.
*	*	*	*	*
Article 2 Emission Standards For Portable Fuel Containers And Spouts Manufactured On Or After August 1, 2010				
5–45–160	Applicability	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Revision extends the applicability to include the Richmond VOC Emissions Control Area.
5–45–170	Exemptions	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Amended.
*	*	*	*	*
5–45–240	Compliance schedules	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Amended.
*	*	*	*	*
Article 3 Emission Standards For Consumer Products Manufactured Before August 1, 2010				
*	*	*	*	*
5–45–310 (Except for subsection B)	Standard for volatile organic compounds.	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Amended.

EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation [former SIP citation]
*	*	*	*	*
Article 4 Emission Standards For Consumer Products Manufactured On or After August 1, 2010				
5–45–400	Applicability	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Revision extends the applicability to include the Richmond VOC Emissions Control Area.
*	*	*	*	*
5–45–420	Definitions	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Amended.
5–45–430 (Except for subsection B)	Standard for volatile organic compounds.	*10/01/13*	08/04/15 [Insert FEDERAL REGISTER citation].	Amended.
*	*	*	*	*
5–45–480	Compliance schedules	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Amended.
*	*	*	*	*
Article 5 Emission Standards For Architectural And Industrial Maintenance Coatings				
5–45–520	Applicability	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Revision extends the applicability to include the Richmond VOC Emissions Control Area.
5–45–530	Exemptions	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Amended.
*	*	*	*	*
5–45–580	Compliance schedules	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Amended.
*	*	*	*	*
Article 6 Emission Standards For Adhesives And Sealants				
5–45–620	Applicability	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Revision extends the applicability to include the Richmond VOC Emissions Control Area.
5–45–630	Exemptions	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Amended.
*	*	*	*	*
5–45–650	Standard for volatile organic compounds.	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Amended.
*	*	*	*	*
5–45–700	Compliance schedules	*10/01/13*	08/04/15 [Insert **Federal Register** citation].	Amended.
*	*	*	*	*

* * * * *

[FR Doc. 2015–18609 Filed 8–3–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 140214145–5582–02]

RIN 0648–BD81

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coral, Coral Reefs, and Live/Hard Bottom Habitats of the South Atlantic Region; Amendment 8; Correction

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

ACTION: Final rule; correction.

SUMMARY: NMFS published a final rule on July 17, 2015, to, in part, implement provisions that would expand a portion of the northern boundary of the Cape Lookout Lophelia Banks Deepwater Coral Habitat Area of Particular Concern (Cape Lookout CHAPC). The final rule included coordinates for only the expansion of the Cape Lookout CHAPC instead of the coordinates for the existing CHAPC plus the expanded area. This notification corrects the coordinates for the Cape Lookout CHAPC to encompass the existing CHAPC plus the expanded area.

DATES: The correction is effective on August 17, 2015.

FOR FURTHER INFORMATION CONTACT: Karla Gore, 727–824–5305; email: *karla.gore@noaa.gov*.

SUPPLEMENTARY INFORMATION: On July 17, 2015, NMFS published a final rule in the **Federal Register** (80 FR 42423) to implement provisions for Amendment 8 to the Fishery Management Plan for Coral, Coral Reefs, and Live/Hard Bottom Habitats of the South Atlantic Region (FMP) (Amendment 8), that expands portions of the northern and western boundaries of the Oculina Bank Habitat Area of Particular Concern (HAPC) and allows transit through the Oculina Bank HAPC by fishing vessels with rock shrimp onboard; modifies vessel monitoring systems (VMS) requirements for rock shrimp fishermen transiting through the Oculina Bank HAPC; expands a portion of the western boundary of the Stetson Reefs, Savannah and East Florida Lithotherms, and Miami Terrace Deepwater Coral HAPC (Stetson-Miami Terrace CHAPC), including modifications to shrimp access area 1; and expands a portion of the northern boundary of the Cape Lookout CHAPC. The purpose of the final rule is to increase protection for deepwater coral based on new information for deepwater coral resources in the South Atlantic. The final rule is effective August 17, 2015.

Need for Correction

After the final rule published, NMFS noticed that the coordinates that describe the CHAPC for ''Cape Lookout Lophelia Banks'' in § 622.224(c)(1)(i) set forth only the expanded CHAPC area of 10 square miles (26 square km) and not the total area that encompasses both the existing CHAPC and the expanded area, which totals 326 square miles (844 square km). Amendment 8 and the implementing proposed and final rules are clear that the CHAPC for Cape Lookout Lophelia Banks would consist of the existing area and the expanded area. NMFS publishes this notification to correct that mistake.

Correction

In the **Federal Register** of July 17, 2015, in FR Doc. 2015–17617, on page 42432, in the first column, the table in § 622.224(c)(1)(i) is corrected to read as follows:

Point	North lat.	West long.
Origin	34°24′37″	75°45′11″
1	34°10′26″	75°58′44″
2	34°05′47″	75°54′54″
3	34°21′02″	75°41′25″
4	34°23′28.998″	75°43′58.002″
5	34°27′00″	75°41′45″
6	34°27′54″	75°42′45″
Origin	34°24′37″	75°45′11″

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

Dated: July 28, 2015.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2015–19009 Filed 8–3–15; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 80, No. 149

Tuesday, August 4, 2015

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–3224; Directorate Identifier 2015–CE–026–AD]

RIN 2120–AA64

Airworthiness Directives; Schempp-Hirth Flugzeugbau GmbH Sailplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Schempp-Hirth Flugzeugbau GmbH Models Duo Discus and Duo Discus T powered sailplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as excessive load on the air brake system. We are issuing this proposed AD to require actions to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by September 18, 2015.

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

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

For service information identified in this proposed AD, contact Schempp-Hirth Flugzeugbau GmbH, Krebenstrasse 25, 73230 Kirchheim/Teck, Germany; telephone: +49 7021 7298–0; fax: +49 7021 7298–199; email: *info@schempp-hirth.com;* Internet: *http://www.schempp-hirth.com.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

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–2015–3224; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4165; fax: (816) 329–4090; email: *jim.rutherford@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–3224; Directorate Identifier 2015–CE–026–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued AD No. 2015–0139R1, dated July 15, 2015 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> Operational experience shows that application of an excessive load on the air brake system may induce damage to the drive funnels in the fuselage and to the air brake bellcrank at the root rips of the wing.
>
> This condition, if not detected and corrected, could lead to an uncontrolled actuation of the air brakes (symmetric and asymmetric), possibly resulting in reduced control of the (powered) sailplane.
>
> To address this potential unsafe condition, Schempp-Hirth Flugzeugbau GmbH issued Technical Note (TN) 380–2, 396–17, 868–22 and 890–14 (published as a single document) to provide inspection instructions.
>
> Consequently EASA issued AD 2015–0139 to require to repetitive inspections of the air brake bellcrank, the air brake drive funnels and the airbrake control system, and replacement of damaged parts.
>
> Since that AD was issued, it was found that the drawing number of the reinforced air brake drive funnel was incorrectly stated in the original issue of the Schempp-Hirth TN. The wrongly referred drawing S14FB703 refers to an existing part, different from air brake drive funnel and cannot be installed as a replacement part for air brake drive funnel. Consequently, Schempp-Hirth Flugzeugbau GmbH issued Revision 1 of TN 380–2, 396–17, 868–22 and 890–14, hearafter referenced to as 'the revised TN' in this AD.
>
> For the reasons described above, this AD is revised to require using the revised TN.

You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3224.

Related Service Information Under 1 CFR Part 51

Schempp-Hirth Flugzeugbau GmbH has issued Technical Note No. 380–2/396–17/868–22/890–14, Revision 1, issued July 13, 2015 (published as a single document), and Working instruction for Technical Note No. 380–2/396–17/868–22/890–14, Ausgabe (English translation: Issue) 1, Datum (English translation: Dated) May 11, 2015. The service information describes

procedures for inspecting and replacing the airbrake bell crank and the airbrake drive funnels and inspecting the airbrake control system for proper clearance and making necessary adjustments. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA's Determination and Requirements of the Proposed AD

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

Costs of Compliance

We estimate that this proposed AD will affect 31 products of U.S. registry. We also estimate that it would take about 2 work-hours per product to comply with the basic inspection requirements of this proposed AD. The average labor rate is $85 per work-hour.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $5,270, or $170 per product.

We estimate that it would take about 4 work-hours per product to comply with the airbrake bell crank replacement requirement of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $500 per product.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $26,040, or $840 per product.

We estimate that it would take about 4 work-hours per product to comply with the airbrake drive funnel replacement requirement of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $500 per product.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $26,040, or $840 per product

In addition, we estimate that any necessary follow-on actions to make any necessary adjustments to the airbrake control system would take about 2 work-hours for a cost of $170 per product. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Schempp-Hirth Flugzeugbau GmbH: Docket No. FAA–2015–3224; Directorate Identifier 2015–CE–026–AD.

(a) Comments Due Date

We must receive comments by September 18, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Schempp-Hirth Flugzeugbau GmbH Model Duo Discus powered sailplane, serial numbers 1 through 639, and Model Duo Discus T powered sailplanes, serial numbers 1 through 110 and 112 through 247, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 27: Flight Controls.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as excessive load on the air brake system. We are issuing this AD to prevent uncontrolled actuation of the air brakes (symmetric or asymmetric), which could result in reduced control.

(f) Actions and Compliance

Unless already done, do the actions in paragraph (f)(1) through (f)(5) of this AD.

(1) Within 40 days after the effective date of this AD and repetitively thereafter at intervals not to exceed 100 hours time-in-service until the terminating replacement action required in paragraphs (f)(2) and (f)(3) of this AD (as applicable) is done, inspect the airbrake bell crank, the airbrake drive funnels, and the airbrake control system.

(i) Inspect the airbrake bell crank and the airbrake drive funnels for cracks and damage following Action 1 in Schempp-Hirth Flugzeugbau GmbH Technical Note No. 380–2/396–17/868–22/890–14, Revision 1, issued July 13, 2015 (published as a single document).

(ii) Inspect the airbrake control system for proper clearance following Paragraph 2.d. of Schempp-Hirth Flugzeugbau GmbH Working instruction for Technical Note No. 380–2/396–17/868–22/890–14, Ausgabe (English translation: issue) 1, Datum (English translation: dated) May 11, 2015.

(2) If cracks or damage is found on the airbrake bell cranks or the airbrake drive funnels during any inspection required in paragraph (f)(1) of this AD, before further flight, replace each cracked or damaged part

with a reinforced part. Installing a reinforced part terminates the repetitive inspections required in paragraph (f)(1) of this AD for that part.

(i) For replacement of the airbrake bell cranks, follow Picture 2: Reinforced version of airbrake bell crank according to HS 11–50.016, Revision a or later, in Schempp-Hirth Flugzeugbau GmbH Working instruction for Technical Note No. 380–2/396–17/868–22/890–14, Ausgabe (English translation: issue) 1, Datum (English translation: dated) May 11, 2015.

(ii) For replacement of the airbrake drive funnels, follow Picture 5: Airbrake drive funnel in fuselage ''Reinforcement of airbrake drive funnel according to drawing S14RB703, Revision a, in Schempp-Hirth Flugzeugbau GmbH Working instruction for Technical Note No. 380–2/396–17/868–22/890–14, Ausgabe (English translation: issue) 1, Datum (English translation: dated) May 11, 2015.

(3) If no cracks or damage were found on the airbrake bell cranks or the airbrake drive funnels during any inspection required in paragraph (f)(1) of this AD, within 12 months after the effective date of this AD, replace each the airbrake bell cranks and airbrake drive funnels with a reinforced part. These replacements terminate the repetitive inspections required in paragraph (f)(1) of this AD.

(i) For replacement of the airbrake bell cranks, follow Picture 2: Reinforced version of airbrake bell crank according to HS 11–50.016, Revision a or later, in Schempp-Hirth Flugzeugbau GmbH Working instruction for Technical Note No. 380–2/396–17/868–22/890–14, Ausgabe (English translation: issue) 1, Datum (English translation: dated) May 11, 2015.

(ii) For replacement of the airbrake drive funnels, follow Picture 5: Airbrake drive funnel in fuselage, ''Reinforcement of airbrake drive funnel according to drawing S14RB703, Revision a,'' in Schempp-Hirth Flugzeugbau GmbH Working instruction for Technical Note No. 380–2/396–17/868–22/890–14, Ausgabe (English translation: issue) 1, Datum (English translation: dated) May 11, 2015.

(4) If the airbrake control system is found to not have proper clearance during the inspection required in paragraph (f)(1) of this AD, before further flight, make all necessary corrective adjustments following Paragraph 2.d. of Schempp-Hirth Flugzeugbau GmbH Working instruction for Technical Note No. 380–2/396–17/868–22/890–14, Ausgabe (English translation: issue) 1, Datum (English translation: dated) May 11, 2015.

(5) As of the effective date of this AD, only install an airbrake bell crank or an airbrake drive funnel that corresponds to Picture 2: Reinforced version of airbrake bell crank according to HS 11–50.016, Revision a or later, and Picture 5: Airbrake drive funnel in fuselage, ''Reinforcement of airbrake drive funnel according to drawing S14RB703, Revision a,'' in Schempp-Hirth Flugzeugbau GmbH Working instruction for Technical Note No. 380–2/396–17/868–22/890–14, Ausgabe (English translation: issue) 1, Datum (English translation: dated) May 11, 2015, as applicable.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4165; fax: (816) 329–4090; email: *jim.rutherford@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

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

(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No. 2015–0139R1, dated July 15, 2015, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3224. For service information related to this AD, contact Schempp-Hirth Flugzeugbau GmbH, Krebenstrasse 25, 73230 Kirchheim/Teck, Germany; telephone: +49 7021 7298–0; fax: +49 7021 7298–199; email: *info@schempp-hirth.com;* Internet: *http://www.schempp-hirth.com.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on July 28, 2015.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–18955 Filed 8–3–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

31 CFR Part 23

RIN 1505–AC51

Nondiscrimination on the Basis of Age in Programs and Activities Receiving Federal Financial Assistance From the Department of the Treasury

AGENCY: Department of the Treasury.

ACTION: Proposed rule.

SUMMARY: This proposed rule sets out the Department of the Treasury's (Treasury) rules for implementing the Age Discrimination Act of 1975, as amended (the Act). The Act prohibits discrimination on the basis of age in programs and activities receiving federal financial assistance. The Act, which applies to persons of all ages, permits the use of certain age distinctions and factors other than age that meet the Act's requirements.

The Act and the related general, government-wide regulations require all agencies that extend federal financial assistance to issue agency-specific regulations implementing the Act. Treasury recipients have been subject to the Act and the government-wide regulations since their effective date in 1979. Accordingly, today's proposed rule does not substantially change Treasury recipients' existing duty to refrain from discrimination on the basis of age. This proposal fulfills the obligation on Treasury to issue agency-specific rules under the Act, clarifies the responsibilities of Treasury recipients under the Act, and describes the Treasury investigation, conciliation, and enforcement procedures to ensure compliance.

DATES: Written comments must be received on or before October 5, 2015.

ADDRESSES: Interested persons are invited to submit comments regarding this notice of proposed rulemaking according to the instructions below. All submissions must refer to the document title. The Department encourages the early submission of comments.

Electronic Submission of Comments: Interested persons may submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt, and assists the Department in making comments available to the public. Comments submitted electronically through the *http://www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Mail: Send comments to Mariam G. Harvey, Director, Office of Civil Rights and Diversity, 1500 Pennsylvania Avenue NW., Washington, DC 20220.

Note: To receive consideration, comments must be submitted through one of the methods specified above.

Public Inspection of Public Comments: All properly submitted comments will be available for inspection and downloading at *http://www.regulations.gov.*

Additional Instructions: In general comments received, including attachments and other supporting materials, are part of the public record and are available to the public. Do not submit any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT: Mariam G. Harvey, Director, Office of Civil Rights and Diversity, Department of the Treasury, (202) 622–0316 (voice).

SUPPLEMENTARY INFORMATION:

I. Background Information

The Age Discrimination Act of 1975, 42 U.S.C. 6101–6107 (''the Act''), which Congress enacted as part of amendments to the Older Americans Act (Pub. L. 94–135, 89 Stat. 713, 728), prohibits discrimination on the basis of age in programs and activities receiving federal financial assistance. The Civil Rights Restoration Act of 1987 (Pub. L. 100–259, 102 Stat. 28, 31 (1988)) amended the Act and other civil rights statutes to define ''program or activity'' to mean all of the operations of specified entities, any part of which is extended federal financial assistance. *See* 42 U.S.C. 6107(4).

The Act applies to discrimination at all age levels. The Act also contains specific exceptions that permit the use of certain age distinctions and factors other than age that meet the Act's requirements.

The Act required the former Department of Health, Education, and Welfare (HEW) to issue general, government-wide regulations, setting standards to be followed by all federal agencies implementing the Act. These government-wide regulations, which were issued on June 12, 1979 (44 FR 33768), and became effective on July 1, 1979, require each federal agency providing financial assistance to any program or activity to publish proposed regulations implementing the Act, and to submit final agency regulations to HEW (now the Department of Health and Human Services (HHS)), before publication in the **Federal Register**. *See* 45 CFR 90.31.

The Act became effective on the effective date of HEW's final government-wide regulations (*i.e.,* July 1, 1979). Treasury has enforced the provisions of the Act since that time. As a practical matter, the absence of Treasury-specific age regulations has not had an impact on Treasury's legal authority to enforce prohibitions against discrimination on the basis of age in programs or activities receiving federal financial assistance from Treasury. Specifically, persons alleging age discrimination have not been hampered in their ability to file complaints nor has Treasury's Office of Civil Rights and Diversity's (OCRD) ability to process these complaints been affected.

II. Overview of Proposed Rule

This proposed rule is designed to fulfill the statutory and regulatory obligations of Treasury to issue a regulation implementing the Act that conforms to the government-wide regulations at 45 CFR part 90. The proposed rule carries out the Act's prohibition of discrimination based on age in programs and activities receiving financial assistance from Treasury and provides appropriate investigative, conciliation, and enforcement procedures. OCRD, part of the Office of the Assistant Secretary for Management, will conduct Treasury enforcement. OCRD enforces all civil rights laws applicable to entities receiving financial assistance from Treasury.

The proposed rule is not intended to alter the legal standards found in the Act or the government-wide regulations, which are applicable to recipients of federal financial assistance from Treasury under other statutes. The proposed rule closely follows the wording and format of rules issued by other federal agencies to implement the Act. In particular, Treasury modeled much of its proposal on the agency-specific regulations issued by HHS, the lead federal agency coordinating implementation of the Act (45 CFR part 91; 47 FR 57850, Dec. 28, 1982); and the Department of Education (ED) (34 CFR part 110; 58 FR 40194, July 27, 1993). The government-wide, HHS, and ED rules were subjected to extensive public scrutiny, and the public comments were considered in finalizing those rules. Readers may review the HHS and ED **Federal Register** publications for historical and explanatory material regarding the Act, the government-wide regulations, and the provisions of the HHS and ED implementing regulations. The following discussion focuses on the sections of today's proposed rule that differ from the government-wide regulations. As explained below, these differences are meant to clarify provisions, and mirror other federal agency-specific regulations implementing the Act.

Subpart A—General

The four sections in Subpart A provide the proposed rule's purpose, application, and definitions, and are consistent with the government-wide regulations.

The definitions in § 23.4 are substantively identical to definitions in the government-wide regulations (45 CFR 90.4), HHS agency-specific regulations (45 CFR 91.4), and ED regulations (34 CFR 110.3).

Subpart B—Standards for Determining Age Discrimination

Subpart B is virtually identical to the corresponding sections of the government-wide regulations at 45 CFR part 90. Some of the provisions have been reordered for greater clarity and coherence.

Section 23.11 follows the government-wide regulations in laying out the general and specific rules prohibiting age discrimination in programs or activities receiving federal financial assistance from Treasury.

Like the government-wide rule, the proposal states that the list of prohibited forms of age discrimination in § 23.11(b) is not exhaustive and, consequently, does not imply that other forms of age discrimination are permitted.

Sections 23.12 and 23.13 follow the government-wide regulations (see 45 CFR 90.13 and 90.14), in defining the terms ''normal operation'' and ''statutory objective'' and delineating the ''normal operation'' and ''statutory objective'' exceptions to the prohibitions against age discrimination that are specified in the Act, 42 U.S.C. 6103.

Section 23.13 sets out the four-prong test, provided in the government-wide regulations (see 45 CFR 90.14), for determining when an action reasonably takes into account ''age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity'' and thus does not violate the Act.

In the proposed rule, provisions concerning affirmative action and special benefits to children and elderly are in subpart B at §§ 23.16 and 23.17; in the government-wide regulations, the analogous provisions are part of subpart D (Investigation, Conciliation, and Enforcement Procedures) at 45 CFR 90.49. The HHS agency-specific regulations also moved these provisions to Subpart B (see 45 CFR 91.16 and 91.17), and Treasury believes this reordering aids comprehension.

Section 23.18 of the proposed rule provides that age distinctions in Treasury regulations are entitled to a presumption of validity. For example, the provision in Internal Revenue Service Publication 1101, which limits participation in the Tax Counseling for the Elderly Program to individuals who are 60 years of age or older, is presumed valid. This presumption of validity is

consistent with the ''statutory objective'' exception in the Act. Section 163 of the Revenue Act of 1978, Public Law 95–600, 92 Stat. 2810, November 6, 1978, authorized the Tax Counseling for the Elderly Program. Analogous provisions are in the HHS and ED agency-specific regulations (45 CFR 91.18; 34 CFR 110.17.)

Subpart C—Duties of Treasury Recipients

Subpart C is consistent with the government-wide regulations at 45 CFR part 90. As described below, language differences between this Subpart of the proposed rule and the government-wide regulations are meant to clarify the duties of Treasury recipients.

The proposed rule fosters awareness of the Act's provisions, by requiring that recipients provide notice concerning obligations and rights under the Act to other recipients and to beneficiaries (§ 23.32) and that recipients complete a written assurance of compliance (§ 23.33). The notice requirements in § 23.32 are modeled after the HHS provision in 45 CFR 91.32 and the ED provisions in 34 CFR 110.21 and 110.25(b). The § 23.33 requirement for assurances of compliance is similar to the HHS rule at 45 CFR 91.33(a) and the ED rule at 34 CFR 110.23(a).

Section 23.33 of this proposed rule provides that OCRD may require a recipient employing the equivalent of 15 or more employees to complete a written self-evaluation as part of a compliance review or complaint investigation. The government-wide regulations at 45 CFR 90.43 contain the requirement that all recipients with the equivalent of 15 or more full-time employees must complete a written self-evaluation of their compliance under the Act. However, the Office of Management and Budget (OMB) subsequently disapproved of this across-the-board self-evaluation requirement as excessively burdensome and inconsistent with the Federal Reports Act of 1942, the precursor of the Paperwork Reduction Act, as amended (44 U.S.C. 3501–3521). Correspondingly, HHS and other federal agencies have rejected imposing self-evaluation requirements on all recipients and instead state in their agency-specific regulations that such evaluations will only be required as part of a compliance review or complaint investigation. *See* 34 CFR 110.24; 45 CFR 91.33. The courts have upheld OMB and HHS determinations to impose self-evaluation requirements only when there is an ongoing compliance review or complaint inspection. *See, e.g., Action Alliance of Senior Citizens of Greater Philadelphia* v. *Sullivan,* 930 F.2d 77 (D.C. Cir.), *cert. denied,* 502 U.S. 938 (1991). Accordingly, the Treasury proposal abides by the OMB determination and closely follows the age discrimination regulations of the other federal agencies.

Section 23.34 lists recordkeeping, reporting, and access to records requirements under the Act. The government-wide regulations already require recipients to maintain records, provide information, and afford access to their records to agencies for the purposes of determining whether the recipients are complying with the Act. *See* 45 CFR 90.42(a). The government-wide regulations also mandate that agencies include in their regulations implementing the Act the requirements that recipients provide information and access to records to the extent the agencies find such information and records necessary to determine compliance with the Act and regulations. *See id.* Proposed § 23.34 follows the format of the analogous HHS provision in 45 CFR 91.34.

Subpart D—Investigation, Conciliation, and Enforcement Procedures

In accordance with the government-wide regulations, subpart D describes procedures for compliance reviews and federal-level complaint processing, and outlines the role of mediation in resolving complaints. This subpart closely follows the HHS and ED age regulations, adopting minor stylistic and organizational changes that Treasury believes will improve clarity.

Section 23.44 incorporates the HHS agency-specific regulation published at 45 CFR 91.44(a)(4). This section provides that settlements during the agency investigation process will not affect the operation of any other enforcement effort by the agency, such as compliance reviews and investigations of other complaints, including those against the same recipient.

Section 2347 provides that the procedural regulations applicable to hearings, decisions, and post-determination proceedings under Title VI of the Civil Rights Act of 1964, as amended, when published, will apply to OCRD's enforcement of the Act and this part.

Section 23.49 of the proposed rule describes procedures for disbursal of funds to an alternate recipient if funds are withheld from the original recipient because of violations of these rules. Section 23.49 is not intended to replace established grant-awarding procedures. The requirements listed in § 23.49(b) are in addition to any requirements contained in other applicable Federal laws or regulations.

III. Regulatory Procedures

Executive Order 12866

This proposed rule is not a ''significant regulatory action'' under Executive Order 12866. Therefore, no regulatory impact analysis has been prepared.

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is hereby certified that this proposed rule would not have a significant economic impact on a substantial number of small entities. The proposed rule, if promulgated, will clarify existing requirements for entities receiving financial assistance from Treasury. The requirements prohibiting age discrimination by recipients of federal financial assistance that are in the Act and the government-wide regulations have been in effect since 1979. In addition, entities receiving financial assistance from Treasury have been expressly informed of their obligations to comply with the Act by the offices administering the assisted programs. Because the proposed rule does not substantively change existing obligations on recipients, but merely clarifies such duties, the Department certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Consequently, a regulatory flexibility analysis is not required.

List of Subjects in 31 CFR Part 23

Aged, Discrimination against aged.

Brodi Fontenot,

Assistant Secretary for Management.

For the reasons stated in the preamble, the Department of the Treasury proposes to add part 23 to subtitle A of title 31 of the CFR to read as follows:

PART 23—NONDISCRIMINATION ON THE BASIS OF AGE IN PROGRAMS AND ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE FROM THE DEPARTMENT OF THE TREASURY

Subpart A—General

Sec.

23.1 What is the purpose of the Age Discrimination Act of 1975?
23.2 What is the purpose of Treasury's discrimination regulations?
23.3 To what programs do these regulations apply?
23.4 Definitions of terms used in these regulations.

Subpart B—Standards for Determining Age Discrimination

23.11 Rules against age discrimination.
23.12 Definitions of ''normal operation'' and ''statutory objective.''
23.13 Exceptions to the rules against age discrimination: Normal operation or statutory objective of any program or activity.
23.14 Exceptions to the rules against age discrimination: Reasonable factors other than age.
23.15 Burden of proof.
23.16 Affirmative action by recipients.
23.17 Special benefits for children and the elderly.
23.18 Age distinctions contained in Treasury's regulations.

Subpart C—Duties of Treasury Recipients

23.31 General responsibilities.
23.32 Notice to subrecipients and beneficiaries.
23.33 Assurance of compliance and recipient assessment of age distinctions.
23.34 Information requirements.

Subpart D—Investigations, Conciliation, and Enforcement Procedures

23.41 Compliance reviews.
23.42 Complaints.
23.43 Mediation.
23.44 Investigation.
23.45 Prohibition against intimidation or retaliation.
23.46 Compliance procedures.
23.47 Hearings, decisions, post-termination proceedings.
23.48 Remedial action by recipient.
23.49 Alternate funds disbursal procedure.
23.50 Exhaustion of administrative remedies.

Authority: Age Discrimination Act of 1975, as amended, 42 U.S.C. 6101 *et seq.* (45 CFR part 90)

Subpart A—General

§ 23.1 What is the purpose of the Age Discrimination Act of 1975?

The Age Discrimination Act of 1975, as amended, is designed to prohibit discrimination on the basis of age in programs or activities receiving federal financial assistance. The Act also permits federally assisted programs and activities, and recipients of federal funds, to continue to use certain age distinctions and factors other than age that meet the requirements of the Act and these regulations.

§ 23.2 What is the purpose of Treasury's age discrimination regulations?

The purpose of these regulations is to set out Treasury's policies and procedures under the Age Discrimination Act of 1975 and the general age discrimination regulations at 45 CFR part 90. The Act and the general regulations prohibit discrimination on the basis of age in programs or activities receiving federal financial assistance. The Act and the general regulations permit federally assisted programs and activities, and recipients of federal funds, to continue to use age distinctions and factors other than age that meet the requirements of the Act and its implementing regulations.

§ 23.3 To what programs do these regulations apply?

(a) These regulations apply any program or activity receiving federal financial assistance from Treasury.

(b) These regulations do not apply to:

(1) An age distinction contained in that part of a federal, state, or local statute or ordinance adopted by an elected, general purpose legislative body that:

(i) Provides any benefits or assistance to persons based on age; or

(ii) Establishes criteria for participation in age-related terms; or

(iii) Describes intended beneficiaries to target groups in age-related terms; or

(2) Any employment practice of any employer, employment agency, labor organization, or any labor-management joint apprenticeship training program, except for any program or activity receiving federal financial assistance for public service employment under the Comprehensive Employment and Training Act (CETA), 29 U.S.C. 801 *et seq.*

§ 23.4 Definition of terms used in these regulations.

As used in these regulations, the term:

Act means the Age Discrimination Act of 1975, as amended, 42 U.S.C. 6101–6107.

Action means any act, activity, policy, rule, standard, or method of administration; or the use of any policy, rule, standard, or method of administration.

Age means how old a person is, or the number of years from the date of a person's birth.

Age distinction means any action using age or an age-related term.

Age-related term means a word or words that necessarily imply a particular age or range of ages (for example, ''children,'' ''adult,'' ''older persons,'' but not ''student'').

Federal financial assistance means any grant, entitlement, loan, cooperative agreement, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which Treasury provides assistance in the form of:

(1) Funds; or

(2) Services of federal personnel; or

(3) Real and personal property or any interest in or use or property, including:

(i) Transfers or leases of property for less than fair market value or for reduced consideration; and

(ii) Proceeds from a subsequent transfer or lease of property if the federal share of its fair market value is not returned to the federal government.

Program or activity means all of the operations of any entity described in paragraphs (1) through (4) of this definition, any part of which is extended federal financial assistance:

(1)(i) A department, agency, special purpose district, or other instrumentality of a state or of a local government; or

(ii) The entity of such state or local government that distributes such assistance and each such department or agency (and each other state or local government entity) to which the assistance is extended, in the case of assistance to a state or local government;

(2)(i) A college, university, or other postsecondary institution, or a public system of higher education; or

(ii) A local educational agency (as defined in 20 U.S.C. 7801), system of vocational education, or other school system;

(3)(i) An entire corporation, partnership, or other private organization, or an entire sole proprietorship—

(A) If assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or

(B) That is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation; or

(ii) The entire plant or other comparable, geographically separate facility to which federal financial assistance is extended, in the case of any other corporation, partnership, private organization, or sole proprietorship; or

(4) Any other entity that is established by two or more of the entities described in paragraph (1), (2), or (3) of this definition.

Recipient means any state or its political subdivision, any instrumentality of a state or its political subdivision, any public or private agency, institution, organization, or other entity, or any person to which federal financial assistance is extended, directly or through another recipient. Recipient includes any successor, assignee, or transferee, but excludes the ultimate beneficiary of the assistance.

Secretary means the Secretary of the Treasury, or his or her designee.

Subrecipient means any of the entities in the definition of *recipient* to which a recipient extends or passes on federal

financial assistance. A subrecipient is generally regarded as a recipient of federal financial assistance and has all the duties of a recipient in these regulations.

Treasury means the United States Department of the Treasury.

United States means the fifty states, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, the Trust Territory of the Pacific Islands, the Northern Marianas, and the territories and possessions of the United States.

Subpart B—Standards for Determining Age Discrimination

§ 23.11 Rule against age discrimination.

The rules stated in this section are limited by the exceptions contained in §§ 23.13 and 23.14.

(a) *General rule:* No person in the United States shall, on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity receiving federal financial assistance.

(b) *Specific rules:* A recipient may not, in any program or activity receiving federal financial assistance, directly or through contractual licensing, or other arrangements, use age distinctions or take any other actions that have the effect, on the basis of age, of:

(1) Excluding individuals from, denying them the benefits of, or subjecting them to discrimination under, a program or activity receiving federal financial assistance; or

(2) Denying or limiting individuals in their opportunity to participate in any program or activity receiving federal financial assistance.

(c) The specific forms of age discrimination listed in paragraph (b) of this section do not necessarily constitute a complete list.

§ 23.12 Definitions of ''normal operation'' and ''statutory objective.''

For purposes of §§ 23.13 and 23.14, the terms ''normal operation'' and ''statutory objective'' shall have the following meaning:

(a) *Normal operation* means the operation of a program or activity without significant changes that would impair its ability to meet its objectives.

(b) *Statutory objective* means any purpose of a program or activity expressly stated in any federal statute, state statute, or local statute or ordinance adopted by an elected, general purpose legislative body.

§ 23.13 Exceptions to the rules against age discrimination: normal operation or statutory objective of any program or activity.

A recipient is permitted to take an action, otherwise prohibited by § 23.11, if the action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity. An action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity, if:

(a) Age is used as a measure or approximation of one or more other characteristics; and

(b) The other characteristic(s) must be measured or approximated for the normal operation of the program or activity to continue, or to achieve any statutory objective of the program or activity; and

(c) The other characteristic(s) can be reasonably measured or approximated by the use of age; and

(d) The other characteristic(s) are impractical to measure directly on an individual basis.

§ 23.14 Exceptions to the rules against age discrimination: Reasonable factors other than age.

A recipient is permitted to take an action otherwise prohibited by § 23.11 that is based on a factor other than age, even though that action may have a disproportionate effect on persons of different ages. An action may be based on a factor other than age only if the factor bears a direct and substantial relationship to the normal operation of the program or activity or to the achievement of a statutory objective.

§ 23.15 Burden of proof.

The burden of proving that an age distinction or other action falls within the exceptions outlined in §§ 23.13 and 23.14 is on the recipient of federal financial assistance.

§ 23.16 Affirmative action by recipient.

Even in the absence of a finding of discrimination, a recipient may take affirmative action to overcome the effects of conditions that resulted in limited participation in the recipient's program or activity on the basis of age.

§ 23.17 Special benefits for children and the elderly.

If a recipient's operation of a program or activity provides special benefits to the elderly or to children, such use of age distinctions shall be presumed to be necessary to the normal operation of the program or activity, notwithstanding the provisions of § 23.13.

§ 23.18 Age distinctions contained in Treasury regulations.

Any age distinctions contained in a rule or regulation issued by Treasury shall be presumed to be necessary to the achievement of a statutory objective of the program or activity to which the rule or regulation applies, notwithstanding the provisions of § 23.13.

Subpart C—Duties of Treasury Recipients

§ 23.31 General responsibilities.

Each Treasury recipient has primary responsibility to ensure that its programs and activities are in compliance with the Act and these regulations, and shall take steps to eliminate violations of the Act. A recipient also has responsibility to maintain records, provide information, and afford Treasury access to its records to the extent Treasury finds necessary to determine whether the recipient is in compliance with the Act and these regulations.

§ 23.32 Notice to subrecipients and beneficiaries.

(a) Where a recipient passes on federal financial assistance from Treasury to subrecipients, the recipient shall provide the subrecipients written notice of their obligations under the Act and these regulations.

(b) Each recipient shall make necessary information about the Act and these regulations available to its program beneficiaries to inform them about the protections against discrimination provided by the Act and these regulations.

§ 23.33 Assurance of compliance and recipient assessment of age distinctions.

(a) Each recipient of federal financial assistance from Treasury shall sign a written assurance as specified by Treasury that it will comply with the Act and these regulations.

(b) *Recipient assessment of age distinctions.* (1) As part of a compliance review under § 23.41 or a complaint investigation under § 23.44, Treasury may require a recipient employing the equivalent of 15 or more employees to complete a written self-evaluation, in a manner specified by the responsible Department official, of any age distinction imposed in its program or activity receiving federal financial assistance from Treasury to assess the recipient's compliance with the Act.

(2) Whenever an assessment indicates a violation of the Act or the Treasury regulations, the recipient shall take corrective action.

§ 23.34 Information requirements.

Each recipient shall:

(a) Keep records in a form and containing information that Treasury determines may be necessary to ascertain whether the recipient is complying with the Act and these regulations.

(b) Provide to Treasury, upon request, information and reports that Treasury determines are necessary to ascertain whether the recipient is complying with the Act and these regulations.

(c) Permit reasonable access by Treasury to the books, records, accounts, and other recipient facilities and sources of information to the extent Treasury determines is necessary to ascertain whether the recipient is complying with the Act and these regulations.

Subpart D—Investigation, Conciliation, and Enforcement Procedures

§ 23.41 Compliance reviews.

(a) Treasury may conduct compliance reviews and pre-award reviews or use other similar procedures that will permit it to investigate and correct violations of the Act and these regulations. Treasury may conduct these reviews even in the absence of a complaint against a recipient. The reviews may be as comprehensive as necessary to determine whether a violation of the Act or these regulations has occurred.

(b) If a compliance review or pre-award review indicates a violation of the Act or these regulations, Treasury will attempt to achieve voluntary compliance. If voluntary compliance cannot be achieved, Treasury will arrange for enforcement as described in § 23.46.

§ 23.42 Complaints.

(a) Any person, individually or as a member of a class or on behalf of others, may file a complaint with Treasury, alleging discrimination prohibited by the Act or these regulations based on an action occurring on or after July 1, 1979. A complainant shall file a complaint within 180 days from the date the complainant first had knowledge of the alleged act of discrimination. However, for good cause shown, Treasury may extend this time limit.

(b) Treasury will consider the date a complaint is filed to be the date upon which the complaint is sufficient to be processed.

(c) Treasury will attempt to facilitate the filing of complaints wherever possible, including taking the following measures:

(1) Accepting as a sufficient complaint any written statement that identifies the parties involved and the date the complainant first had knowledge of the alleged violation, describes generally the action or practice complained of, and is signed by the complainant.

(2) Freely permitting a complainant to add information to the complaint to meet the requirements of a sufficient complaint.

(3) Notifying the complainant and the recipient of their rights and obligations under the complaint procedure, including the right to have a representative at all stages of the complaint resolution process.

(4) Notifying the complainant and the recipient (or their representatives) of their right to contact Treasury for information and assistance regarding the complaint resolution process.

(d) Treasury will notify the complainant when the complaint falls outside the jurisdiction of these regulations, and will state the reason(s) why it is outside the jurisdiction of these regulations.

§ 23.43 Mediation.

(a) Treasury will promptly refer to a mediation agency designated by the Secretary of the Department of Health and Human Services (HHS) all sufficient complaints that:

(1) Fall within the jurisdiction of the Act and these regulations, unless the age distinction complained of is clearly within an exception; and,

(2) Contain all information necessary for further processing.

(b) Both the complainant and the recipient shall participate in the mediation process to the extent necessary to reach an agreement or make an informed judgment that an agreement is not possible.

(c) If the complainant and the recipient reach an agreement, the mediator shall prepare a written statement of the agreement and have the complainant and the recipient sign it. The mediator shall send a copy of the agreement to Treasury. Treasury will take no further action on the complaint unless the complainant or the recipient fails to comply with the agreement.

(d) The mediator shall protect the confidentially of all information obtained in the course of the mediation process. No mediator shall testify in any adjudicative proceeding, produce any document, or otherwise disclose any information obtained in the course of the mediation process without prior approval of the head of the mediation agency.

(e)(1) The mediation will proceed for a maximum of 60 days after a complaint is filed with Treasury. Mediation ends if:

(i) 60 days elapse from the time the complaint is filed; or

(ii) Prior to the end of that 60-day period, an agreement is reached; or

(iii) Prior to the end of that 60-day period, the mediator determines that an agreement cannot be reached.

(2) This 60-day period may be extended by the mediator, with the concurrence of Treasury, for not more than 30 days if the mediator determines that agreement likely will be reached during such extended period.

(f) The mediator shall notify Treasury when mediation is not successful and Treasury will continue processing the complaint.

§ 23.44 Investigation.

(a) *Informal investigation.* (1) Treasury will investigate complaints that are unresolved after mediation or are reopened because of a violation of a mediation agreement.

(2) As part of the initial investigation, Treasury will use informal fact finding methods, including joint or separate discussions with the complainant and recipient, to establish the facts and, if possible, settle the complaint on terms that are mutually agreeable to the parties. Treasury may seek the assistance of any involved state agency.

(3) Any settlement agreement will be put in writing and the parties will sign it.

(4) The settlement shall not affect the operation of any other enforcement effort of Treasury, including compliance reviews and investigation of other complaints that may involve the recipient.

(5) The settlement is not a finding of discrimination against a recipient.

(b) *Formal investigation.* If Treasury cannot resolve the complaint through informal investigation, it will begin to develop formal findings through further investigation of the complaint. If the investigation indicates a violation of these regulations, Treasury will attempt to obtain voluntary compliance. If Treasury cannot obtain voluntary compliance, it will begin enforcement as described in § 23.46

§ 23.45 Prohibition against intimidation or retaliation.

A recipient may not engage in acts of intimidation or retaliation against any person who:

(a) Attempts to assert a right protected by the Act or these regulations; or

(b) Cooperates in any mediation, investigation, hearing, or other part of Treasury's investigation, conciliation, and enforcement process.

§ 23.46 Compliance procedure.

(a) Treasury may enforce the Act and these regulations through:

(1) Termination of a recipient's federal financial assistance from Treasury under the program or activity involved where the recipient has violated the Act or these regulations. The determination of the recipient's violation may be made only after a recipient has had an opportunity for a hearing on the record before an administrative law judge.

(2) Any other means authorized by law, including but not limited to:

(i) Referral to the Department of Justice for proceedings to enforce any rights of the United States or obligations of the recipient created by the Act or these regulations.

(ii) Use of any requirement of or referral to any federal, state, or local government agency that will have the effect of correcting a violation of the Act or these regulations.

(b) Treasury will limit any termination under § 23.46(a)(1) to the particular recipient and particular program or activity or part of such program or activity Treasury finds in violation of these regulations. Treasury will not base any part of a termination on a finding with respect to any program or activity of the recipient that does not receive federal financial assistance from Treasury.

(c) Treasury will take no action under paragraph (a) of this section until:

(1) The Secretary has advised the recipient of its failure to comply with the Act and these regulations and has determined that voluntary compliance cannot be obtained.

(2) Thirty days have elapsed after the Secretary has sent a written report of the circumstances and grounds of the action to the committees of Congress having legislative jurisdiction over the federal program or activity involved. The Secretary will file a report whenever any action is taken under paragraph (a) of this section.

(d) Treasury also may defer granting new federal financial assistance to a recipient when a hearing under paragraph (a)(1) of this section is initiated.

(1) New federal financial assistance from Treasury includes all assistance for which Treasury requires an application or approval, including renewal or continuation of existing activities, or authorization of new activities, during the deferral period. New federal financial assistance from Treasury does not include increases in funding as a result of changed computation of formula awards or assistance approved prior to the beginning of a hearing under paragraph (a)(1) of this section.

(2) Treasury will not begin a deferral until the recipient has received a notice of an opportunity for a hearing under paragraph (a)(1) of this section. Treasury will not continue a deferral for more than 60 days unless a hearing has begun within that time or the time for beginning the hearing has been extended by mutual consent of the recipient and the Secretary. Treasury will not continue a deferral for more than 30 days after the close of the hearing, unless the hearing results in a finding against the recipient.

(3) Treasury will limit any deferral to the particular recipient and particular program or activity or part of such program or activity Treasury finds in violation of these regulations. Treasury will not base any part of a deferral on a finding with respect to any program or activity of the recipient that does not, and would not in connection with the new funds, receive federal financial assistance from Treasury.

§ 23.47 Hearings, decisions, post-termination proceedings.

Treasury procedural provisions for hearings, decisions, and post-termination proceedings applicable to Title VI of the Civil Rights Act of 1964 (if and when such procedural regulations become published) shall apply to Treasury enforcement of these regulations. Such regulations will be published within title 31 of the Code of Federal Regulations.

§ 23.48 Remedial action by recipient.

Where Treasury finds a recipient has discriminated on the basis of age in violation of the Act or this part, the recipient shall take any remedial action that Treasury may require to overcome the effects of the discrimination.

§ 23.49 Alternate funds disbursal procedure.

(a) When Treasury withholds funds from a recipient under these regulations, the Secretary may disburse the withheld funds directly to an alternate recipient: Any public or non-profit private organization or agency, or state or political subdivision of the state.

(b) The Secretary will require any alternate recipient to demonstrate:

(1) The ability to comply with these regulations; and

(2) The ability to achieve the goals of the federal statute authorizing the federal financial assistance.

§ 23.50 Exhaustion of administrative remedies.

(a) A complainant may file a civil action following the exhaustion of administrative remedies under the Act. Administrative remedies are exhausted if:

(1) 180 days have elapsed since the complainant filed the complaint and Treasury has made no finding with regard to the complainant; or

(2) Treasury issues any finding in favor of the recipient.

(b) If Treasury fails to make a finding within 180 days or issues a finding in favor of the recipient, Treasury shall:

(1) Promptly advise the complainant of this fact; and

(2) Advise the complainant of his or her right to bring a civil action for injunctive relief; and

(3) Inform the complainant:

(i) That the complainant may bring a civil action only in a United States district court for the district in which the recipient is found or transacts business;

(ii) That a complainant prevailing in a civil action has the right to be awarded the costs of the action, including reasonable attorney's fee, but that the complainant must demand these costs in the complaint.

(iii) That before commencing the action the complainant shall give 30 days notice by registered mail to the Secretary, the Secretary of HHS, the Attorney General of the United States, and the recipient.

(iv) That the notice must state: The alleged violation of the Act; the relief requested; the court in which the complainant is bringing the action; and whether or not attorney's fees are demanded in the event the complainant prevails; and

(v) That the complainant may not bring an action if the same alleged violation of the Act by the same recipient is the subject of a pending action in any court of the United States.

[FR Doc. 2015–19096 Filed 8–3–15; 8:45 am]

BILLING CODE 4810–25–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3050

[Docket No. RM2015–15; Order No. 2624]

Periodic Reporting

AGENCY: Postal Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission is noticing a recent Postal Service filing requesting that the Commission initiate an informal rulemaking proceeding to consider a change to analytical principles relating to periodic reports (Proposal Six). This notice informs the public of the filing,

invites public comment, and takes other administrative steps.

DATES: *Comments are due:* September 2, 2015. *Reply Comments are due:* September 11, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Summary of Proposal
III. Initial Commission Action
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I. Introduction

On July 27, 2015, the Postal Service filed a petition pursuant to 39 CFR 3050.11 requesting that the Commission initiate an informal rulemaking proceeding in order to consider changes in analytical principles relating to periodic reports.[1] Proposal Six is attached to the Petition and identifies the proposed analytical method change as a change related to the methodology used for measuring the national totals of revenue, pieces, and weight in the Revenue, Pieces, and Weight (RPW) Report for Click-N-Ship (CNS) Priority Mail. The Postal Service concurrently filed a non-public library reference, along with an application for non-public treatment of materials.[2]

II. Summary of Proposal

The Postal Service explains that the current RPW methodology relies on two sources for CNS: (1) CNS system census data regarding transactions involving insured extra services; and (2) statistical estimates from the Origin Destination Information System (ODIS)–RPW probability sampling system for CNS Priority mail that are not associated with insured transactions (including Priority Mail transactions where insurance is included). Petition, Proposal Six at 3. Under Proposal Six, ODIS–RPW statistical sampling estimates would be replaced with the remaining CNS system census transactional data. *Id.* All data for CNS would therefore be census derived from CNS system generated transactions, with the exception of flat-rate products.[3] In addition, CNS census activity would be adjusted to reflect refunds from the corresponding time period. *Id.* at 5.

As part of the public Excel spreadsheet filed with the Petition, the Postal Service provides an example of the kind of impact that a switch to census data would have on RPW Report data from the first quarter of Fiscal Year 2015. *Id.* at 7–8. Table A compares current ODIS–RPW report totals to RPW totals when incorporating new census sources. *Id.* at 8. The results show that the CNS portion of Priority Mail revenue, volume, and weight would have decreased, respectively, by 13.7, 14.3, and 4.4 percent, while extra service revenue would have increased by 18 percent. *Id.*

The Postal Service asserts that the proposed changes will provide ''a complete source of transaction-level data for mail piece revenue and volume characteristics, and their associated extra services needed for RPW reporting.'' *Id.* at 7. The Postal Service also states that the proposed changes would provide a more accurate report of flat-rate product weights and would provide a process for adjusting revenue and transactions thereby aligning them with the accounting treatment of refund revenue. *Id.*

III. Initial Commission Action

The Commission establishes Docket No. RM2015–15 for consideration of matters raised by the Petition. Additional information concerning the Petition may be accessed via the Commission's Web site at *http://www.prc.gov.* Interested persons may submit comments on the Petition and Proposal Six no later than September 2, 2015. Reply comments are due no later than September 11, 2015. Pursuant to 39 U.S.C. 505, Lyudmila Y. Bzhilyanskaya is designated as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. RM2015–15 for consideration of the matters raised by the Petition of the United States Postal Service Requesting Initiation of a Proceeding to Consider a Proposed Change in Analytical Principles (Proposal Six), filed July 27, 2015.

2. Comments are due no later than September 2, 2015. Reply comments are due no later than September 11, 2015.

3. Pursuant to 39 U.S.C. 505, the Commission appoints Lyudmila Y. Bzhilyanskaya to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–19029 Filed 8–3–15; 8:45 am]

BILLING CODE 7710–FW–P

[1] Petition of the United States Postal Service Requesting Initiation of a Proceeding to Consider a Proposed Change in Analytical Principles (Proposal Six), July 27, 2015 (Petition).

[2] Notice of Filing of USPS–RM2015–15/NP1 and Application for Nonpublic Treatment, July 27, 2015 (Notice). The Library Reference is USPS–RM2015–15/NP1—Nonpublic Material Relating to Proposal Six (Click-N-Ship). The Notice incorporates by reference the Application for Non-Public Treatment of Materials contained in Attachment Two to the United States Postal Service Fiscal Year 2014 Annual Compliance Report, December 29, 2014. Notice at 1. *See* 39 CFR part 3007 for information on access to non-public material.

[3] *Id.* As weight is not required for flat-rate products within the CNS system, ODIS–RPW estimated weight per piece would be used to estimate weight for flat-rate products. *Id.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, and 484

[CMS–1625–CN]

RIN 0938–AS46

Medicare and Medicaid Programs; CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects technical errors in the proposed rule that appeared in the July 10, 2015 **Federal Register** entitled ''Medicare and Medicaid Programs; CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements.''

DATES: Comments on the proposed rule published on July 10, 2015 (80 FR 39839), continue to be accepted until September 4, 2015.

FOR FURTHER INFORMATION CONTACT: Hillary Loeffler, (410) 786–0456.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2015–16790, published in the **Federal Register** of July 10, 2015 (80

FR 39839), there were technical errors that are identified and corrected in the Correction of Errors section of this correcting document.

II. Summary of Errors

On page 39854, in our discussion of case-mix weights, there was a sorting error in Table 9: CY 2016 Case-Mix Payment Weights.

On page 39906, in our discussion of the overall impact of the home health prospective payment system in CY 2016, we inadvertently provided the incorrect percent decrease in expenditures when comparing CY 2015 payments to estimated CY 2016 payments.

III. Correction of Errors

In FR Doc. 2015–16790 of July 10, 2015 (80 FR 39839), make the following corrections:

On page 39854, Table 9—CY 2016 Case-Mix Payment Weights is corrected to read as follows:

TABLE 9—CY 2016 CASE-MIX PAYMENT WEIGHTS

Payment group	Step (episode and/or therapy visit ranges)	Clinical and functional levels (1 = low; 2 = medium; 3= high)	CY 2016 Case-mix weights
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1S1	0.5969
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1S2	0.7216
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8462
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1S4	0.9708
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0954
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2S1	0.7123
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2S2	0.8240
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2S3	0.9357
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2S4	1.0474
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1591
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3S1	0.7709
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3S2	0.8868
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3S3	1.0027
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3S4	1.1186
10135	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F3S5	1.2345
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1S1	0.6339
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1S2	0.7637
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8935
10214	1st and 2nd Episodes, 10 Therapy Visits	C2F1S4	1.0234
10215	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1532
10221	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F2S1	0.7492
10222	1st and 2nd Episodes, 6 Therapy Visits	C2F2S2	0.8661
10223	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9830
10224	1st and 2nd Episodes, 10 Therapy Visits	C2F2S4	1.0999
10225	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2S5	1.2169
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3S1	0.8079
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3S2	0.9290
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3S3	1.0501
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3S4	1.1712
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2923
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6876
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1S2	0.8424
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9973
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1S4	1.1522
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3071
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2S1	0.8029
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2S2	0.9449
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0868
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2S4	1.2288
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3707
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3S1	0.8616
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3S2	1.0077
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3S3	1.1539
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3S4	1.3000
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3S5	1.4462
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2201
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1S2	1.4237
21113	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1S3	1.6273
21121	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2708
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4643
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2S3	1.6578
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3504
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3S2	1.5410
21133	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3S3	1.7316
21211	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2830
21212	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4994

TABLE 9—CY 2016 CASE-MIX PAYMENT WEIGHTS—Continued

Payment group	Step (episode and/or therapy visit ranges)	Clinical and functional levels (1 = low; 2 = medium; 3= high)	CY 2016 Case-mix weights
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1S3	1.7157
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3338
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5400
21223	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2S3	1.7461
21231	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F3S1	1.4134
21232	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F3S2	1.6167
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3S3	1.8200
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4619
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6962
21313	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1S3	1.9304
21321	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5127
21322	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F2S2	1.7368
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2S3	1.9609
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3S1	1.5923
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3S2	1.8135
21333	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3S3	2.0347
22111	3rd+ Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2795
22112	3rd+ Episodes, 16 to 17 Therapy Visits	C1F1S2	1.4633
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1S3	1.6471
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2952
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4806
22123	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2S3	1.6659
22131	3rd+ Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3761
22132	3rd+ Episodes, 16 to 17 Therapy Visits	C1F3S2	1.5581
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3S3	1.7401
22211	3rd+ Episodes, 14 to 15 Therapy Visits	C2F1S1	1.3660
22212	3rd+ Episodes, 16 to 17 Therapy Visits	C2F1S2	1.5546
22213	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1S3	1.7433
22221	3rd+ Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3817
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5719
22223	3rd+ Episodes, 18 to 19 Therapy Visits	C2F2S3	1.7621
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3S1	1.4626
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3S2	1.6495
22233	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3S3	1.8364
22311	3rd+ Episodes, 14 to 15 Therapy Visits	C3F1S1	1.5916
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1S2	1.7826
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1S3	1.9736
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2S1	1.6073
22322	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2S2	1.7999
22323	3rd+ Episodes, 18 to 19 Therapy Visits	C3F2S3	1.9924
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3S1	1.6882
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3S2	1.8774
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3S3	2.0667
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1S1	0.4805
30112	3rd+ Episodes, 6 Therapy Visits	C1F1S2	0.6403
30113	3rd+ Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8001
30114	3rd+ Episodes, 10 Therapy Visits	C1F1S4	0.9599
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1S5	1.1197
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2S1	0.5648
30122	3rd+ Episodes, 6 Therapy Visits	C1F2S2	0.7109
30123	3rd+ Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8570
30124	3rd+ Episodes, 10 Therapy Visits	C1F2S4	1.0031
30125	3rd+ Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1492
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3S1	0.6114
30132	3rd+ Episodes, 6 Therapy Visits	C1F3S2	0.7644
30133	3rd+ Episodes, 7 to 9 Therapy Visits	C1F3S3	0.9173
30134	3rd+ Episodes, 10 Therapy Visits	C1F3S4	1.0703
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3S5	1.2232
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1S1	0.4961
30212	3rd+ Episodes, 6 Therapy Visits	C2F1S2	0.6700
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8440
30214	3rd+ Episodes, 10 Therapy Visits	C2F1S4	1.0180
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1920
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2S1	0.5803
30222	3rd+ Episodes, 6 Therapy Visits	C2F2S2	0.7406
30223	3rd+ Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9009
30224	3rd+ Episodes, 10 Therapy Visits	C2F2S4	1.0612
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2S5	1.2214

TABLE 9—CY 2016 CASE-MIX PAYMENT WEIGHTS—Continued

Payment group	Step (episode and/or therapy visit ranges)	Clinical and functional levels (1 = low; 2 = medium; 3= high)	CY 2016 Case-mix weights
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3S1	0.6270
30232	3rd+ Episodes, 6 Therapy Visits	C2F3S2	0.7941
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9612
30234	3rd+ Episodes, 10 Therapy Visits	C2F3S4	1.1284
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2955
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6211
30312	3rd+ Episodes, 6 Therapy Visits	C3F1S2	0.8152
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1S3	1.0093
30314	3rd+ Episodes, 10 Therapy Visits	C3F1S4	1.2034
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3975
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7054
30322	3rd+ Episodes, 6 Therapy Visits	C3F2S2	0.8858
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0662
30324	3rd+ Episodes, 10 Therapy Visits	C3F2S4	1.2466
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2S5	1.4269
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7521
30332	3rd+ Episodes, 6 Therapy Visits	C3F3S2	0.9393
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3S3	1.1265
30334	3rd+ Episodes, 10 Therapy Visits	C3F3S4	1.3138
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3S5	1.5010
40111	All Episodes, 20+ Therapy Visits	C1F1S1	1.8309
40121	All Episodes, 20+ Therapy Visits	C1F2S1	1.8512
40131	All Episodes, 20+ Therapy Visits	C1F3S1	1.9222
40211	All Episodes, 20+ Therapy Visits	C2F1S1	1.9320
40221	All Episodes, 20+ Therapy Visits	C2F2S1	1.9523
40231	All Episodes, 20+ Therapy Visits	C2F3S1	2.0233
40311	All Episodes, 20+ Therapy Visits	C3F1S1	2.1647
40321	All Episodes, 20+ Therapy Visits	C3F2S1	2.1850
40331	All Episodes, 20+ Therapy Visits	C3F3S1	2.2559

On page 39906, second column, line 31 the number ''0.1'' is corrected to read ''1.8''.

Dated: July 29, 2015.

Madhura Valverde,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2015–19079 Filed 8–3–15; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 20

[Docket No. FWS–HQ–MB–2014–0064; FF09M21200–134–FXMB1231099BPP0]

RIN 1018–BA67

Migratory Bird Hunting; Proposed Migratory Bird Hunting Regulations on Certain Federal Indian Reservations and Ceded Lands for the 2015–16 Season

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The U.S. Fish and Wildlife Service (hereinafter, Service or we) proposes special migratory bird hunting regulations for certain Tribes on Federal Indian reservations, off-reservation trust lands, and ceded lands for the 2015–16 migratory bird hunting season.

DATES: You must submit comments on the proposed regulations by August 14, 2015.

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

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–MB–2014–0064.
- *U.S. mail or hand delivery:* Public Comments Processing, Attn: FWS–HQ–MB–2014–0064; Division of Policy, Performance, and Management Programs; U.S. Fish and Wildlife Service, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We will post all comments on *http://www.regulations.gov.* This generally means that your entire submission—including any personal identifying information—will be posted on the Web site. See the Public Comments section, below, for more information.

FOR FURTHER INFORMATION CONTACT: Ron W. Kokel, U.S. Fish and Wildlife Service, Department of the Interior, MS: MB, 5275 Leesburg Pike, Falls Church, VA 22041–3803; (703) 358–1967.

SUPPLEMENTARY INFORMATION: In the April 13, 2015, **Federal Register** (80 FR 19852), we requested proposals from Indian Tribes wishing to establish special migratory bird hunting regulations for the 2015–16 hunting season, under the guidelines described in the June 4, 1985, **Federal Register** (50 FR 23467). In this supplemental proposed rule, we propose special migratory bird hunting regulations for 31 Indian Tribes, based on the input we received in response to the April 13, 2015, proposed rule, and our previous rules. As described in that proposed rule, the promulgation of annual migratory bird hunting regulations involves a series of rulemaking actions each year. This proposed rule is part of that series.

We developed the guidelines for establishing special migratory bird hunting regulations for Indian Tribes in response to tribal requests for recognition of their reserved hunting rights and, for some Tribes, recognition of their authority to regulate hunting by

both tribal and nontribal hunters on their reservations. The guidelines include possibilities for:

(1) On-reservation hunting by both tribal and nontribal hunters, with hunting by nontribal hunters on some reservations to take place within Federal frameworks but on dates different from those selected by the surrounding State(s);

(2) On-reservation hunting by tribal members only, outside of the usual Federal frameworks for season dates and length, and for daily bag and possession limits; and

(3) Off-reservation hunting by tribal members on ceded lands, outside of usual framework dates and season length, with some added flexibility in daily bag and possession limits.

In all cases, the regulations established under the guidelines must be consistent with the March 10 to September 1 closed season mandated by the 1916 Convention between the United States and Great Britain (for Canada) for the Protection of Migratory Birds (Treaty). The guidelines apply to those Tribes having recognized reserved hunting rights on Federal Indian reservations (including off-reservation trust lands) and on ceded lands. They also apply to establishing migratory bird hunting regulations for nontribal hunters on all lands within the exterior boundaries of reservations where Tribes have full wildlife management authority over such hunting or where the Tribes and affected States otherwise have reached agreement over hunting by nontribal hunters on lands owned by non-Indians within the reservation.

Tribes usually have the authority to regulate migratory bird hunting by nonmembers on Indian-owned reservation lands, subject to Service approval. The question of jurisdiction is more complex on reservations that include lands owned by non-Indians, especially when the surrounding States have established or intend to establish regulations governing hunting by non-Indians on these lands. In such cases, we encourage the Tribes and States to reach agreement on regulations that would apply throughout the reservations. When appropriate, we will consult with a Tribe and State with the aim of facilitating an accord. We also will consult jointly with tribal and State officials in the affected States where Tribes wish to establish special hunting regulations for tribal members on ceded lands. Because of past questions regarding interpretation of what events trigger the consultation process, as well as who initiates it, we provide the following clarification.

We routinely provide copies of **Federal Register** publications pertaining to migratory bird management to all State Directors, Tribes, and other interested parties. It is the responsibility of the States, Tribes, and others to notify us of any concern regarding any feature(s) of any regulations. When we receive such notification, we will initiate consultation.

Our guidelines provide for the continued harvest of waterfowl and other migratory game birds by tribal members on reservations where such harvest has been a customary practice. We do not oppose this harvest, provided it does not take place during the closed season defined by the Treaty, and does not adversely affect the status of the migratory bird resource. Before developing the guidelines, we reviewed available information on the current status of migratory bird populations, reviewed the current status of migratory bird hunting on Federal Indian reservations, and evaluated the potential impact of such guidelines on migratory birds. We concluded that the impact of migratory bird harvest by tribal members hunting on their reservations is minimal.

One area of interest in Indian migratory bird hunting regulations relates to hunting seasons for nontribal hunters on dates that are within Federal frameworks, but which are different from those established by the State(s) where the reservation is located. A large influx of nontribal hunters onto a reservation at a time when the season is closed in the surrounding State(s) could result in adverse population impacts on one or more migratory bird species. The guidelines make this unlikely, and we may modify regulations or establish experimental special hunts, after evaluation of information obtained by the Tribes.

We believe the guidelines provide appropriate opportunity to accommodate the reserved hunting rights and management authority of Indian Tribes while ensuring that the migratory bird resource receives necessary protection. The conservation of this important international resource is paramount. Further, the guidelines should not be viewed as inflexible. In this regard, we note that they have been employed successfully since 1985. We believe they have been tested adequately and, therefore, we made them final beginning with the 1988–89 hunting season (53 FR 31612, August 18, 1988). We should stress here, however, that use of the guidelines is not mandatory and no action is required if a Tribe wishes to observe the hunting regulations established by the State(s) in which the reservation is located.

Service Migratory Bird Regulations Committee Meetings

Participants at the June 24–25, 2015, meetings reviewed information on the current status of migratory shore and upland game birds and developed 2015–16 migratory game bird regulations recommendations for these species plus regulations for migratory game birds in Alaska, Puerto Rico, and the U.S. Virgin Islands; special September waterfowl seasons in designated States; special sea duck seasons in the Atlantic Flyway; and extended falconry seasons. In addition, we reviewed and discussed preliminary information on the status of waterfowl.

Participants at the previously announced July 29–30, 2015, meetings reviewed information on the current status of waterfowl and developed recommendations for the 2015–16 regulations pertaining to regular waterfowl seasons and other species and seasons not previously discussed at the early-season meetings. In accordance with Department of the Interior policy, these meetings were open to public observation and you may submit comments on the matters discussed.

Population Status and Harvest

Preliminary information on the status of waterfowl and information on the status and harvest of migratory shore and upland game birds was excerpted from various reports and provided in the July 21, 2015, **Federal Register** (80 FR 43266). For more detailed information on methodologies and results, you may obtain complete copies of the various reports at the address indicated under **FOR FURTHER INFORMATION CONTACT** or from our Web site at *http://www.fws.gov/migratorybirds/NewsPublicationsReports.html*.

Hunting Season Proposals From Indian Tribes and Organizations

For the 2015–16 hunting season, we received requests from 25 Tribes and Indian organizations. In this proposed rule, we respond to these requests and also evaluate anticipated requests for seven Tribes from whom we usually hear but from whom we have not yet received proposals. We actively solicit regulatory proposals from other tribal groups that are interested in working cooperatively for the benefit of waterfowl and other migratory game birds. We encourage Tribes to work with us to develop agreements for management of migratory bird resources on tribal lands.

It should be noted that this proposed rule includes generalized regulations for both early- and late-season hunting. A final rule will be published in a late-August 2015 **Federal Register** that will include tribal regulations for the early-hunting season. Early seasons generally begin around September 1 each year, and most commonly include such species as American woodcock, sandhill cranes, mourning doves, and white-winged doves. Late seasons generally begin on or around September 24, and most commonly include waterfowl species.

In this current rulemaking, because of the compressed timeframe for establishing regulations for Indian Tribes and because final frameworks dates and other specific information are not available, the regulations for many tribal hunting seasons are described in relation to the season dates, season length, and limits that will be permitted when final Federal frameworks are announced for early- and late-season regulations. For example, daily bag and possession limits for ducks on some areas are shown as the same as permitted in Pacific Flyway States under final Federal frameworks, and limits for geese will be shown as the same permitted by the State(s) in which the tribal hunting area is located.

The proposed frameworks for early-season regulations were published in the **Federal Register** on July 21, 2015 (80 FR 43266); early-season final frameworks will be published in late August. Proposed late-season frameworks for waterfowl and coots will be published in mid-August, and the final frameworks for the late seasons will be published in mid-September. We will notify affected Tribes of season dates, bag limits, etc., as soon as final frameworks are established. As previously discussed, no action is required by Tribes wishing to observe migratory bird hunting regulations established by the State(s) where they are located. The proposed regulations for the 31 Tribes that meet the established criteria are shown below.

(a) Colorado River Indian Tribes, Colorado River Indian Reservation, Parker, Arizona (Tribal Members and Nontribal Hunters)

The Colorado River Indian Reservation is located in Arizona and California. The Tribes own almost all lands on the reservation, and have full wildlife management authority.

In their 2015–16 proposal, the Colorado River Indian Tribes request split dove seasons. They propose that their early season begin September 1 and end September 15, 2015. Daily bag limits would be 15 mourning or white-winged doves in the aggregate, of which no more than 10 may be white-winged dove. Possession limit would be 45, of which no more than 30 may be white-winged dove. The late season for doves is proposed to open November 7, 2015, and close December 20, 2015. The daily bag limit would be 15 mourning doves. The possession limit would be 45. Shooting hours would be from one-half hour before sunrise to noon in the early season and until sunset in the late season. Other special tribally set regulations would apply.

The Tribes also propose duck hunting seasons. The season would open October 17, 2015, and close January 25, 2016. The Tribes propose the same season dates for mergansers, coots, and common moorhens. The daily bag limit for ducks, including mergansers, would be seven, except that the daily bag limits could contain no more than two hen mallards, two redheads, two Mexican ducks, two goldeneye, three scaup, one pintail, two cinnamon teal, and one canvasback. The possession limit would be twice the daily bag limit after the first day of the season. The daily bag and possession limit for coots and common moorhens would be 25, singly or in the aggregate. Shooting hours would be from one-half hour before sunrise to sunset.

For geese, the Colorado River Indian Tribes propose a season of October 18, 2015, through January 19, 2016. The daily bag limit for geese would be three light geese and three dark geese. The possession limit would be six light geese and six dark geese after opening day. Shooting hours would be from one-half hour before sunrise to sunset.

In 1996, the Tribes conducted a detailed assessment of dove hunting. Results showed approximately 16,100 mourning doves and 13,600 white-winged doves were harvested by approximately 2,660 hunters who averaged 1.45 hunter-days. Field observations and permit sales indicate that fewer than 200 hunters participate in waterfowl seasons. Under the proposed regulations described here and based upon past seasons, we and the Tribes estimate harvest will be similar.

Hunters must have a valid Colorado River Indian Reservation hunting permit and a Federal Migratory Bird Stamp in their possession while hunting. Other special tribally set regulations would apply. As in the past, the regulations would apply both to tribal and nontribal hunters, and nontoxic shot is required for waterfowl hunting.

We propose to approve the Colorado River Indian Tribes regulations for the 2015–16 hunting season, given the seasons' dates fall within final flyway frameworks (applies to nontribal hunters only).

(b) Confederated Salish and Kootenai Tribes, Flathead Indian Reservation, Pablo, Montana (Tribal and Nontribal Hunters)

For the past several years, the Confederated Salish and Kootenai Tribes and the State of Montana have entered into cooperative agreements for the regulation of hunting on the Flathead Indian Reservation. The State and the Tribes are currently operating under a cooperative agreement signed in 1990, which addresses fishing and hunting management and regulation issues of mutual concern. This agreement enables all hunters to utilize waterfowl hunting opportunities on the reservation.

As in the past, tribal regulations for nontribal hunters would be at least as restrictive as those established for the Pacific Flyway portion of Montana. Goose, duck, and coot season dates would also be at least as restrictive as those established for the Pacific Flyway portion of Montana. Shooting hours for waterfowl hunting on the Flathead Reservation are one-half hour before sunrise to one-half hour after sunset. Steel shot or other federally approved nontoxic shots are the only legal shotgun loads on the reservation for waterfowl or other game birds.

For tribal members, the Tribe proposes outside frameworks for ducks and geese of September 1, 2015, through March 9, 2016. Daily bag and possession limits were not proposed for tribal members.

The requested season dates and bag limits are similar to past regulations. Harvest levels are not expected to change significantly. Standardized check station data from the 1993–94 and 1994–95 hunting seasons indicated no significant changes in harvest levels and that the large majority of the harvest is by nontribal hunters.

We propose to approve the Tribes' request for special migratory bird regulations for the 2015–16 hunting season.

(c) Fond du Lac Band of Lake Superior Chippewa Indians, Cloquet, Minnesota (Tribal Members Only)

Since 1996, the Service and the Fond du Lac Band of Lake Superior Chippewa Indians have cooperated to establish special migratory bird hunting regulations for tribal members. The Fond du Lac's May 26, 2015, proposal covers land set apart for the band under the Treaties of 1837 and 1854 in

northeastern and east-central Minnesota and the Band's Reservation near Duluth.

The band's proposal for 2015–16 is essentially the same as that approved last year. The proposed 2015–16 waterfowl hunting season regulations for Fond du Lac are as follows:

Ducks

A. 1854 and 1837 Ceded Territories

Season Dates: Begin September 12 and end November 30, 2015.

Daily Bag Limit: 18 ducks, including no more than 12 mallards (only 3 of which may be hens), 9 black ducks, 9 scaup, 9 wood ducks, 9 redheads, 9 pintails, and 9 canvasbacks.

B. Reservation

Season Dates: Begin September 1 and end November 30, 2015.

Daily Bag Limit: 12 ducks, including no more than 8 mallards (only 2 of which may be hens), 6 black ducks, 6 scaup, 6 redheads, 6 pintails, 6 wood ducks, and 6 canvasbacks.

Mergansers

A. 1854 and 1837 Ceded Territories

Season Dates: Begin September 12 and end November 30, 2015.

Daily Bag Limit: 15 mergansers, including no more than 6 hooded mergansers.

B. Reservation

Season Dates: Begin September 1 and end November 30, 2015.

Daily Bag Limit: 10 mergansers, including no more than 4 hooded mergansers.

Canada Geese

A. 1854 and 1837 Ceded Territories

Season Dates: Begin September 1 and end November 30, 2015.

Daily Bag Limit: 20 geese.

B. Reservation

Season Dates: Begin September 1 and end November 30, 2015.

Daily Bag Limit: 20 geese.

Sandhill Cranes

1854 and 1837 Ceded Territories Only

Season Dates: Begin September 1 and end November 30, 2015.

Daily Bag Limit: One sandhill crane. A crane carcass tag is required prior to hunting.

Coots and Common Moorhens (Common Gallinules)

A. 1854 and 1837 Ceded Territories

Season Dates: Begin September 12 and end November 30, 2015.

Daily Bag Limit: 20 coots and common moorhens, singly or in the aggregate.

B. Reservation

Season Dates: Begin September 1 and end November 30, 2015.

Daily Bag Limit: 20 coots and common moorhens, singly or in the aggregate.

Sora and Virginia Rails

All Areas

Season Dates: Begin September 1 and end November 30, 2015.

Daily Bag Limit: 25 sora and Virginia rails, singly or in the aggregate.

Common Snipe

All Areas

Season Dates: Begin September 1 and end November 30, 2015.

Daily Bag Limit: Eight common snipe.

Woodcock

All Areas

Season Dates: Begin September 1 and end November 30, 2015.

Daily Bag Limit: Three woodcock.

Mourning Dove

All Areas

Season Dates: Begin September 1 and end November 30, 2015.

Daily Bag Limit: 30 mourning doves.

The following general conditions apply:

1. While hunting waterfowl, a tribal member must carry on his/her person a valid Ceded Territory License.

2. Shooting hours for migratory birds are one-half hour before sunrise to one-half hour after sunset.

3. Except as otherwise noted, tribal members will be required to comply with tribal codes that will be no less restrictive than the provisions of Chapter 10 of the Model Off-Reservation Code. Except as modified by the Service rules adopted in response to this proposal, these amended regulations parallel Federal requirements in 50 CFR part 20 as to hunting methods, transportation, sale, exportation, and other conditions generally applicable to migratory bird hunting.

4. Band members in each zone will comply with State regulations providing for closed and restricted waterfowl hunting areas.

5. There are no possession limits for migratory birds. For purposes of enforcing bag limits, all migratory birds in the possession or custody of band members on ceded lands will be considered to have been taken on those lands unless tagged by a tribal or State conservation warden as having been taken on-reservation. All migratory birds that fall on reservation lands will not count as part of any off-reservation bag or possession limit.

The band anticipates harvest will be fewer than 500 ducks and geese, and fewer than 10 sandhill cranes.

We propose to approve the request for special migratory bird hunting regulations for the Fond du Lac Band of Lake Superior Chippewa Indians.

(d) Grand Traverse Band of Ottawa and Chippewa Indians, Suttons Bay, Michigan (Tribal Members Only)

In the 1995–96 migratory bird seasons, the Grand Traverse Band of Ottawa and Chippewa Indians and the Service first cooperated to establish special regulations for waterfowl. The Grand Traverse Band is a self-governing, federally recognized Tribe located on the west arm of Grand Traverse Bay in Leelanau County, Michigan. The Grand Traverse Band is a signatory Tribe of the Treaty of 1836. We have approved special regulations for tribal members of the 1836 treaty's signatory Tribes on ceded lands in Michigan since the 1986–87 hunting season.

For the 2015–16 season, the Tribe requests that the tribal member duck season run from September 1, 2015, through January 15, 2016. A daily bag limit of 25 would include no more than 6 pintail, 4 canvasback, 1 hooded merganser, 6 black ducks, 6 wood ducks, 5 redheads, and 12 mallards (only 6 of which may be hens).

For Canada and snow geese, the Tribe proposes a September 1 through January 31, 2016, season. For white-fronted geese and brant, the Tribe proposes a September 20 through December 30, 2015, season. The daily bag limit for Canada and snow geese would be 10, and the daily bag limit for white-fronted geese and including brant would be 5 birds. We further note that, based on available data (of major goose migration routes), it is unlikely that any Canada geese from the Southern James Bay Population will be harvested by the Tribe.

For woodcock, the Tribe proposes a September 1 through November 14, 2015, season. The daily bag limit will not exceed five birds. For mourning doves, snipe, and rails, the Tribe proposes a September 1 through November 14, 2015, season. The daily bag limit would be 10 per species.

For sandhill crane, the Tribe proposes a September 1 through November 14, 2015, season. The daily bag limit would be two birds and a season limit of six birds.

Shooting hours would be from one-half hour before sunrise to one-half hour after sunset. All other Federal regulations contained in 50 CFR part 20 would apply. The Tribe proposes to monitor harvest closely through game bag checks, patrols, and mail surveys. Harvest surveys from the 2013–14 hunting season indicated that approximately 30 tribal hunters harvested an estimated 100 ducks and 45 Canada geese.

We propose to approve the Grand Traverse Band of Ottawa and Chippewa Indians 2015–16 special migratory bird hunting proposal.

(e) Great Lakes Indian Fish and Wildlife Commission, Odanah, Wisconsin (Tribal Members Only)

Since 1985, various bands of the Lake Superior Tribe of Chippewa Indians have exercised judicially recognized, off-reservation hunting rights for migratory birds in Wisconsin. The specific regulations were established by the Service in consultation with the Wisconsin Department of Natural Resources and the Great Lakes Indian Fish and Wildlife Commission (GLIFWC) (GLIFWC is an intertribal agency exercising delegated natural resource management and regulatory authority from its member Tribes in portions of Wisconsin, Michigan, and Minnesota). Beginning in 1986, a Tribal season on ceded lands in the western portion of the Michigan Upper Peninsula was developed in coordination with the Michigan Department of Natural Resources. We have approved regulations for Tribal members in both Michigan and Wisconsin since the 1986–87 hunting season. In 1987, GLIFWC requested, and we approved, regulations to permit Tribal members to hunt on ceded lands in Minnesota, as well as in Michigan and Wisconsin. The States of Michigan and Wisconsin originally concurred with the regulations, although both Wisconsin and Michigan have raised various concerns over the years. Minnesota did not concur with the original regulations, stressing that the State would not recognize Chippewa Indian hunting rights in Minnesota's treaty area until a court with jurisdiction over the State acknowledges and defines the extent of these rights. In 1999, the U.S. Supreme Court upheld the existence of the tribes' treaty reserved rights in *Minnesota* v. *Mille Lacs Band,* 199 S.Ct. 1187 (1999).

We acknowledge all of the States' concerns, but point out that the U.S. Government has recognized the Indian treaty reserved rights, and that acceptable hunting regulations have been successfully implemented in Minnesota, Michigan, and Wisconsin. Consequently, in view of the above, we have approved regulations since the 1987–88 hunting season on ceded lands in all three States. In fact, this recognition of the principle of treaty reserved rights for band members to hunt and fish was pivotal in our decision to approve a 1991–92 season for the 1836 ceded area in Michigan. Since then, in the 2007 Consent Decree the 1836 Treaty Tribes' and Michigan Department of Natural Resources and Environment established court-approved regulations pertaining to off-reservation hunting rights for migratory birds.

For 2015, the GLIFWC proposes off-reservation special migratory bird hunting regulations on behalf of the member Tribes of the Voigt Intertribal Task Force of the GLIFWC (for the 1837 and 1842 Treaty areas in Wisconsin and Michigan), the Mille Lacs Band of Ojibwe and the six Wisconsin Bands (for the 1837 Treaty area in Minnesota), and the Bay Mills Indian Community (for the 1836 Treaty area in Michigan). Member Tribes of the Task Force are: The Bad River Band of the Lake Superior Tribe of Chippewa Indians, the Lac Courte Oreilles Band of Lake Superior Chippewa Indians, the Lac du Flambeau Band of Lake Superior Chippewa Indians, the Red Cliff Band of Lake Superior Chippewa Indians, the St. Croix Chippewa Indians of Wisconsin, and the Sokaogon Chippewa Community (Mole Lake Band), all in Wisconsin; the Mille Lacs Band of Chippewa Indians and the Fond du Lac Band of Lake Superior Chippewa Indians in Minnesota; and the Lac Vieux Desert Band of Chippewa Indians and the Keweenaw Bay Indian Community in Michigan.

The GLIFWC 2015 proposal has two changes from regulations approved last season. In the 1837 and 1842 Treaty Areas, the GLIFWC proposal would allow the use of electronic calls for any open season under a limited and experimental design with up to only 50 Tribal hunters to obtain permits and use electronic calls during any open season. In addition to obtaining a special permit, the Tribal hunter would be required to complete and submit a hunt diary for each hunt where electronic calls were used. In addition, GLIFWC would also like to extend the mourning dove season dates from September 1 through November 9 to September 1 through November 29.

GLIFWC states that the proposed regulatory changes are intended to increase the subsistence opportunities for tribal migratory bird hunters and provide opportunities for more efficient harvesting. Under the GLIFWC's proposed regulations, GLIFWC expects total ceded territory harvest to be approximately 1,650 ducks, 375 geese, 20 sandhill cranes, and 20 swans, which is roughly similar to anticipated levels in previous years for those species for which seasons were established. GLIWFC further anticipates that tribal harvest will remain low given the small number of tribal hunters and the limited opportunity to harvest more than a small number of birds on most hunting trips.

Recent GLIFWC harvest surveys (1996–98, 2001, 2004, 2007–08, 2011, and 2012) indicate that tribal off-reservation waterfowl harvest has averaged fewer than 1,100 ducks and 250 geese annually. In the latest survey year for which we have specific results (2012), an estimated 86 hunters took an estimated 1,090 trips and harvested 1,799 ducks (1.7 ducks per trip) and 822 geese. Two sandhill cranes were reported harvested in each of the first three Tribal sandhill crane seasons, and no swans were harvested in 2014. Analysis of hunter survey data over 1996–2012 indicates a general downward trend in both harvest and hunter participation. While we acknowledge that tribal harvest and participation has declined in recent years, we do not believe that allowing the use of electronic calls at this time for tribal waterfowl seasons on ceded lands in Wisconsin, Michigan, and Minnesota for the 2015–16 season is in the best interest of the conservation of migratory birds. We have no issues with extending the mourning dove season. More specific discussion on the use of electronic calls follows below.

Allowing Electronic Calls

As we have stated the last four years (76 FR 54676, September 1, 2011; 77 FR 54451, September 5, 2012; 78 FR 53218, August 28, 2013; 79 FR 52226, September 3, 2014), the issue of allowing electronic calls and other electronic devices for migratory game bird hunting has been highly debated and highly controversial over the last 40 years, similar to other prohibited hunting methods such as baiting. Electronic calls, *i.e.,* the use or aid of recorded or electronic amplified bird calls or sounds, or recorded or electrically amplified imitations of bird calls or sounds to lure or attract migratory game birds to hunters, was Federally prohibited in 1957, because of their effectiveness in attracting and aiding the harvest of ducks and geese and are generally not considered a legitimate component of hunting. In

1999, after much debate, the migratory bird regulations were revised to allow the use of electronic calls for the take of light geese (lesser snow geese and Ross geese) during a light-goose-only season when all other waterfowl and crane hunting seasons, excluding falconry, were closed (64 FR 7507, February 16, 1999; 64 FR 71236, December 20, 1999; 73 FR 65926, November 5, 2008). The regulations were also changed in 2006, to allow the use of electronic calls for the take of resident Canada geese during Canada-goose-only September seasons when all other waterfowl and crane seasons, excluding falconry, were closed (71 FR 45964, August 10, 2006). In both instances, these changes were made in order to significantly increase the take of these species due to either serious population overabundance, depredation issues, or public health and safety issues, or a combination of these.

In our previous responses on this issue, we have also provided discussion on available information from the use of electronic calls during the special light-goose seasons and our belief to its applicability to most waterfowl species. Given available evidence on the effectiveness of electronic calls, we continue to be concerned about the large biological uncertainty surrounding any widespread use of electronic calls. Additionally, given the fact that tribal waterfowl hunting covered by this proposal would occur on ceded lands that are not in the ownership of the Tribes, we remain very concerned that the use of electronic calls to take waterfowl would lead to confusion on the part of the public, wildlife-management agencies, and law enforcement officials in implementing the requirements of 50 CFR part 20. Further, similar to the impacts of baiting, uncertainties concerning the zone of influence attributed to the use of electronic calls could potentially increase harvest from nontribal hunters operating within areas electronic calls are being used during the dates of the general hunt.

Notwithstanding our concerns, we understand GLIFWC's position on this issue, their desire to increase tribal hunter opportunity, harvest, and participation, and the importance that GLIFWC has ascribed to these issues. In our recent discussions with them this summer, they have expressed a willingness to work with us to further discuss these issues, all the uncertainties and difficulties surrounding them, and the overall Federal-Tribal process for addressing these and other such issues. However, we have only recently begun such discussions. As such, we are not yet at a point that would allow our approval of this proposal, or any such proposal. Further, we believe it would be premature at his time to approve such a measure, or any such measure, until we finalize the Federal-Tribal process, roles, and responsibilities for addressing this and other such issues. It is our hope that over the next year, we can continue these discussions. We remain hopeful that we can reach a mutually agreeable resolution.

Thus, at this time, removal of the electronic call prohibition, even with the proposed limited and experimental design, would be inconsistent with our long-standing concerns, and we do not support allowing the use of electronic calls in the 1837 and 1842 Treaty Areas for any open season.

The proposed 2015–16 waterfowl hunting season regulations apply to all treaty areas (except where noted) for GLIFWC as follows:

Ducks

Season Dates: Begin September 1 and end December 31, 2015.

Daily Bag Limit: 50 ducks in the 1837 and 1842 Treaty Area; 30 ducks in the 1836 Treaty Area.

Mergansers

Season Dates: Begin September 1 and end December 31, 2015.

Daily Bag Limit: 10 mergansers.

Geese

Season Dates: Begin September 1 and end December 31, 2015. In addition, any portion of the ceded territory that is open to State-licensed hunters for goose hunting outside of these dates will also be open concurrently for tribal members.

Daily Bag Limit: 20 geese in aggregate.

Other Migratory Birds

A. Coots and Common Moorhens (Common Gallinules)

Season Dates: Begin September 1 and end December 31, 2015.

Daily Bag Limit: 20 coots and common moorhens (common gallinules), singly or in the aggregate.

B. Sora and Virginia Rails

Season Dates: Begin September 1 and end December 31, 2015.

Daily Bag and Possession Limits: 20, singly, or in the aggregate, 25.

C. Common Snipe

Season Dates: Begin September 1 and end December 31, 2015.

Daily Bag Limit: 16 common snipe.

D. Woodcock

Season Dates: Begin September 2 and end December 31, 2015.

Daily Bag Limit: 10 woodcock.

E. Mourning Dove: 1837 and 1842 Ceded Territories only.

Season Dates: Begin September 1 and end November 29, 2015.

Daily Bag Limit: 15 mourning doves.

F. Sandhill Cranes: 1837 and 1842 Ceded Territories only.

Season Dates: Begin September 1 and end December 31, 2015.

Daily Bag Limit: 2 cranes.

G. Swans: 1837 and 1842 Ceded Territories only.

Season Dates: Begin November 1 and end December 31, 2015.

Daily Bag Limit: 2 swans. All harvested swans must be registered by presenting the fully-feathered carcass to a tribal registration station or GLIFWC warden. If the total number of trumpeter swans harvested reaches 10, the swan season will be closed by emergency tribal rule.

General Conditions

A. All tribal members will be required to obtain a valid tribal waterfowl hunting permit.

B. Except as otherwise noted, tribal members will be required to comply with tribal codes that will be no less restrictive than the model ceded territory conservation codes approved by Federal courts in the *Lac Courte Oreilles* v. *State of Wisconsin (Voigt)* and *Mille Lacs Band* v. *State of Minnesota* cases. Chapter 10 in each of these model codes regulates ceded territory migratory bird hunting. Both versions of Chapter 10 parallel Federal requirements as to hunting methods, transportation, sale, exportation, and other conditions generally applicable to migratory bird hunting. They also automatically incorporate by reference the Federal migratory bird regulations adopted in response to this proposal.

C. Particular Regulations of Note Include

1. Nontoxic shot will be required for all waterfowl hunting by tribal members.

2. Tribal members in each zone will comply with tribal regulations providing for closed and restricted waterfowl hunting areas. These regulations generally incorporate the same restrictions contained in parallel State regulations.

3. There are no possession limits, with the exception of 2 swans (in the aggregate) and 25 rails (in the aggregate). For purposes of enforcing bag limits, all migratory birds in the possession and custody of tribal members on ceded

lands will be considered to have been taken on those lands unless tagged by a tribal or State conservation warden as taken on reservation lands. All migratory birds that fall on reservation lands will not count as part of any off-reservation bag or possession limit.

4. The baiting restrictions included in the respective section 10.05(2)(h) of the model ceded territory conservation codes will be amended to include language which parallels that in place for nontribal members as published at 64 FR 29799, June 3, 1999.

5. There are no shell limit restrictions.

6. Hunting hours are from 30 minutes before sunrise to 30 minutes after sunset.

We propose to approve the above GLIFWC regulations for the 2015–16 hunting season.

(f) Jicarilla Apache Tribe, Jicarilla Indian Reservation, Dulce, New Mexico (Tribal Members and Nontribal Hunters)

The Jicarilla Apache Tribe has had special migratory bird hunting regulations for tribal members and nonmembers since the 1986–87 hunting season. The Tribe owns all lands on the reservation and has recognized full wildlife management authority. In general, the proposed seasons would be more conservative than allowed by the Federal frameworks of last season and by States in the Pacific Flyway.

The Tribe proposes a 2015–16 waterfowl and Canada goose season beginning October 10, 2015, and a closing date of November 30, 2015. Daily bag and possession limits for waterfowl would be the same as Pacific Flyway States. The Tribe proposes a daily bag limit for Canada geese of two. Other regulations specific to the Pacific Flyway guidelines for New Mexico would be in effect.

During the Jicarilla Game and Fish Department's 2014–15 season, estimated duck harvest was 83, which is the lowest on record. The species composition included mainly mallards, northern shovelor, gadwall, American wigeon, and teal. The estimated harvest of geese was 7 birds.

The proposed regulations are essentially the same as were established last year. The Tribe anticipates the maximum 2015–16 waterfowl harvest would be around 300 ducks and 30 geese.

We propose to approve the Tribe's requested 2015–16 hunting seasons.

(g) Kalispel Tribe, Kalispel Reservation, Usk, Washington (Tribal Members and Nontribal Hunters)

The Kalispel Reservation was established by Executive Order in 1914, and currently comprises approximately 4,600 acres. The Tribe owns all Reservation land and has full management authority. The Kalispel Tribe has a fully developed wildlife program with hunting and fishing codes. The Tribe enjoys excellent wildlife management relations with the State. The Tribe and the State have an operational memorandum of understanding with emphasis on fisheries but also for wildlife.

The nontribal member seasons described below pertain to a 176-acre waterfowl management unit and 800 acres of reservation land with a guide for waterfowl hunting. The Tribe is utilizing this opportunity to rehabilitate an area that needs protection because of past land use practices, as well as to provide additional waterfowl hunting in the area. Beginning in 1996, the requested regulations also included a proposal for Kalispel-member-only migratory bird hunting on Kalispel-ceded lands within Washington, Montana, and Idaho.

For the 2015–16 migratory bird hunting seasons, the Kalispel Tribe proposes tribal and nontribal member waterfowl seasons. The Tribe requests that both duck and goose seasons open at the earliest possible date and close on the latest date under Federal frameworks.

For nontribal hunters on Tribally managed lands, the Tribe requests the seasons open at the earliest possible date and remain open, for the maximum amount of open days. Specifically, the Tribe requests that the season for ducks begin October 3, 2015, and end January 17, 2016. In that period, nontribal hunters would be allowed to hunt approximately 107 days. Hunters should obtain further information on specific hunt days from the Kalispel Tribe.

For nontribal hunters on Tribally managed lands, the Tribe also requests the season for geese run from September 5 to September 13, 2015, and from October 3, 2015, to January 17, 2016. Total number of days should not exceed 107. Nontribal hunters should obtain further information on specific hunt days from the Tribe. Daily bag and possession limits would be the same as those for the State of Washington.

The Tribe reports past nontribal harvest of 1.5 ducks per day. Under the proposal, the Tribe expects harvest to be similar to last year, that is, fewer than 100 geese and 200 ducks.

All other State and Federal regulations contained in 50 CFR part 20, such as use of nontoxic shot and possession of a signed migratory bird hunting stamp, would be required.

For tribal members on Kalispel-ceded lands, the Kalispel Tribe proposes season dates for ducks of October 3, 2015, through January 31, 2016, and for geese of September 5, 2015, through January 31, 2016. Daily bag and possession limits would parallel those in the Federal regulations contained in 50 CFR part 20.

The Tribe reports that there was no tribal harvest. Under the proposal, the Tribe expects harvest to be fewer than 200 birds for the season with fewer than 100 geese. Tribal members would be required to possess a signed Federal migratory bird stamp and a tribal ceded lands permit.

We propose to approve the regulations requested by the Kalispel Tribe, provided that the nontribal seasons conform to Treaty limitations and final Federal frameworks for the Pacific Flyway.

(h) Klamath Tribe, Chiloquin, Oregon (Tribal Members Only)

The Klamath Tribe currently has no reservation, per se. However, the Klamath Tribe has reserved hunting, fishing, and gathering rights within its former reservation boundary. This area of former reservation, granted to the Klamaths by the Treaty of 1864, is over 1 million acres. Tribal natural resource management authority is derived from the Treaty of 1864, and carried out cooperatively under the judicially enforced Consent Decree of 1981. The parties to this Consent Decree are the Federal Government, the State of Oregon, and the Klamath Tribe. The Klamath Indian Game Commission sets the seasons. The tribal biological staff and tribal regulatory enforcement officers monitor tribal harvest by frequent bag checks and hunter interviews.

For the 2015–16 season, we have not yet heard from the Tribe; however, the Tribe usually requests proposed season dates of October 1, 2015, through January 31, 2016. Daily bag limits would be 9 for ducks, 9 for geese, and 9 for coot, with possession limits twice the daily bag limit. Shooting hours would be one-half hour before sunrise to one-half hour after sunset. Steel shot is required.

Based on the number of birds produced in the Klamath Basin, this year's harvest would be similar to last year's. Information on tribal harvest suggests that more than 70 percent of the annual goose harvest is local birds produced in the Klamath Basin.

If we receive a proposal that matches the Tribe's usual request, we propose to approve those 2015–16 special migratory bird hunting regulations.

(i) Leech Lake Band of Ojibwe, Cass Lake, Minnesota (Tribal Members Only)

The Leech Lake Band of Ojibwe is a federally recognized Tribe located in Cass Lake, Minnesota. The reservation employs conservation officers to enforce conservation regulations. The Service and the Tribe have cooperatively established migratory bird hunting regulations since 2000.

For the 2015–16 season, the Tribe requests a duck season starting on September 15 and ending December 31, 2015, and a goose season to run from September 1 through December 31, 2015. Daily bag limits for ducks would be 10, including no more than 5 pintail, 5 canvasback, and 5 black ducks. Daily bag limits for geese would be 10. Possession limits would be twice the daily bag limit. Shooting hours are one-half hour before sunrise to one-half hour after sunset.

The annual harvest by tribal members on the Leech Lake Reservation is estimated at 250 to 500 birds.

We propose to approve the Leech Lake Band of Ojibwe's requested 2015–16 special migratory bird hunting season.

(j) Little River Band of Ottawa Indians, Manistee, Michigan (Tribal Members Only)

The Little River Band of Ottawa Indians is a self-governing, federally recognized Tribe located in Manistee, Michigan, and a signatory Tribe of the Treaty of 1836. We have approved special regulations for tribal members of the 1836 treaty's signatory Tribes on ceded lands in Michigan since the 1986–87 hunting season. Ceded lands are located in Lake, Mason, Manistee, and Wexford Counties. The Band normally proposes regulations to govern the hunting of migratory birds by Tribal members within the 1836 Ceded Territory as well as on the Band's Reservation.

For the 2015–16 season, we have yet to hear from the Little River Band of Ottawa Indians. The Little River Band of Ottawa Indians usually proposes a duck and merganser season from September 12, 2015, through January 25, 2016. A daily bag limit of 12 ducks would include no more than 2 pintail, 2 canvasback, 3 black ducks, 3 wood ducks, 3 redheads, 6 mallards (only 2 of which may be a hen), and 1 hooded merganser. Possession limits would be twice the daily bag limit.

For white-fronted geese, snow geese, and brant, the Tribe usually proposes a September 19 through November 30, 2015, season. Daily bag limits would be five geese.

For Canada geese only, the Tribe usually proposes a September 1, 2015, through February 8, 2016, season with a daily bag limit of five. The possession limit would be twice the daily bag limit.

For snipe, woodcock, rails, and mourning doves, the Tribe usually proposes a September 1 to November 14, 2015, season. The daily bag limit would be 10 common snipe, 5 woodcock, 10 rails, and 10 mourning doves. Possession limits for all species would be twice the daily bag limit.

The Tribe monitors harvest through mail surveys. General conditions are as follows:

A. All tribal members will be required to obtain a valid tribal resource card and 2015–16 hunting license.

B. Except as modified by the Service rules adopted in response to this proposal, these amended regulations parallel all Federal regulations contained in 50 CFR part 20.

C. Particular regulations of note include:

(1) Nontoxic shot will be required for all waterfowl hunting by tribal members.

(2) Tribal members in each zone will comply with tribal regulations providing for closed and restricted waterfowl hunting areas. These regulations generally incorporate the same restrictions contained in parallel State regulations.

D. Tribal members hunting in Michigan will comply with tribal codes that contain provisions parallel to Michigan law regarding duck blinds and decoys.

We plan to approve Little River Band of Ottawa Indians' 2015–16 special migratory bird hunting seasons upon receipt of their proposal.

(k) The Little Traverse Bay Bands of Odawa Indians, Petoskey, Michigan (Tribal Members Only)

The Little Traverse Bay Bands of Odawa Indians (LTBB) is a self-governing, federally recognized Tribe located in Petoskey, Michigan, and a signatory Tribe of the Treaty of 1836. We have approved special regulations for tribal members of the 1836 treaty's signatory Tribes on ceded lands in Michigan since the 1986–87 hunting season.

For the 2015–16 season, the Little Traverse Bay Bands of Odawa Indians propose regulations similar to those of other Tribes in the 1836 treaty area. LTBB proposes the regulations to govern the hunting of migratory birds by tribal members on the LTBB reservation and within the 1836 Treaty Ceded Territory. The tribal member duck and merganser season would run from September 1, 2015, through January 31, 2016. A daily bag limit of 20 ducks and 10 mergansers would include no more than 5 hen mallards, 5 pintail, 5 canvasback, 5 scaup, 5 hooded merganser, 5 black ducks, 5 wood ducks, and 5 redheads.

For Canada geese, the LTBB proposes a September 1, 2015, through February 8, 2016, season. The daily bag limit for Canada geese would be 20 birds. We further note that, based on available data (of major goose migration routes), it is unlikely that any Canada geese from the Southern James Bay Population would be harvested by the LTBB. Possession limits are twice the daily bag limit.

For woodcock, the LTBB proposes a September 1 to December 1, 2015, season. The daily bag limit will not exceed 10 birds. For snipe, the LTBB proposes a September 1 to December 31, 2015, season. The daily bag limit will not exceed 16 birds. For mourning doves, the LTBB proposes a September 1 to November 14, 2015, season. The daily bag limit will not exceed 15 birds. For Virginia and sora rails, the LTBB proposes a September 1 to December 31, 2015, season. The daily bag limit will not exceed 20 birds per species. For coots and gallinules, the LTBB proposes a September 15 to December 31, 2015, season. The daily bag limit will not exceed 20 birds per species. The possession limit will not exceed 2 days' bag limit for all birds.

The LTBB also proposes a sandhill crane season to begin September 1 and end December 1, 2015. The daily bag limit will not exceed one bird. The possession limit will not exceed two times the bag limit.

All other Federal regulations contained in 50 CFR part 20 would apply.

Harvest surveys from 2014–15 hunting season indicated that approximately 10 hunters harvested 10 different waterfowl species totaling 69 birds. No sandhill cranes were reported harvested during the 2014–15 season. The LTBB proposes to monitor harvest closely through game bag checks, patrols, and mail surveys. In particular, the LTBB proposes monitoring the harvest of Southern James Bay Canada geese and sandhill cranes to assess any impacts of tribal hunting on the population.

We propose to approve the Little Traverse Bay Bands of Odawa Indians' requested 2015–16 special migratory bird hunting regulations.

(l) Lower Brule Sioux Tribe, Lower Brule Reservation, Lower Brule, South Dakota (Tribal Members and Nontribal Hunters)

The Lower Brule Sioux Tribe first established tribal migratory bird hunting regulations for the Lower Brule Reservation in 1994. The Lower Brule Reservation is about 214,000 acres in size and is located on and adjacent to the Missouri River, south of Pierre. Land ownership on the reservation is mixed, and until recently, the Lower Brule Tribe had full management authority over fish and wildlife via a memorandum of agreement (MOA) with the State of South Dakota. The MOA provided the Tribe jurisdiction over fish and wildlife on reservation lands, including deeded and U.S. Army Corps of Engineers-taken lands. For the 2015–16 season, the two parties have come to an agreement that provides the public a clear understanding of the Lower Brule Sioux Wildlife Department license requirements and hunting season regulations. The Lower Brule Reservation waterfowl season is open to tribal and nontribal hunters.

For the 2015–16 migratory bird hunting season, the Lower Brule Sioux Tribe proposes a nontribal member duck, merganser, and coot season length of 97 days, or the maximum number of days allowed by Federal frameworks in the High Plains Management Unit for this season. The Tribe proposes a duck season from October 10, 2015, through January 14, 2016. The daily bag limit would be six birds or the maximum number that Federal regulations allow, including no more than two hen mallard and five mallards total, two pintail, two redhead, two canvasback, three wood duck, three scaup, and one mottled duck. The daily bag limit for mergansers would be five, only two of which could be a hooded merganser. The daily bag limit for coots would be 15. Possession limits would be three times the daily bag limits.

The Tribe's proposed nontribal-member Canada goose season would run from October 31, 2015, through February 14, 2016 (107-day season length), with a daily bag limit of six Canada geese. The Tribe's proposed nontribal member white-fronted goose season would run from October 31, 2015, through January 26, 2016, with a daily bag and possession limits concurrent with Federal regulations. The Tribe's proposed nontribal-member light goose season would run from October 31, 2015, through February 14, 2016, and February 15 through May 3, 2016. The light goose daily bag limit would be 20 or the maximum number that Federal regulations allow with no possession limits.

For tribal members, the Lower Brule Sioux Tribe proposes a duck, merganser, and coot season from September 1, 2015, through March 10, 2016. The daily bag limit would be six ducks, including no more than two hen mallard and five mallards total, two pintail, two redheads, two canvasback, three wood ducks, three scaup, and one mottled duck or the maximum number that Federal regulations allow. The daily bag limit for mergansers would be five, only two of which could be hooded mergansers. The daily bag limit for coots would be 15. Possession limits would be three times the daily bag limits.

The Tribe's proposed Canada goose season for tribal members would run from September 1, 2015, through March 10, 2016, with a daily bag limit of six Canada geese. The Tribe's proposed white-fronted goose tribal season would run from September 1, 2015, through March 10, 2016, with a daily bag limit of two white-fronted geese or the maximum number that Federal regulations allow. The Tribe's proposed light goose tribal season would run from September 1, 2015, through March 10, 2016. The light goose daily bag limit would be 20 or the maximum number that Federal regulations allow, with no possession limits.

In the 2013–14 season, non-tribal members harvested 641 geese and 1,616 ducks. In the 2013–14 season, duck harvest species composition was primarily mallard (67 percent), gadwall (5 percent), green-winged teal (7 percent), and wigeon (5 percent).

The Tribe anticipates a duck and goose harvest similar to those of the previous years. All basic Federal regulations contained in 50 CFR part 20, including the use of nontoxic shot, Migratory Waterfowl Hunting and Conservation Stamps, etc., would be observed by the Tribe's proposed regulations. In addition, the Lower Brule Sioux Tribe has an official Conservation Code that was established by Tribal Council Resolution in June 1982 and updated in 1996.

We plan to approve the Tribe's requested regulations for the Lower Brule Reservation if the seasons' dates fall within final Federal flyway frameworks (applies to nontribal hunters only).

(m) Lower Elwha Klallam Tribe, Port Angeles, Washington (Tribal Members Only)

Since 1996, the Service and the Point No Point Treaty Tribes, of which Lower Elwha was one, have cooperated to establish special regulations for migratory bird hunting. The Tribes are now acting independently, and the Lower Elwha Klallam Tribe would like to establish migratory bird hunting regulations for tribal members for the 2015–16 season. The Tribe has a reservation on the Olympic Peninsula in Washington State and is a successor to the signatories of the Treaty of Point No Point of 1855.

For the 2015–16 season, we have yet to hear from the Lower Elwha Klallam Tribe. The Tribe usually requests special migratory bird hunting regulations for ducks (including mergansers), geese, coots, band-tailed pigeons, snipe, and mourning doves. The Lower Elwha Klallam Tribe usually requests a duck and coot season from September 13, 2015, to January 4, 2016. The daily bag limit will be seven ducks, including no more than two hen mallards, one pintail, one canvasback, and two redheads. The daily bag and possession limit on harlequin duck will be one per season. The coot daily bag limit will be 25. The possession limit will be twice the daily bag limit, except as noted above.

For geese, the Tribe usually requests a season from September 13, 2015, to January 4, 2016. The daily bag limit will be four, including no more than three light geese. The season on Aleutian Canada geese will be closed.

For brant, the Tribe usually proposes to close the season.

For mourning doves, band-tailed pigeon, and snipe, the Tribe usually requests a season from September 1, 2015, to January 11, 2016, with a daily bag limit of 10, 2, and 8, respectively. The possession limit will be twice the daily bag limit.

All Tribal hunters authorized to hunt migratory birds are required to obtain a tribal hunting permit from the Lower Elwha Klallam Tribe pursuant to tribal law. Hunting hours would be from one-half hour before sunrise to sunset. Only steel, tungsten-iron, tungsten-polymer, tungsten-matrix, and tin shot are allowed for hunting waterfowl. It is unlawful to use or possess lead shot while hunting waterfowl.

The Tribe typically anticipates harvest to be fewer than 10 birds. Tribal reservation police and Tribal fisheries enforcement officers have the authority to enforce these migratory bird hunting regulations.

The Service proposes to approve the special migratory bird hunting regulations for the Lower Elwha Klallam Tribe upon receipt of their proposal.

(n) Makah Indian Tribe, Neah Bay, Washington (Tribal Members Only)

The Makah Indian Tribe and the Service have been cooperating to establish special regulations for migratory game birds on the Makah Reservation and traditional hunting land off the Makah Reservation since the 2001–02 hunting season. Lands off the Makah Reservation are those contained within the boundaries of the State of Washington Game Management Units 601–603.

The Makah Indian Tribe proposes a duck and coot hunting season from September 26, 2015, to January 31, 2016. The daily bag limit is seven ducks, including no more than five mallards (only two hen mallard), one canvasback, one pintail, three scaup, and one redhead. The daily bag limit for coots is 25. The Tribe has a year-round closure on wood ducks and harlequin ducks. Shooting hours for all species of waterfowl are one-half hour before sunrise to sunset.

For geese, the Tribe proposes that the season open on September 26, 2015, and close January 31, 2016. The daily bag limit for geese is four and one brant. The Tribe notes that there is a year-round closure on Aleutian and dusky Canada geese.

For band-tailed pigeons, the Tribe proposes that the season open September 12, 2015, and close October 25, 2015. The daily bag limit for band-tailed pigeons is two.

The Tribe anticipates that harvest under this regulation will be relatively low since there are no known dedicated waterfowl hunters and any harvest of waterfowl or band-tailed pigeons is usually incidental to hunting for other species, such as deer, elk, and bear. The Tribe expects fewer than 50 ducks and 10 geese to be harvested during the 2015–16 migratory bird hunting season.

All other Federal regulations contained in 50 CFR part 20 would apply. The following restrictions are also usually proposed by the Tribe:

(1) As per Makah Ordinance 44, only shotguns may be used to hunt any species of waterfowl. Additionally, shotguns must not be discharged within 0.25 miles of an occupied area.

(2) Hunters must be eligible, enrolled Makah tribal members and must carry their Indian Treaty Fishing and Hunting Identification Card while hunting. No tags or permits are required to hunt waterfowl.

(3) The Cape Flattery area is open to waterfowl hunting, except in designated wilderness areas, or within 1 mile of Cape Flattery Trail, or in any area that is closed to hunting by another ordinance or regulation.

(4) The use of live decoys and/or baiting to pursue any species of waterfowl is prohibited.

(5) Steel or bismuth shot only for waterfowl is allowed; the use of lead shot is prohibited.

(6) The use of dogs is permitted to hunt waterfowl.

The Service proposes to approve the Makah Indian Tribe's requested 2015–16 special migratory bird hunting regulations.

(o) Navajo Nation, Navajo Indian Reservation, Window Rock, Arizona (Tribal Members and Nontribal Hunters)

Since 1985, we have established uniform migratory bird hunting regulations for tribal members and nonmembers on the Navajo Indian Reservation (in parts of Arizona, New Mexico, and Utah). The Navajo Nation owns almost all lands on the reservation and has full wildlife management authority.

For the 2015–16 season, the Tribe requests the earliest opening dates and longest duck, mergansers, Canada geese and coots seasons, and the same daily bag and possession limits allowed to Pacific Flyway States under final Federal frameworks for tribal and non-tribal members.

For both mourning dove and band-tailed pigeons, the Navajo Nation proposes seasons of September 1 through September 30, 2015, with daily bag limits of 10 and 5, respectively. Possession limits would be twice the daily bag limits.

The Nation requires tribal members and nonmembers to comply with all basic Federal migratory bird hunting regulations in 50 CFR part 20 pertaining to shooting hours and manner of taking. In addition, each waterfowl hunter 16 years of age or over must carry on his/her person a valid Migratory Bird Hunting and Conservation Stamp (Duck Stamp), which must be signed in ink across the face. Special regulations established by the Navajo Nation also apply on the reservation.

The Tribe anticipates a total harvest of fewer than 500 mourning doves; fewer than 10 band-tailed pigeons; fewer than 1,000 ducks, coots, and mergansers; and fewer than 1,000 Canada geese for the 2015–16 season. The Tribe measures harvest by mail survey forms. Through the established Navajo Nation Code, titles 17 and 18, and 23 U.S.C. 1165, the Tribe will take action to close the season, reduce bag limits, or take other appropriate actions if the harvest is detrimental to the migratory bird resource.

We propose to approve those the Navajo Nation's 2015–16 special migratory bird hunting regulations.

(p) Oneida Tribe of Indians of Wisconsin, Oneida, Wisconsin (Tribal Members Only)

Since 1991–92, the Oneida Tribe of Indians of Wisconsin and the Service have cooperated to establish uniform regulations for migratory bird hunting by tribal and nontribal hunters within the original Oneida Reservation boundaries. Since 1985, the Oneida Tribe's Conservation Department has enforced the Tribe's hunting regulations within those original reservation limits. The Oneida Tribe also has a good working relationship with the State of Wisconsin and the majority of the seasons and limits are the same for the Tribe and Wisconsin.

For the 2015–16 season, the Tribe submitted a proposal requesting special migratory bird hunting regulations. For ducks, the Tribe proposal describes the general outside dates as being September 19 through December 6, 2015, with a closed segment of November 21 to 29, 2015. The Tribe proposes a daily bag limit of six birds, which could include no more than six mallards (three hen mallards), six wood ducks, one redhead, two pintails, and one hooded merganser.

For geese, the Tribe requests a season between September 1 and December 31, 2015, with a daily bag limit of five Canada geese. The Tribe will close the season November 21 to 29, 2015. If a quota of 500 geese is attained before the season concludes, the Tribe will recommend closing the season early.

For woodcock, the Tribe proposes a season between September 5 and November 1, 2015, with a daily bag and possession limit of two and four, respectively.

For mourning dove, the Tribe proposes a season between September 5 and November 1, 2015, with a daily bag and possession limit of 10 and 20, respectively.

The Tribe proposes shooting hours be one-half hour before sunrise to one-half hour after sunset. Nontribal hunters hunting on the Reservation or on lands under the jurisdiction of the Tribe must comply with all State of Wisconsin regulations, including shooting hours of one-half hour before sunrise to sunset, season dates, and daily bag limits. Tribal members and nontribal hunters hunting on the Reservation or on lands under the jurisdiction of the Tribe must observe all basic Federal migratory bird hunting regulations found in 50 CFR part 20, with the following exceptions: Oneida members would be exempt from

the purchase of the Migratory Waterfowl Hunting and Conservation Stamp (Duck Stamp); and shotgun capacity is not limited to three shells.

The Service proposes to approve the 2015–16 special migratory bird hunting regulations for the Oneida Tribe of Indians of Wisconsin.

(q) Point No Point Treaty Council Tribes, Kingston, Washington (Tribal Members Only)

We are establishing uniform migratory bird hunting regulations for tribal members on behalf of the Point No Point Treaty Council Tribes, consisting of the Port Gamble S'Klallam and Jamestown S'Klallam Tribes. The two tribes have reservations and ceded areas in northwestern Washington State and are the successors to the signatories of the Treaty of Point No Point of 1855. These proposed regulations will apply to tribal members both on and off reservations within the Point No Point Treaty Areas; however, the Port Gamble S'Klallam and Jamestown S'Klallam Tribal season dates differ only where indicated below.

For the 2015–16 season, the Point No Point Treaty Council requests special migratory bird hunting regulations for both the Jamestown S'Klallam and Port Gamble S'Klallam Tribes. For ducks, the Jamestown S'Klallam Tribe season would open September 1, 2015, and close March 10, 2016, and coots would open September 13, 2015, and close February 1, 2016. The Port Gamble S'Klallam Tribes duck and coot seasons would open from September 1, 2015, to March 10, 2016. The daily bag limit would be seven ducks, including no more than two hen mallards, one canvasback, one pintail, two redhead, and four scoters. The daily bag limit for coots would be 25. The daily bag limit and possession limit on harlequin ducks would be one per season. The daily possession limits are double the daily bag limits except where noted.

For geese, the Point No Point Treaty Council proposes the season open on September 9, 2015, and close March 10, 2016, for the Jamestown S'Klallam Tribe, and open on September 1, 2015, and close March 10, 2016, for the Port Gamble S'Klallam Tribe. The daily bag limit for geese would be four, not to include more than three light geese. The Council notes that there is a year-round closure on dusky Canada geese. For brant, the Council proposes the season open on November 9, 2015, and close January 31, 2016, for the Port Gamble S'Klallam Tribe, and open on January 10 and close January 25, 2016, for the Jamestown S'Klallam Tribe. The daily bag limit for brant would be two.

For band-tailed pigeons, the Port Gamble S'Klallam Tribe season would open September 1, 2015, and close March 10, 2016. The Jamestown S'Klallam Tribe season would open September 13, 2015, and close January 18, 2016. The daily bag limit for band-tailed pigeons would be two. For snipe, the Port Gamble S'Klallam Tribe season would open September 1, 2015, and close March 10, 2016. The Jamestown S'Klallam Tribe season would open September 13, 2015, and close March 10, 2016. The daily bag limit for snipe would be eight. For mourning dove, the Port Gamble S'Klallam Tribe season would open September 1, 2015, and close January 31, 2016. The Jamestown S'Klallam Tribe would open September 13, 2015, and close January 18, 2016. The daily bag limit for mourning dove would be 10.

The Tribe anticipates a total harvest of fewer than 200 birds for the 2015–16 season. The tribal fish and wildlife enforcement officers have the authority to enforce these tribal regulations.

We propose to approve the Point No Point Treaty Council Tribe's requested 2015–16 special migratory bird seasons.

(r) Saginaw Tribe of Chippewa Indians, Mt. Pleasant, Michigan (Tribal Members Only)

The Saginaw Tribe of Chippewa Indians is a federally recognized, self-governing Indian Tribe, located on the Isabella Reservation lands bound by Saginaw Bay in Isabella and Arenac Counties, Michigan.

In a May 28, 2015, letter, the Tribe proposes special migratory bird hunting regulations. For ducks, mergansers, and common snipe, the Tribe proposes outside dates as September 1, 2015, through January 31, 2016. The Tribe proposes a daily bag limit of 20 ducks, which could include no more than five each of the following: Hen mallards; wood duck; black duck; pintail; red head; scaup; and canvasback. The merganser daily bag limit is 10 with no more than 5 hooded mergansers and 16 for common snipe.

For geese, coot, gallinule, sora, and Virginia rail, the Tribe requests a season from September 1, 2015, to January 31, 2016. The daily bag limit for geese is 20, in the aggregate. The daily bag limit for coot, gallinule, sora, and Virginia rail is 20 in the aggregate.

For woodcock and mourning dove, the Tribe proposes a season between September 1, 2015, and January 31, 2016, with daily bag limits of 10 and 25, respectively.

For sandhill crane, the Tribe proposes a season between September 1, 2015, and January 31, 2016, with a daily bag limit of one.

All Saginaw Tribe members exercising hunting treaty rights are required to comply with Tribal Ordinance 11. Hunting hours would be from one-half hour before sunrise to one-half hour after sunset. All other regulations in 50 CFR part 20 apply including the use of only nontoxic shot for hunting waterfowl.

The Service proposes to approve the request for 2015–16 special migratory bird hunting regulations for the Saginaw Tribe of Chippewa Indians.

(s) Sault Ste. Marie Tribe of Chippewa Indians, Sault Ste. Marie, Michigan (Tribal Members Only)

The Sault Ste. Marie Tribe of Chippewa Indians is a federally recognized, self-governing Indian Tribe, distributed throughout the eastern Upper Peninsula and northern Lower Peninsula of Michigan. The Tribe has retained the right to hunt, fish, trap, and gather on the lands ceded in the Treaty of Washington (1836).

The Tribe proposes special migratory bird hunting regulations. For ducks, mergansers, and common snipe, the Tribe proposes outside dates as September 15 through December 31, 2015. The Tribe proposes a daily bag limit of 20 ducks, which could include no more than 10 mallards (5 hen mallards), 5 wood duck, 5 black duck, and 5 canvasbacks. The merganser daily bag limit is 10 in the aggregate and 16 for common snipe.

For geese, teal, coot, gallinule, sora, and Virginia rail, the Tribe requests a season from September 1 to December 31, 2015. The daily bag limit for geese is 20, in the aggregate. The daily bag limit for coot, teal, gallinule, sora, and Virginia rail is 20 in the aggregate.

For woodcock, the Tribe proposes a season between September 2 and December 1, 2015, with a daily bag and possession limit of 10 and 20, respectively.

For mourning dove, the Tribe proposes a season between September 1 and November 14, 2015, with a daily bag and possession limit of 10 and 20, respectively.

In 2014, the total estimated waterfowl hunters were 266. All Sault Ste. Marie Tribe members exercising hunting treaty rights within the 1836 Ceded Territory are required to submit annual harvest reports including date of harvest, number and species harvested, and location of harvest. Hunting hours would be from one-half hour before sunrise to one-half hour after sunset. All other regulations in 50 CFR part 20

apply including the use of only nontoxic shot for hunting waterfowl.

The Service proposes to approve the request for 2015–16 special migratory bird hunting regulations for the Sault Ste. Marie Tribe of Chippewa Indians.

(t) Shoshone–Bannock Tribes, Fort Hall Indian Reservation, Fort Hall, Idaho (Nontribal Hunters)

Almost all of the Fort Hall Indian Reservation is tribally owned. The Tribes claim full wildlife management authority throughout the reservation, but the Idaho Fish and Game Department has disputed tribal jurisdiction, especially for hunting by nontribal members on reservation lands owned by non-Indians. As a compromise, since 1985, we have established the same waterfowl hunting regulations on the reservation and in a surrounding off-reservation State zone. The regulations were requested by the Tribes and provided for different season dates than in the remainder of the State. We agreed to the season dates because they would provide additional protection to mallards and pintails. The State of Idaho concurred with the zoning arrangement. We have no objection to the State's use of this zone again in the 2015–16 hunting season, provided the duck and goose hunting season dates are the same as on the reservation.

In a proposal for the 2015–16 hunting season, the Shoshone–Bannock Tribes request a continuous duck (including mergansers and coots) season, with the maximum number of days and the same daily bag and possession limits permitted for Pacific Flyway States under the final Federal frameworks. The Tribes propose a duck and coot season with, if the same number of hunting days is permitted as last year, an opening date of October 3, 2015, and a closing date of January 19, 2016. The Tribes anticipate harvest will be about 7,000 ducks.

The Tribes also request a continuous goose season with the maximum number of days and the same daily bag and possession limits permitted in Idaho under Federal frameworks. The Tribes propose that, if the same number of hunting days is permitted as in previous years, the season would have an opening date of October 3, 2015, and a closing date of January 19, 2016. The Tribes anticipate harvest will be about 5,000 geese.

The Tribes request a common snipe season with the maximum number of days and the same daily bag and possession limits permitted in Idaho under Federal frameworks. The Tribes propose that, if the same number of hunting days is permitted as in previous years, the season would have an opening date of October 3, 2015, and a closing date of January 19, 2016.

Nontribal hunters must comply with all basic Federal migratory bird hunting regulations in 50 CFR part 20 pertaining to shooting hours, use of steel shot, and manner of taking. Special regulations established by the Shoshone-Bannock Tribes also apply on the reservation.

We note that the requested regulations are nearly identical to those of last year, and we propose to approve them for the 2015–16 hunting season if the seasons' dates fall within the final Federal flyway frameworks (applies to nontribal hunters only).

(u) Skokomish Tribe, Shelton, Washington (Tribal Members Only)

Since 1996, the Service and the Point No Point Treaty Tribes, of which the Skokomish Tribe was one, have cooperated to establish special regulations for migratory bird hunting. The Tribes have been acting independently since 2005, and the Skokomish Tribe would like to establish migratory bird hunting regulations for tribal members for the 2015–16 season. The Tribe has a reservation on the Olympic Peninsula in Washington State and is a successor to the signatories of the Treaty of Point No Point of 1855.

The Skokomish Tribe requests a duck and coot season from September 16, 2015, to February 28, 2016. The daily bag limit is seven ducks, including no more than two hen mallards, one pintail, one canvasback, and two redheads. The daily bag and possession limit on harlequin duck is one per season. The coot daily bag limit is 25. The possession limit is twice the daily bag limit, except as noted above.

For geese, the Tribe requests a season from September 16, 2015, to February 28, 2016. The daily bag limit is four, including no more than three light geese. The season on Aleutian Canada geese is closed. For brant, the Tribe proposes a season from November 1, 2015, to February 15, 2016, with a daily bag limit of two. The possession limit is twice the daily bag limit.

For mourning doves, band-tailed pigeon, and snipe, the Tribe requests a season from September 16, 2015, to February 28, 2016, with a daily bag limit of 10, 2, and 8, respectively. The possession limit is twice the daily bag limit.

All Tribal hunters authorized to hunt migratory birds are required to obtain a tribal hunting permit from the Skokomish Tribe pursuant to tribal law. Hunting hours would be from one-half hour before sunrise to sunset. Only steel, tungsten-iron, tungsten-polymer, tungsten-matrix, and tin shot are allowed for hunting waterfowl. It is unlawful to use or possess lead shot while hunting waterfowl.

The Tribe anticipates harvest to be fewer than 150 birds. The Skokomish Public Safety Office enforcement officers have the authority to enforce these migratory bird hunting regulations.

We propose to approve the Skokomish Tribe's 2015–16 migratory bird hunting season.

(v) Spokane Tribe of Indians, Spokane Indian Reservation, Wellpinit, Washington (Tribal Members Only)

The Spokane Tribe of Indians wishes to establish waterfowl seasons on their reservation for its membership to access as an additional resource. An established waterfowl season on the reservation will allow access to a resource for members to continue practicing a subsistence lifestyle.

The Spokane Indian Reservation is located in northeastern Washington State. The reservation comprises approximately 157,000 acres. The boundaries of the Reservation are the Columbia River to the west, the Spokane River to the south (now Lake Roosevelt), Tshimikn Creek to the east, and the 48th Parallel as the north boundary. Tribal membership comprises approximately 2,300 enrolled Spokane Tribal Members.

These proposed regulations would allow Tribal Members, spouses of Spokane Tribal Members, and first-generation descendants of a Spokane Tribal Member with a tribal permit and Federal Waterfowl stamp an opportunity to utilize the reservation and ceded lands for waterfowl hunting. These regulations would also benefit tribal membership through access to this resource throughout Spokane Tribal ceded lands in eastern Washington. By Spokane Tribal Referendum, spouses of Spokane Tribal Members and children of Spokane Tribal Members not enrolled are allowed to harvest game animals within the Spokane Indian Reservation with the issuance of hunting permits.

For the 2015–16 season, the Tribe requests to establish duck seasons that would run from September 2, 2015, through January 31, 2016. The tribe is requesting the daily bag limit for ducks to be consistent with final Federal frameworks. The possession limit is twice the daily bag limit.

The Tribe proposes a season on geese starting September 2, 2015, and ending on January 31, 2016. The tribe is requesting the daily bag limit for geese to be consistent with final Federal

frameworks. The possession limit is twice the daily bag limit.

Based on the quantity of requests the Spokane Tribe of Indians has received, the tribe anticipates harvest levels for the 2015–16 season for both ducks and geese to be fewer than 100 total birds with goose harvest at fewer than 50. Hunter success will be monitored through mandatory harvest reports returned within 30 days of the season closure.

We propose to approve the Spokane Tribe's requested 2015–16 special migratory bird hunting regulations.

(w) Squaxin Island Tribe, Squaxin Island Reservation, Shelton, Washington (Tribal Members Only)

The Squaxin Island Tribe of Washington and the Service have cooperated since 1995, to establish special tribal migratory bird hunting regulations. These special regulations apply to tribal members on the Squaxin Island Reservation, located in western Washington near Olympia, and all lands within the traditional hunting grounds of the Squaxin Island Tribe.

For the 2015–16 season, we have yet to hear from the Squaxin Island Tribe. The Tribe usually requests to establish duck and coot seasons that would run from September 1, 2015, through January 15, 2016. The daily bag limit for ducks would be five per day and could include only one canvasback. The season on harlequin ducks is closed. For coots, the daily bag limit is 25. For snipe, the Tribe usually proposes that the season start on September 15, 2015, and end on January 15, 2016. The daily bag limit for snipe would be eight. For band-tailed pigeon, the Tribe usually proposes that the season start on September 1, 2015, and end on December 31, 2015. The daily bag limit would be five. The possession limit would be twice the daily bag limit.

The Tribe usually proposes a season on geese starting September 15, 2015, and ending on January 15, 2016. The daily bag limit for geese would be four, including no more than two snow geese. The season on Aleutian and cackling Canada geese would be closed. For brant, the Tribe usually proposes that the season start on September 1, 2015, and end on December 31, 2015. The daily bag limit for brant would be two. The possession limit would be twice the daily bag limit.

We propose to approve the Tribe's 2015–16 special migratory bird hunting regulations, upon receipt of their proposal.

(x) Stillaguamish Tribe of Indians, Arlington, Washington (Tribal Members Only)

The Stillaguamish Tribe of Indians and the Service have cooperated to establish special regulations for migratory game birds since 2001. For the 2015–16 season, the Tribe requests regulations to hunt all open and unclaimed lands under the Treaty of Point Elliott of January 22, 1855, including their main hunting grounds around Camano Island, Skagit Flats, and Port Susan to the border of the Tulalip Tribes Reservation. Ceded lands are located in Whatcom, Skagit, Snohomish, and Kings Counties, and a portion of Pierce County, Washington. The Stillaguamish Tribe of Indians is a federally recognized Tribe and reserves the Treaty Right to hunt (*U.S.* v. *Washington*).

The Tribe proposes their duck (including mergansers and coot) and goose seasons run from October 1, 2015, to March 10, 2016. The daily bag limit on ducks (including sea ducks and mergansers) is 10. The daily bag limit for coot is 25. For geese, the daily bag limit is six. The season on brant is closed. Possession limits are totals of these three daily bag limits.

The Tribe proposes the snipe seasons run from October 1, 2015, to January 31, 2016. The daily bag limit for snipe is 10. Possession limits are three times the daily bag limit.

Harvest is regulated by a punch card system. Tribal members hunting on lands under this proposal will observe all basic Federal migratory bird hunting regulations found in 50 CFR part 20, which will be enforced by the Stillaguamish Tribal law enforcement. Tribal members are required to use steel shot or a nontoxic shot as required by Federal regulations.

The Tribe anticipates a total harvest of 200 ducks, 100 geese, 50 mergansers, 100 coots, and 100 snipe. Anticipated harvest needs include subsistence and ceremonial needs. Certain species may be closed to hunting for conservation purposes, and consideration for the needs of certain species will be addressed.

The Service proposes to approve the Stillaguamish Tribe's request for 2015–16 special migratory bird hunting regulations upon receipt of the proposal.

(y) Swinomish Indian Tribal Community, LaConner, Washington (Tribal Members Only)

In 1996, the Service and the Swinomish Indian Tribal Community began cooperating to establish special regulations for migratory bird hunting. The Swinomish Indian Tribal Community is a federally recognized Indian Tribe consisting of the Swinomish, Lower Skagit, Samish, and Kikialous. The Swinomish Reservation was established by the Treaty of Point Elliott of January 22, 1855, and lies in the Puget Sound area north of Seattle, Washington.

For the 2015–16 season, the Tribal Community requests to establish a migratory bird hunting season on all areas that are open and unclaimed and consistent with the meaning of the treaty. The Tribal Community requests to establish duck, merganser, Canada goose, brant, and coot seasons opening on the earliest possible date allowed by the final Federal frameworks for the Pacific Flyway and closing 30 days after the State of Washington closes its season. On reservation, the Tribal Community requests to establish duck, merganser, Canada goose, brant, and coot seasons opening on the earliest possible date allowed by the final Federal frameworks for the Pacific Flyway and closing March 9, 2016. The Swinomish Indian Tribal Community requests double the daily bag and possession limits allowed by the State for each species, except for ceremonial permit which stipulate species and numbers for harvest.

The Community usually anticipates that the regulations will result in the harvest of approximately 600 ducks and 200 geese. The Swinomish utilize a report card and permit system to monitor harvest and will implement steps to limit harvest where conservation is needed. All tribal regulations will be enforced by tribal fish and game officers.

We propose to approve these 2015–16 special migratory bird hunting regulations.

(z) The Tulalip Tribes of Washington, Tulalip Indian Reservation, Marysville, Washington (Tribal Members Only)

The Tulalip Tribes are the successors in interest to the Tribes and bands signatory to the Treaty of Point Elliott of January 22, 1855. The Tulalip Tribes' government is located on the Tulalip Indian Reservation just north of the City of Everett in Snohomish County, Washington. The Tribes or individual tribal members own all of the land on the reservation, and they have full wildlife management authority. All lands within the boundaries of the Tulalip Tribes Reservation are closed to nonmember hunting unless opened by Tulalip Tribal regulations.

The Tribe proposes tribal hunting regulations for the 2015–16 season. Migratory waterfowl hunting by Tulalip

Tribal members is authorized by Tulalip Tribal Ordinance No. 67. For ducks, mergansers, coot, and snipe, the proposed season for tribal members is from September 3, 2015, through February 28, 2016. Daily bag and possession limits would be 7 and 14 ducks, respectively, except that for blue-winged teal, canvasback, harlequin, pintail, and wood duck, the bag and possession limits would be the same as those established in accordance with final Federal frameworks. For coot, daily bag and possession limits are 25 and 50, respectively, and for snipe 8 and 16, respectively. Ceremonial hunting may be authorized by the Department of Natural Resources at any time upon application of a qualified tribal member. Such a hunt must have a bag limit designed to limit harvest only to those birds necessary to provide for the ceremony.

For geese, tribal members propose a season from September 3, 2015, through February 28, 2016. The goose daily bag and possession limits would be 7 and 14, respectively, except that the bag limits for brant, cackling Canada geese, and dusky Canada geese would be those established in accordance with final Federal frameworks.

All hunters on Tulalip Tribal lands are required to adhere to shooting hour regulations set at one-half hour before sunrise to sunset, special tribal permit requirements, and a number of other tribal regulations enforced by the Tribe. Each nontribal hunter 16 years of age and older hunting pursuant to Tulalip Tribes' Ordinance No. 67 must possess a valid Federal Migratory Bird Hunting and Conservation Stamp and a valid State of Washington Migratory Waterfowl Stamp. Each hunter must validate stamps by signing across the face.

Although the season length requested by the Tulalip Tribes appears to be quite liberal, harvest information indicates a total take by tribal and nontribal hunters of fewer than 1,000 ducks and 500 geese annually.

We propose to approve the Tulalip Tribe's request for 2015–16 special migratory bird hunting regulations.

(aa) Upper Skagit Indian Tribe, Sedro Woolley, Washington (Tribal members only)

The Upper Skagit Indian Tribe and the Service have cooperated to establish special regulations for migratory game birds since 2001. The Tribe has jurisdiction over lands within Skagit, Island, and Whatcom Counties, Washington. The Tribe issues tribal hunters a harvest report card that will be shared with the State of Washington.

For the 2015–16 season, the Tribe requests a duck season starting October 1, 2015, and ending February 28, 2016. The Tribe proposes a daily bag limit of 15 with a possession limit of 20. The Tribe requests a coot season starting October 1, 2015, and ending February 15, 2016. The coot daily bag limit is 20 with a possession limit of 30.

The Tribe proposes a goose season from October 1, 2015, to February 28, 2016, with a daily bag limit of 7 geese and a possession limit of 10. For brant, the Tribe proposes a season from November 1 to November 10, 2015, with a daily bag and possession limit of 2.

The Tribe proposes a mourning dove season between September 1 and December 31, 2015, with a daily bag limit of 12 and possession limit of 15.

The anticipated migratory bird harvest under this proposal would be 100 ducks, 5 geese, 2 brant, and 10 coots. Tribal members must have the tribal identification and tribal harvest report card on their person to hunt. Tribal members hunting on the Reservation will observe all basic Federal migratory bird hunting regulations found in 50 CFR part 20, except shooting hours would be 15 minutes before official sunrise to 15 minutes after official sunset.

We propose to approve the Tribe's 2015–16 special migratory bird hunting regulations.

(bb) Wampanoag Tribe of Gay Head, Aquinnah, Massachusetts (Tribal Members Only)

The Wampanoag Tribe of Gay Head is a federally recognized Tribe located on the island of Martha's Vineyard in Massachusetts. The Tribe has approximately 560 acres of land, which it manages for wildlife through its natural resources department. The Tribe also enforces its own wildlife laws and regulations through the natural resources department.

For the 2015–16 season, we have not yet heard from the Tribe. The Tribe usually proposes a duck season of October 14, 2015, through February 22, 2016. The Tribe usually proposes a daily bag limit of eight birds, which could include no more than four hen mallards, four mottled ducks, one fulvous whistling duck, four mergansers, three scaup, two hooded mergansers, three wood ducks, one canvasback, two redheads, two pintail, and four of all other species not listed. The season for harlequin ducks is usually closed. The Tribe usually proposes a teal (green-winged and blue) season of October 10, 2015, through February 22, 2016. A daily bag limit of six teal would be in addition to the daily bag limit for ducks.

For sea ducks, the Tribe usually proposes a season between October 7, 2015, and February 22, 2016, with a daily bag limit of seven, which could include no more than one hen eider and four of any one species unless otherwise noted above.

For Canada geese, the Tribe usually requests a season between September 4 and September 21, 2015, and October 28, 2015, and February 22, 2016, with a daily bag limit of 8 Canada geese. For snow geese, the tribe usually requests a season between September 4 to September 21, 2015, and November 25, 2015, to February 22, 2016, with a daily bag limit of 15 snow geese.

For woodcock, the Tribe usually proposes a season between October 10 and November 23, 2015, with a daily bag limit of three. For sora and Virginia rails, the Tribe usually requests a season of September 2, 2015, through November 10, 2015, with a daily bag limit of 5 sora and 10 Virginia rails. For snipe, the Tribe usually requests a season of September 2, 2015, through December 16, 2015, with a daily bag limit of 8.

Prior to 2012, the Tribe had 22 registered tribal hunters and estimates harvest to be no more than 15 geese, 25 mallards, 25 teal, 50 black ducks, and 50 of all other species combined. Tribal members hunting on the Reservation will observe all basic Federal migratory bird hunting regulations found in 50 CFR part 20. The Tribe requires hunters to register with the Harvest Information Program.

If we receive a proposal that matches the Tribe's usual request, we propose to approve those 2015–16 special migratory bird hunting regulations.

(cc) White Earth Band of Ojibwe, White Earth, Minnesota (Tribal Members Only)

The White Earth Band of Ojibwe is a federally recognized tribe located in northwest Minnesota and encompasses all of Mahnomen County and parts of Becker and Clearwater Counties. The reservation employs conservation officers to enforce migratory bird regulations. The Tribe and the Service first cooperated to establish special tribal regulations in 1999.

For the 2015–16 migratory bird hunting season, the White Earth Band of Ojibwe requests a duck season to start September 12 and end December 15, 2015. For ducks, they request a daily bag limit of 10, including no more than 2 hen mallards, 1 pintail, and 1 canvasback. For mergansers, the Tribe proposes the season to start September 12 and end December 15, 2015. The

merganser daily bag limit would be five with no more than two hooded mergansers. For geese, the Tribe proposes an early season from September 1 through September 25, 2015, and a late season from September 26, 2015, through December 15, 2015. The early season daily bag limit is 12 geese, and the late season daily bag limit is 5 geese.

For coots, the Tribe proposes a September 1 through November 30, 2015, season with daily bag limits of 20 coots. For snipe, woodcock, rail, and mourning dove, the Tribe proposes a September 1 through November 30, 2015, season with daily bag limits of 10, 10, 25, and 25 respectively. Shooting hours are one-half hour before sunrise to one-half hour after sunset. Nontoxic shot is required.

Based on past harvest surveys, the Tribe anticipates harvest of 1,000 to 2,000 Canada geese and 1,000 to 1,500 ducks. The White Earth Reservation Tribal Council employs four full-time conservation officers to enforce migratory bird regulations.

We propose to approve the Tribe's 2015–16 special migratory bird hunting regulations.

(dd) White Mountain Apache Tribe, Fort Apache Indian Reservation, Whiteriver, Arizona (Tribal Members and Nontribal Hunters)

The White Mountain Apache Tribe owns all reservation lands, and the Tribe has recognized full wildlife management authority. As in past years, the White Mountain Apache Tribe has requested regulations that are essentially unchanged from those agreed to since the 1997–98 hunting year.

The hunting zone for waterfowl is restricted and is described as: The length of the Black River west of the Bonito Creek and Black River confluence and the entire length of the Salt River forming the southern boundary of the reservation; the White River, extending from the Canyon Day Stockman Station to the Salt River; and all stock ponds located within Wildlife Management Units 4, 5, 6, and 7. Tanks located below the Mogollon Rim, within Wildlife Management Units 2 and 3, will be open to waterfowl hunting during the 2015–16 season. The length of the Black River east of the Black River/Bonito Creek confluence is closed to waterfowl hunting. All other waters of the reservation would be closed to waterfowl hunting for the 2015–16 season.

For nontribal and tribal hunters, the Tribe proposes a continuous duck, coot, merganser, gallinule, and moorhen hunting season, with an opening date of October 17, 2015, and a closing date of January 24, 2016. The Tribe proposes a separate pintail and canvasback season, with an opening date of October 17, 2015, and a closing date of November 29, 2015. The season on scaup is closed. The Tribe proposes a daily duck (including mergansers) bag limit of seven, which may include no more than two redheads, two pintail, seven mallards (including no more than two hen mallards), and one canvasback. The daily bag limit for coots, gallinules, and moorhens would be 25, singly or in the aggregate.

For geese, the Tribe proposes a season from October 17, 2015, through January 24, 2016. Hunting would be limited to Canada geese, and the daily bag limit would be three.

Season dates for band-tailed pigeons and mourning doves would run from September 1, and end September 15, 2015, in Wildlife Management Unit 10 and all areas south of Y–70 and Y–10 in Wildlife Management Unit 7, only. Proposed daily bag limits for band-tailed pigeons and mourning doves would be 3 and 10, respectively.

Possession limits for the above species are twice the daily bag limits. Shooting hours would be from one-half hour before sunrise to sunset. There would be no open season for sandhill cranes, rails, and snipe on the White Mountain Apache lands under this proposal.

A number of special regulations apply to tribal and nontribal hunters, which may be obtained from the White Mountain Apache Tribe Game and Fish Department.

We plan to approve the White Mountain Apache Tribe's requested 2015–16 special migratory bird hunting regulations.

(ee) Yankton Sioux Tribe, Marty, South Dakota (Tribal Members and Nontribal Hunters)

The Yankton Sioux Tribe has yet to submit a waterfowl hunting proposal for the 2015–16 season. The Yankton Sioux tribal waterfowl hunting season usually would be open to both tribal members and nontribal hunters. The waterfowl hunting regulations would apply to tribal and trust lands within the external boundaries of the reservation.

For ducks (including mergansers) and coots, we expect the Yankton Sioux Tribe to, as usual, propose a season starting October 9, 2015, and running for the maximum amount of days allowed under the final Federal frameworks. Daily bag and possession limits would be six ducks, which may include no more than five mallards (no more than two hens), one canvasback (when the season is open), two redheads, three scaup, one pintail, or two wood ducks. The bag limit for mergansers would be five, which would include no more than one hooded merganser. The coot daily bag limit would be 15.

For geese, the Tribe will likely request a dark goose (Canada geese, brant, white-fronted geese) season starting October 29, 2015, and closing January 31, 2016. The daily bag limit would be three geese (including no more than one white-fronted goose or brant). Possession limits would be twice the daily bag limit.

For white geese, the proposed hunting season would start October 29, 2015, and run for the maximum amount of days allowed under the final Federal frameworks for the State of South Dakota. Daily bag and possession limits would equal the maximum allowed under Federal frameworks.

All hunters would have to be in possession of a valid tribal license while hunting on Yankton Sioux trust lands. Tribal and nontribal hunters must comply with all basic Federal migratory bird hunting regulations in 50 CFR part 20 pertaining to shooting hours and the manner of taking. Special regulations established by the Yankton Sioux Tribe also apply on the reservation.

During the 2005–06 hunting season, the Tribe reported that 90 nontribal hunters took 400 Canada geese, 75 light geese, and 90 ducks. Forty-five tribal members harvested fewer than 50 geese and 50 ducks.

If we receive a proposal that matches the Tribe's usual request, we propose to approve those 2015–16 special migratory bird hunting regulations.

Public Comments

The Department of the Interior's policy is, whenever possible, to afford the public an opportunity to participate in the rulemaking process. Accordingly, we invite interested persons to submit written comments, suggestions, or recommendations regarding the proposed regulations. Before promulgating final migratory game bird hunting regulations, we will consider all comments we receive. These comments, and any additional information we receive, may lead to final regulations that differ from these proposals.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in the **ADDRESSES** section. We will not accept comments sent by email or fax. We will not consider hand-delivered comments that we do not receive, or mailed comments that are not postmarked, by the date specified in the **DATES** section.

We will post all comments in their entirety—including your personal identifying information—on *http://www.regulations.gov*. 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.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Division of Migratory Bird Management, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

For each series of proposed rulemakings, we will establish specific comment periods. We will consider, but possibly may not respond in detail to, each comment. As in the past, we will summarize all comments we receive during the comment period and respond to them after the closing date in the preambles of any final rules.

Required Determinations

Based on our most current data, we are affirming our required determinations made in the proposed rule; for descriptions of our actions to ensure compliance with the following statutes and Executive Orders, see our April 13, 2015, proposed rule (80 FR 19852):

- National Environmental Policy Act;
- Endangered Species Act;
- Regulatory Planning and Review;
- Regulatory Flexibility Act;
- Small Business Regulatory Enforcement Fairness Act;
- Paperwork Reduction Act;
- Unfunded Mandates Reform Act;
- Executive Orders 12630, 12988, 13175, 13132, and 13211.

List of Subjects in 50 CFR Part 20

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

The rules that eventually will be promulgated for the 2015–16 hunting season are authorized under 16 U.S.C. 703–712 and 16 U.S.C. 742 a–j.

Dated: July 27, 2015.

Michael J. Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2015–19053 Filed 8–3–15; 8:45 am]

BILLING CODE 4310–55–P

Notices

Federal Register

Vol. 80, No. 149

Tuesday, August 4, 2015

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

July 30, 2015.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by September 3, 2015 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW., Washington, DC 20503. 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. 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.

National Agricultural Statistics Service

Title: Field Crops Production.

OMB Control Number: 0535–0002.

Summary of Collection: One of the National Agricultural Statistics Services' (NASS) primary functions is to prepare and issue current state and national estimates of crop and livestock production, prices, and disposition. The general authority for these data collection activities is granted under U.S. Code Title 7, Section 2204. NASS collects information on field crops to monitor agricultural developments across the country that may impact on the nation's food supply. To help set these estimates, field crops production data is collected. NASS will use surveys to collect information through a combination of the internet, mail, telephone, and personnel interviews.

Need and use of the Information: NASS collects information on field crops to monitor agricultural developments across the country that may impact on the nation's food supply. The Secretary of Agriculture uses estimates of crop production to administer farm program legislation and to make decisions relative to the export-import programs. Collecting this information less frequently would eliminate the data needed to keep the Department abreast of changes at the State and national level.

Description of Respondents: Farms; Business or other for-profits.

Number of Respondents: 650,635.

Frequency of Responses: Reporting: Weekly, Monthly, Quarterly, Annually.

Total Burden Hours: 200,919.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2015–19153 Filed 8–3–15; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

July 30, 2015.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food Safety and Inspection Service

Title: Voluntary Recalls of Meat and Poultry Products.

OMB Control Number: 0583–0135.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise

the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) These statutes mandate that FSIS protect the public by ensuring that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged. A firm that has produced or imported meat or poultry that is adulterated or misbranded and is being distributed in commerce, may voluntarily recall the product in question. When a firm voluntarily recalls a product, FSIS will conduct a recall effectiveness check.

Need and Use of the Information: In conducting a recall, the establishment will be asks to provide FSIS with some basic information, including the identity of the recalled product, the reason for the recall, and information about the distributors and customers of the product. FSIS will check on the effectiveness of the recall to ensure that all products subject to recall are accounted for. FSIS field personnel will use FSIS form 8400–4 A to determine (1) if the retail consignee received notification of the recall and (2) the amount of recalled products received. FSIS field personnel will also use FSIS form 8400–4 B to verify that product held by the retail consignee was properly disposed.

Description of Respondents: Business or other for-profit.

Number of Respondents: 6.090.

Frequency of Responses: Reporting: On Occasion.

Total Burden Hours: 8,600.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2015–19154 Filed 8–3–15; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

July 30, 2015.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by September 3, 2015 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), 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. Copies of the submission(s) may be obtained by calling (202) 720–8958.

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Agricultural Research Service

Title: Information Collection for Document Delivery Services.

OMB Control Number: 0518–0027.

Summary of Collection: The National Agricultural Library (NAL) accepts requests from libraries and other organizations in accordance with the national and international interlibrary loan code and guidelines. In its national role, NAL collects and supplies copies or loans of agricultural materials not found elsewhere. 7 U.S.C. 3125a and 7 CFR 505 gives NAL the authority to collect this information. NAL provides photocopies and loans of materials directly to USDA staff, other Federal agencies, libraries and other institutions, and indirectly to the public through their libraries. The Library charges for some of these activities through a fee schedule. In order to fill a request for reproduction or loan of items the library must have the name, mailing address, phone number of the respondent initiating the request, and may require either a fax number, email address, or Ariel IP address. The collected information is used to deliver the material to the respondent, bill for and track payment of applicable fees, monitor the return to NAL of loaned material, identify and locate the requested material in NAL collections, and determine whether the respondent consents to the fees charged by NAL.

Need and use of the Information: The NAL document delivery staff uses the information collected to identify the protocol for processing the request. The information collected determines whether the respondent is charged or exempt from any charges and what process the recipient uses to make payment if the request is chargeable. The staff also uses the information provided to process/package the reproduction or loan for delivery. Without the requested information NAL has no way to locate and deliver the loan or reproduction to the respondent, and thus cannot meet its mandate to supply agricultural material.

Description of Respondents: Federal Government; Not-for-profit institutions; State, Local or Tribal Government; Business or other for-profit.

Number of Respondents: 700.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 93.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2015–19152 Filed 8–3–15; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

July 29, 2015.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk

Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), 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 by September 3, 2015. 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 Business Cooperative Service

Title: 7 CFR part 1980–E, Business and Industry Loan Program.

OMB Control Number: 0570–0014.

Summary of Collection: Section 310B of the Consolidated Farm and Rural Development Act (Con Act), legislated in 1972 the Business and Industry (B&I) program. The purpose of the program is to improve, develop, or finance businesses, industries, and employment and improve the economic and environmental climate in rural communities, including pollution abatement and control. This purpose is achieved through bolstering the existing private credit structure by making direct loans, thereby providing lasting community benefits. The B&I program is administered by the Agency through Rural Development State and sub-State Offices serving the State.

7 CFR 1980–E, in conjunction with 7 CFR 1942–A, and other regulations, is currently used only for making B&I Direct Loans. 7 CFR 1951–E is used for servicing B&I Direct and Community Facility loans. All reporting and recordkeeping burden estimates for making and servicing B&I Guaranteed Loans have been moved to the B&I Guaranteed Loan Program regulations, 7 CFR 4279–A and B and 4287–B. Consequently, only a fraction of the total reporting and recordkeeping burden for making and servicing B&I Direct Loans is reflected in this document.

Need and Use of the Information: RD will collect the minimum information needed from loan applicants and commercial lenders to make determinations regarding program eligibility, the current financial condition of a business and loan security as required by the Con Act. The majority of the information is collected only once and the agency monitors the progress of the business through the analysis of annual borrower financial statements and visits to the borrower.

Description Of Respondents: Business or other for profit and not for profit institutions.

Number of Respondents: 40.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 600.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2015–19008 Filed 8–3–15; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2015–0006]

Notice of Affirmation of Revision of a Treatment Schedule for Hot Water Treatment of Mangoes

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are affirming our earlier determination that it was necessary to immediately amend hot water treatment schedule T102–a in the Plant Protection and Quarantine Treatment Manual to extend the applicability of the treatment to additional mango commodities. In a previous notice, we made available to the public for review and comment a treatment evaluation document that described the revised treatment schedule and explained why we have determined that it is effective at neutralizing certain target pests.

DATES: Effective August 4, 2015, we are affirming the addition to the Plant Protection and Quarantine Treatment Manual of the revised treatment described in the notice published at 80 FR 22702–22703 on April 23, 2015.

FOR FURTHER INFORMATION CONTACT: Dr. Inder P.S. Gadh, Senior Risk Manager—Treatments, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737; (301) 851–2018.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR chapter III are intended, among other things, to prevent the introduction or dissemination of plant pests and noxious weeds into or within the United States. Under the regulations, certain plants, fruits, vegetables, and other articles must be treated before they may be moved into the United States or interstate. The phytosanitary treatments regulations contained in 7 CFR part 305 (referred to below as the regulations) set out standards for treatments required in 7 CFR parts 301, 318, and 319 for fruits, vegetables, and other articles.

In § 305.2, paragraph (b) states that approved treatment schedules are set out in the Plant Protection and Quarantine (PPQ) Treatment Manual.[1] Section 305.3 sets out a process for adding, revising, or removing treatment schedules in the PPQ Treatment Manual. In that section, paragraph (b) sets out the process for adding, revising, or removing treatment schedules when there is an immediate need to make a change. The circumstances in which an immediate need exists are described in § 305.3(b)(1). They are:

- PPQ has determined that an approved treatment schedule is ineffective at neutralizing the targeted plant pest(s).
- PPQ has determined that, in order to neutralize the targeted plant pest(s), the treatment schedule must be administered using a different process than was previously used.
- PPQ has determined that a new treatment schedule is effective, based on efficacy data, and that ongoing trade in a commodity or commodities may be adversely impacted unless the new treatment schedule is approved for use.
- The use of a treatment schedule is no longer authorized by the U.S. Environmental Protection Agency or by any other Federal entity.

In accordance with § 305.3(b), we published a notice[2] in the **Federal Register** on April 23, 2015 (80 FR 22702–22703, Docket No. APHIS–2015–0006), announcing our determination that a revised T102–a hot water treatment schedule is an efficacious phytosanitary treatment for eggs and larvae of *Ceratitis capitata* and *Anastrepha* spp. fruit flies in mangoes weighing 651 to 900 grams and that the treatment is effective for these oversized

[1] The PPQ Treatment Manual is available on the Internet at *http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf* or by contacting the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Manuals Unit, 92 Thomas Johnson Drive, Suite 200, Frederick, MD 21702.

[2] To view the notice, a subsequent correction to that notice, the TED, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0006.*

mangoes regardless of their country of origin. This determination was based on evidence presented in a treatment evaluation document (TED) we made available with the notice. The treatment was added to the PPQ Treatment Manual, but was subject to change based on public comment.

We solicited comments on the notice for 60 days ending on June 22, 2015. We received six comments by that date. They were from private citizens, exporters, industry groups, and representatives of State and foreign governments. The responses were in favor of the revised treatment schedule to extend the applicability of the treatment to additional mango commodities. Therefore, in accordance with the regulations in § 305.3(b)(3), we are affirming our revision of a hot water treatment schedule for mango to control certain pests, as described in the TED made available with the previous notice. The treatment schedule is numbered T102–a. The treatment schedule will be listed in the PPQ Treatment Manual, which is available as described in footnote 1 of this document.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 29th day of July 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–19084 Filed 8–3–15; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Assessment of Fees for Dairy Import Licenses for the 2016 Tariff-Rate Import Quota Year

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces a fee of $250 to be charged for the 2016 tariff-rate quota (TRQ) year for each license issued to a person or firm by the Department of Agriculture authorizing the importation of certain dairy articles, which are subject to tariff-rate quotas set forth in the Harmonized Tariff Schedule (HTS) of the United States.

DATES: August 4, 2015.

FOR FURTHER INFORMATION CONTACT: Abdelsalam El-Farra, Dairy Import Licensing Program, Import Policies and Export Reporting Division, STOP 1021, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250–1021 or telephone at (202) 720–9439 or email at *abdelsalam.el-farra@fas.usda.gov.*

SUPPLEMENTARY INFORMATION: The Dairy Tariff-Rate Import Quota Licensing Regulation promulgated by the Department of Agriculture and codified at 7 CFR 6.20–6.37 provides for the issuance of licenses to import certain dairy articles that are subject to TRQs set forth in the HTS. Those dairy articles may only be entered into the United States at the in-quota TRQ tariff-rates by or for the account of a person or firm to whom such licenses have been issued and only in accordance with the terms and conditions of the regulation.

Licenses are issued on a calendar year basis, and each license authorizes the license holder to import a specified quantity and type of dairy article from a specified country of origin. The use of such licenses is monitored by the Dairy Import Licensing Program, Import Policies and Export Reporting Division, Foreign Agricultural Service, U.S. Department of Agriculture, and the U.S. Customs and Border Protection, U.S. Department of Homeland Security.

The regulation at 7 CFR 6.33(a) provides that a fee will be charged for each license issued to a person or firm by the Licensing Authority in order to defray the Department of Agriculture's costs of administering the licensing system under this regulation.

The regulation at 7 CFR 6.33(a) also provides that the Licensing Authority will announce the annual fee for each license and that such fee will be set out in a notice to be published in the **Federal Register**. Accordingly, this notice sets out the fee for the licenses to be issued for the 2016 calendar year.

Notice: The total cost to the Department of Agriculture of administering the licensing system for 2016 has been estimated to be $624,300.00 and the estimated number of licenses expected to be issued is 2,500. Of the total cost, $479,200.00 represents staff and supervisory costs directly related to administering the licensing system, and $145,100.00 represents other miscellaneous costs, including travel, postage, publications, forms, and ADP system support.

Accordingly, notice is hereby given that the fee for each license issued to a person or firm for the 2016 calendar year, in accordance with 7 CFR 6.33, will be $250 per license.

Issued at Washington, DC, the 16th day of July, 2015.

Ronald Lord,

Licensing Authority.

[FR Doc. 2015–19081 Filed 8–3–15; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket No. NRCS–2015–0004]

Notice of Availability (NOA) of the Finding of No Significant Impact (FONSI) and Final Environmental Assessment (EA) for the Voluntary Public Access and Habitat Incentive Program (VPA–HIP)

AGENCY: Natural Resources Conservation Service.

ACTION: Notice of availability.

SUMMARY: On April 27, 2015, the Natural Resources Conservation Service (NRCS) published an NOA in the **Federal Register** announcing the availability of a draft EA for VPA–HIP and requesting public comment. The draft EA was available for a 30-day public comment period that ended May 27, 2015. The draft EA was prepared to meet the requirements of the National Environmental Policy Act (NEPA) of 1969 and NRCS implementing regulations. Brief comments were received from one State and those comments expressed no concerns about the analysis or the effects of the program. NRCS has determined that implementing VPA–HIP is not a major Federal action significantly affecting the quality of the human environment within the context of NEPA and, therefore, an Environmental Impact Statement will not be prepared.

FOR FURTHER INFORMATION CONTACT: A copy of the final Programmatic EA and FONSI can be accessed on the Internet by clicking on the appropriate link at *www.nrcs.usda.gov/ea.* Single copies of the FONSI and Programmatic EA or additional information may also be obtained by contacting Ms. Andrée DuVarney, National Environmental Coordinator, USDA–NRCS, Ecological Sciences Division, Room 6158–S, P.O. Box 2890, Washington, DC 20013–2890 or by sending a request via email to *andree.duvarney@wdc.usda.gov.*

SUPPLEMENTARY INFORMATION:

Background: VPA–HIP is a competitive grants program that is available to State and Tribal governments. The program is authorized under the Food, Conservation, and Energy Act of 2008, as amended (2008 Farm Bill, as amended) (16 U.S.C. 3839bb–5). Regulations at 7 CFR part 1455 govern implementation of VPA–HIP. The primary objective of VPA–HIP is to support State and Tribal government programs that encourage owners and operators of privately held

farm, ranch, and forest land to voluntarily make that land available for access by the public for hunting, fishing, and other wildlife-dependent recreation. Grant recipients may also use VPA–HIP funds to improve habitat on enrolled public access program lands.

NRCS expects most actions carried out with VPA–HIP funds to follow NRCS conservation practice standards and fall within existing categorical exclusions. Although VPA–HIP applicants that agree to follow NRCS conservation practice standards will receive preference for acceptance and funding, there is no requirement they do so. It is also possible some actions may not fall within a categorical exclusion. Therefore, NRCS decided to prepare a Programmatic EA to review the effects of activities that are likely to occur with VPA–HIP grants.

Proposed Action: The Proposed Action is to award VPA–HIP grants as authorized by the 2008 Farm Bill, as amended. Under this alternative, NRCS will provide an opportunity for State and Tribal governments to apply for grants to encourage owners and operators of privately held farm, ranch, and forest land to voluntarily make that land available for access by the public for hunting, fishing, and other wildlife-dependent recreation, and to improve and manage fish and wildlife habitat on their land under programs administered by State or Tribal governments. Grants will be awarded through a competitive process.

Alternatives: The Programmatic EA evaluates the environmental impacts of the Proposed Action and the no-action alternative. The Proposed Action is the agency's preferred alternative, and it meets the purpose of and need for the project with only minor, short-term adverse impacts to the environment anticipated. The no-action alternative does not meet the purpose and need for the action, and results in more adverse impacts to the environment than the preferred alternative.

Scoping: In developing the Programmatic EA, NRCS conducted internal scoping with various agency discipline experts, and used experience gained from previous VPA–HIP grants and associated EAs. Potential adverse impacts identified through the scoping process include localized, temporary, minor increases in soil erosion, sediment transport, and particulate matter from ground-disturbing activities and the use of agricultural equipment during the installation of conservation practices. In the longer term, there will be habitat improvements, and increased recreational and economic benefits. NRCS solicited comments from the public for 30 days on its analysis and received only one comment that expressed no concerns.

Other Environmental Review and Coordination Requirements: VPA–HIP grant recipients will conduct site-specific evaluations of lands where habitat improvement projects are planned to address project compliance with applicable laws and regulations, including NEPA, Clean Water Act, Endangered Species Act, and the National Historic Preservation Act. NRCS will conduct or oversee any required consultation with the VPA–HIP grant recipients in accordance with applicable regulations.

Signed this 22nd day of July 2015, in Washington, DC.

Jason A. Weller,

Chief, Natural Resources Conservation Service.

[FR Doc. 2015–19036 Filed 8–3–15; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Upper North River Watershed Dam No. 77, Augusta County, Virginia

AGENCY: Natural Resources Conservation Service, USDA.

ACTION: Notice of a Finding of No Significant Impact.

SUMMARY: Pursuant to Section 102[2][c] of the National Environmental Policy Act of 1969, the Council on Environmental Quality Regulations [40 CFR part 1500]; and the Natural Resources Conservation Service Regulations [7 CFR part 650]; the Natural Resources Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the rehabilitation of Upper North River Watershed Dam No. 77, Augusta County, Virginia.

FOR FURTHER INFORMATION CONTACT: John A. Bricker, State Conservationist, Natural Resources Conservation Service, 1606 Santa Rosa Road, Suite 209, Richmond, Virginia 23229. Telephone (804) 287–1691, email *jack.bricker@va.usda.gov.*

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, John A. Bricker, State Conservationist, has determined that the preparation and review of an environmental impact statement is not needed for this project.

The project purpose is continued flood prevention. The planned works of improvement include upgrading an existing floodwater retarding structure.

The Notice of a Finding of No Significant Impact (FONSI) has been forwarded to the various Federal, State, and local agencies and interested parties. A limited number of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting John A. Bricker at the above number.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register**.

John A. Bricker,

State Conservationist.

[This activity is listed in the Catalog of Federal Domestic Assistance under 10.904, Watershed Protection and Flood Prevention, and is subject to the provisions of Executive Order 12372, which requires inter-government consultation with State and local officials].

[FR Doc. 2015–19091 Filed 8–3–15; 8:45 am]

BILLING CODE 3410–16–P

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket Number 150721631–5631–01]

2017 Economic Census

AGENCY: Bureau of the Census, Commerce.

ACTION: Notice of Determination and Request for Comment.

SUMMARY: The Bureau of the Census (U.S. Census Bureau) publishes this notice to announce that it is planning to conduct the 2017 Economic Census. The Census Bureau also is requesting public comment on the 2017 Economic Census content. This collection will be fully electronic using a secure encrypted Internet data collection system called Centurion. The Economic Census is conducted at 5-year intervals (years ending in 2 and 7) and is the most comprehensive compilation of statistics about U.S. businesses and the economy. The granting of specific authority to conduct the program is Title 13, United States Code (U.S.C.), Section 131, which authorizes and requires the Economic Census.

DATES: The Census Bureau will begin the electronic mailout for the 2017 Economic Census in the Fall of 2017,

and responses will be due by February 12, 2018. Written comments must be submitted on or before October 5, 2015 to ensure consideration of your comments on the 2017 Economic Census content.

ADDRESSES: Direct all written comments regarding the 2017 Economic Census to Kevin Deardorff, Chief, Economy Wide Statistics Division, U.S. Census Bureau, Room 8K154, Washington, DC 20233; or Email [*ec.frn17@census.gov*].

FOR FURTHER INFORMATION CONTACT: Economy-Wide Statistics Division, U.S. Census Bureau, 4600 Silver Hill Road, Room 6K141, Washington, DC 20233–6700, by phone (800) 242–2184, or by email *ec.frn17@census.gov*>.

SUPPLEMENTARY INFORMATION:

A. Background

Section 131 of Title 13 U.S.C. directs the Secretary [of Commerce] to ''. . . take, compile, and publish censuses of manufactures, of mineral industries, and of other businesses, including the distributive trades, service establishments, and transportation (exclusive of means of transportation for which statistics are required by law to be filed with, and are compiled and published by, a designated regulatory body), in the year 1964, then in the year 1968, and every fifth year thereafter, and each such census shall relate to the year immediately preceding the taking thereof.''

This notice announces that the Census Bureau is preparing to conduct the 2017 Economic Census. The Economic Census is the U.S. Government's official 5-year measure of American Business and the economy, and has been taken periodically since 1810. The Economic Census is the most comprehensive source of information about American businesses from the national to the local level. These Economic Census data products provide uniquely detailed basic measures that are summarized by North American Industry Classification System (NAICS) industry for the U.S., states, metropolitan areas, counties, economic places, and ZIP Code areas. Data include details on the product composition of industry sales, receipts, revenue, or shipments; and on a great variety of industry-specific subjects. Additionally, the Economic Census produces statistics about businesses in Puerto Rico, American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the U.S. Virgin Islands, and it provides data on selected special-interest topics, including the characteristics of business owners, domestic freight shipments, and business expenses. Published data cover close to 1,000 industries, 8,000 goods and services, every state, the District of Columbia, over 3,000 counties and 15,000 cities and towns.

The Economic Census is a primary source of facts about the structure and functioning of the U.S. economy. Economic Census statistics are more complete, specific, and reliable than any other single set of economic information. It provides comprehensive, detailed, high quality, and authoritative statistics that meet the needs of government, businesses, policymakers, academic researchers, and the American public. The program's data products inform policies and programs that promote business vitality, job creation, and sustainable growth. Moreover, they provide the official measures of output for industries and geographic areas and serve much of the foundation for the National Income and Product Accounts, Gross Domestic Product estimates, and other composite measures of the Nation's economic performance. These data supply weights and benchmarks for indexes of industrial production, productivity, and prices; and provide benchmarks for other Federal statistical series. Some of these statistical series include current business surveys done by the Census Bureau, which are used by trade associations, business organizations, economic development agencies, and individual businesses to assess and improve business performance.

B. Electronic Collection

The 2017 Economic Census will be the first to be conducted completely by electronic collection (100 percent Internet Collection). The electronic instrument, Centurion, provides improved quality with automatic data checks and is context-sensitive to assist the data provider in identifying potential reporting problems before submission, thus reducing the need for follow-up. Centurion is Internet-based, eliminating the need for downloading software and increasing the integrity and confidentiality of the data. The Census Bureau will furnish usernames and passwords for the electronic instrument to the organizations included in the survey, and an image of the electronic instrument will be available on the 2017 Economic Census Web site once the census has launched.

C. Economic Census Content

The Census Bureau posted copies of the 2012 Economic Census forms on its Web site at: *https://bhs.econ.census.gov/ec12/php/census-form.php*. Please take a moment to review the forms relevant to your interests and provide us with your comments for us to consider as we prepare content for the 2017 questionnaires. In particular, Item 26 ''Special Inquiries'' may be of the most interest to you. The Special Inquiries item is dedicated to variable questions of particular interest to the industries to which the questionnaire is directed. While general questions are asked of all establishments, these variable questions allow special data to be collected, which measure important changes in our economy and support the needs of individual industries. We are particularly interested in comments on the usefulness of existing inquiries for continued inclusion and in suggestions for new measures that would be appropriate to include in the Economic Census.

Notwithstanding any other provision of law, no person is 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 (PRA) unless that collection of information displays a current valid Office of Management and Budget (OMB) control number. The Census Bureau, through the proper established procedures, will be obtaining an OMB control number under the PRA as we get closer to launching the program in 2017.

I have, therefore, directed that the 2017 Economic Census be conducted for the purpose of collecting these data.

Dated: July 30, 2015.

John H. Thompson,

Director, Bureau of the Census.

[FR Doc. 2015–19147 Filed 8–3–15; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; 2016 Census Test

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: To ensure consideration, written comments must be submitted on or before October 5, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the Internet at *jjessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Robin Pennington, Census Bureau, HQ–4K065, Washington, DC 20233; (301) 763–8132 (or via email at *robin.a.pennington@census.gov*).

SUPPLEMENTARY INFORMATION:

I. Abstract

During the years preceding the 2020 Census, the Census Bureau will pursue its commitment to reduce the costs of conducting a decennial census, while maintaining our commitment to quality. A primary decennial census cost driver is collection of data from members of the public from which the Census Bureau received no reply via initially offered response options. Improving our methods for increasing the number of people who take advantage of self-response options (''Optimizing Self-Response'') and further refining the questionnaire content will help increase the efficiency and effectiveness of census operations and substantially reduce costs. Additionally, making our methods for enumerating households that do not initially respond (''Nonresponse Followup'') more efficient can contribute to a less costly census while maintaining high-quality results.

The Census Bureau will conduct a 2016 Census Test, with components designed to test new approaches or validate existing approaches and systems integration related to (1) Optimizing Self-Response, including contact strategies, language support, and questionnaire content; and (2) Nonresponse Followup, including administrative records usage, and technological and operational improvements.

Optimizing Self-Response

The 2016 Census Test is designed to evaluate several strategies to optimize the rate at which the public self-responds to the census. A higher rate of self-response will mean fewer cases for the Nonresponse Followup operation, saving taxpayer money. Significant areas of continued testing are:

- Evaluation and refinement of our ''Internet push'' strategy, where we do not initially send paper questionnaires to households, but rather invite them to complete the questionnaire online. We will evaluate the number of online invitations necessary before sending a full paper questionnaire to an address.
- Updated and modernized household contact strategies to encourage self response, including text/short message service (SMS) communication and postcard reminders.
- Refinement of our non-English support for respondents with limited English proficiency, the inclusion of non-English language letters and/or brochures in mailings, and web response addresses (Uniform Resource Locators, or URLs) in various languages on the incoming envelope.
- Further evaluation of questionnaire content:
  - We will include testing of a combined race and Hispanic origin question that is similar to one the Census Bureau is using in the 2015 National Content Test. Based on results from the 2010 Race and Hispanic Origin Alternative Questionnaire Experiment (Compton, et. al. 2012), the 2016 Census Test provides an opportunity to further test a combined race and Hispanic origin question.
  - On the Internet instrument only, we will test a terminology change in the race and ethnicity question specific to the ''Black and African American'' category, by comparing the use of ''American'' to the abbreviated ''Am.'' This addresses a problem with this abbreviation related to software providing Section 508 compliance [1]. We are testing this on the Internet initially because the path for testing and screens on the Internet are more easily deployed than paper versions. We will continue and expand testing this terminology change with paper questionnaires (self-response) in future testing.
  - For the relationship question, the 2016 Census Test will include testing new response categories for opposite sex and same sex husband/wife/spouse and unmarried partner. In addition, the Internet data collection instrument will also provide two versions of the relationship question, with one version eliminating the response categories associated with unrelated household members (''roomer or boarder'' and ''housemate or roommate'').
  - The Internet data collection instrument will also include various ways to collect and confirm the number of persons residing at an address. Respondents will see one of three screens about the existence of people on the roster: one that displays the residence rule and asks for the number of people in the household, one that asks for the number of people who live in the household but puts the residence rule in the help text, and one that asks if any other people live at the household with the residence rule in the help text. After the names of the roster members are collected, the respondent will then see one of two series of undercount questions: one series asks for additional people on two separate screens, and another series asks for additional people on only one screen. After the demographic items are collected, the respondent will then see overcount questions in one of three forms, depending on test panel. Some respondents will see seven topic-based questions that ask if anyone in the household stayed at a particular type of place. Some respondents who live in small households (that is, households with three or fewer people) will see one person-based question that asks if a specific person stayed in any of a number of places. Other respondents will see two household-level questions that first ask if anyone in the household stayed in another housing unit or if anyone in the household stayed in a group quarters. The quality of the final household roster created from these experimentally applied questions will be evaluated by a coverage reinterview conducted by telephone that will contain extensive probes about missed roster members or other places that people sometimes stay.

Nonresponse Followup (NRFU)

The 2016 Census Test will be instrumental to the Census Bureau in testing new implementation and management processes, the use of automated data collection tools, and approaches such as using administrative records and third party data to reduce the NRFU workload. This test allows us to refine our use of administrative records, technologies to support field data collection and management, and operational procedures.

- Administrative Records
- Continued evaluation of our plan to use administrative records and other third party data (such as from the Internal Revenue Service, Center for Medicare and Medicaid Services, United States Postal Service, etc.) to identify vacant housing units that do not require a field visit during the nonresponse follow-up operation. Historically, the costs to verify and follow up with these types of units have been significant
- Continued evaluation of our plan to use the ''occupancy'' status of administrative records sources to

[1] *Section 508 of the Rehabilitation Act* (29 U.S.C. '794 d) as amended by the Workforce Investment Act of 1998 (Pub. L. 205–220)

enumerate housing units after a certain number of NRFU contact attempts. This includes quality evaluations of the sources of the administrative records, and reviews of the procedures by which those administrative records are produced (working with the source agencies, etc.). This will help us to decide in what scenarios the use of administrative records is most appropriate, the ideal number of personal visits to attempt before enumerating with these records, and several other research questions.

- Supplemental mailings to housing units that have been removed from the NRFU operation, giving respondents an additional chance to respond to the 2016 Census Test before final disposition using administrative record source data.
- Technological Improvements:
- Evaluation of our refined operational control system and case assignment processes, including identifying efficiencies for field data collection, as well as automated assignments that are based on enumerator availability and other criteria.
- Continued testing of a software to record housing unit status, interview, and enumerations at nonresponding housing units for operational readiness, as well as the ability to deploy the software on mobile devices that are Census owned, personally owned, or provided as a service.
- Continued evaluation of automated training for field employees.
- The inclusion of additional language translations to our enumeration software. Previous versions of this software provided translations in Spanish only.
- Operational Procedures:
- Comparison of the effectiveness of data collection modes (in-field enumeration vs. centralized telephone contact) to conduct telephone follow up activities.
- Use of innovative survey methodologies for NRFU cases, including the continued testing of different stopping rules for enumerators (maximum visits before stopping work, etc.); further evaluation of in-person vs. phone contacts, and continued research on when and how to attempt to obtain proxy responses for a housing unit.
- Implementation of a refined field management structure, designed to lessen the number of supervisors required in the field for conducting the NRFU operation.
- Testing our re-interview operation, including the rules by which cases are selected for re-interview, the use of a handheld device to input re-interview data, and a re-designed approach to using call center staff to make the first attempt at re-interviewing each case, where appropriate. We will also test the use of paradata collected from our automated data collection instrument, such as the recorded Global Positioning System (GPS) location of field interviews and the length of time for interviews to be conducted, to help detect and deter falsification by enumerators.

II. Method of Collection

Test Sites

The Census Bureau will conduct the 2016 Census Test concurrently in portions of Harris County, TX and Los Angeles County, CA. These locations offer particular characteristics that support the Census Bureau's research goals. Conducting the 2016 Census Test in urban areas will allow us to test our assignment routing strategies in densely populated areas and understand challenges to field enumeration. Both sites have populations that are linguistically diverse and provide an appropriate context to test our language and translation services. Lastly, both areas contain ''hard to count'' populations and areas with high vacancy rates that will allow us to test our follow-up activities with these populations in this environment.

Self-Response

The housing units in the selected areas included in the 2016 Census Test will be contacted by mail and invited to complete their questionnaire via the Internet. Internet self response contact methods include a letter, postcard, and text (either as an invitation or as reminders), a multi-lingual brochure (either with a letter or in the envelope with URL). We will also test optimal strategies for delivering mail materials, including paper questionnaires, to households who do not or cannot respond online.

We will continue to test our Non-ID processing methodology as another strategy for optimizing self-response. Non-ID Processing refers to address matching and geocoding for Census responses that lack a preassigned Census identification code. In the 2016 Census Test, we will continue to develop our capability to conduct real-time Non-ID processing. This test will allow us to interactively prompt a respondent (while they are still online filling out the form) for additional address and location information if the respondent's address cannot be matched to a Census ID or geocoded. A Non-ID respondent whose address cannot be matched to our address database will be prompted during his or her Internet self-response session to confirm the address information they provided while filling out the form, or to indicate the location of their address on an on-screen map. This test will allow us to better understand requirements related to scalability of planned systems and determine metrics for ongoing monitoring and evaluation. If the address match is not resolved during automated processing Census staff will attempt to manually match or geocode addresses. We estimate that about one percent of the overall Non-ID respondents will be contacted as part of the manual matching process. Additionally, we plan to test a mechanism for validating all Non-ID respondents through the use of administrative records. To further explore our methodology for validating Non-ID responses, a sample of Non-ID responses will be selected for re-contact. The re-contact is intended to validate and re-collect information from a respondent to confirm the existence of the address and the persons enumerated at that address. The re-contact may occur through centralized phone contacts or in-field enumeration.

Nonresponse Followup (NRFU)

If a household does not ultimately respond to the self-response portion of the test by a specified date, it is included in the universe for the NRFU portion of the test, during which enumerators will attempt to follow up with nonresponding households to collect data. The Census Bureau will test centralized phone contacts to nonresponding cases prior to sending cases to an enumerator in the field. In advance of the full deployment of enumerators following up with nonresponding households, a small number of the nonresponding cases may be subject to early followup to allow for live testing of systems, data collection applications, and field procedures.

The Census Bureau will continue to test our use of administrative records for the removal of vacant housing units from the NRFU universe and to determine rules for when we can stop making visit attempts to households, and refer to administrative record data instead. For each of these cases, we will test a supplemental mailout to any household that is removed from the NRFU workload in this way as a final attempt to generate a self-response.

The Census Bureau will conduct NRFU with a combination of Census-owned, enumerator-owned, and mobile devices provided as a service using the Census developed enumeration

software. The use of employee-owned equipment/services is commonly referred to as ''Bring Your Own Device,'' or BYOD. It is important to note, that for Census-owned devices, BYOD devices, or devices provided as a service that the data collection application collects and securely transmits respondents' data. The use of mobile devices that are Census-owned, enumerator-owned, or provided as a service will enable the Census Bureau to assess options for a secure and cost-effective approach to the NRFU data collection.

Nonresponse Followup Quality Control Reinterview (NRFU–RI)

A sample of cases that have been enumerated via Nonresponse Followup will be selected for reinterview. This operation is intended to help us pinpoint possible cases of enumerator falsification. Like the NRFU operation before it, NRFU–RI will use the Census Bureau's enumeration software on mobile devices (Census-owned, BYOD, and devices provided as a service). We will also test centralized phone contacts of reinterview cases before sending them to an enumerator in the field, providing potential cost savings.

Additional Followup Operations

Understanding the accuracy of administrative records usage to identify vacant addresses and for the household composition of occupied housing units will inform decisions associated with the design of the 2020 Census. The Census Bureau may conduct additional followup with cases to obtain the most accurate Census Day status of each housing unit. The intent is to revisit addresses where we find discrepancies between the NRFU results and administrative records information for the address. This mostly will include those addresses where information collected during NRFU conflicts with information we have from administrative records for that address.

Language Services

Telephone questionnaire assistance will be available in languages other than English.

Focus Groups

To evaluate the use of new contact strategies, enumeration methods, and efforts to reduce burden, the Census Bureau will conduct focus groups, comprised of various categories of respondents and non-respondents. These focus groups are intended to gather information about respondent perspectives. Participants will be asked about their experiences with the 2016 Census Test, including but not limited to: Their reactions and thoughts about being contacted by the Census Bureau by alternative methods, the perceived legitimacy of these contacts; opinions about Bring Your Own Device; and their opinions on the use of administrative records by the Census Bureau. Participants will also be asked about their general concerns with government collection, cyber security, and protection of confidential data. At the end of the focus groups, we may be asking participants for whom we have acquired additional data from a commercial third party to verify whether this information is accurate.

III. Data

OMB Control Number: 0607–XXXX.

Form Number(s): Paper and electronic questionnaires; numbers to be determined.

Type of Review: Regular submission.

Affected Public: Households/Individuals.

Estimated Number of Respondents: Self responders [Internet/Telephone/Paper]: 250,000 respondents.

Nonresponse Followup Cases: 120,000 respondents.

Nonresponse Followup Quality Control Re-Interview Cases: 12,000 respondents.

Manual Non-ID Processing Cases requiring a phone call to the respondent: 400.

Validation of Non-ID responses: 5000.

Administrative Records Followup: 5000.

Focus Groups:

Focus Group Selection Contact: 288.

Focus Groups: 160 participants.

Total: 392,848 respondents.

Estimated Time Per Response:

Paper/Internet Responders: 10 minutes per response.

Nonresponse Followup Cases: 10 minutes per response.

Nonresponse Followup Quality Control Re-Interview Cases: 10 minutes per response.

Non-ID Manual Processing Cases: 5 minutes.

Non-ID Respondent Validation: 10 minutes per response.

Administrative Records Followup: 10 minutes per response.

Focus Groups:

Focus Group Selection Contact: 3 minutes per response.

Focus Groups: 120 minutes per response.

Estimated Total Annual Burden Hours:

Self responders [Internet/Paper/Telephone]: 41,667 hours.

Nonresponse Followup Cases: 20,000 hours.

Nonresponse Followup Quality Control Re-Interview Cases: 2,000 hours.

Non-ID Manual Processing Cases: 33 hours.

Non-ID Respondent Validation: 834 hours.

Administrative Records Followup: 834 hours.

Focus Groups:

Focus Group Selection Contact: 16 hours.

Focus Groups: 320 hours.

Total: 65,704 hours.

Estimated Total Annual Cost to Public: For the 2016 Census Test, respondents who are contacted by text message may incur charges depending on their plan with their service provider. The Census Bureau estimates that the total cost to respondents will be no more than $20,000. There are no other costs to respondents other than their time to participate in this data collection.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 U.S.C. Sections 141 and 193.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: July 29, 2015.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2015–19005 Filed 8–3–15; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Proposed Information Collection; Comment Request; Services Surveys: BE–125, Quarterly Survey of Transactions in Selected Services and Intellectual Property With Foreign Persons

AGENCY: Bureau of Economic Analysis, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before October 5, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230, or via email at *jjessup@doc.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Christopher Stein, Chief, Services Surveys Branch BE–50 (SSB), Bureau of Economic Analysis, U.S. Department of Commerce, Washington, DC 20230; phone: (202) 606–9850; fax: (202) 606–5318; or via email at *christopher.stein@bea.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Quarterly Survey of Transactions in Selected Services and Intellectual Property with Foreign Persons (BE–125) is a survey that collects data from U.S. persons that engage in covered transactions with foreign persons in selected services or intellectual property. A U.S. person must report if it had sales of covered services or intellectual property to foreign persons that exceeded $6 million for the previous fiscal year, or are expected to exceed that amount during the current fiscal year, or if it had purchases of covered services or intellectual property from foreign persons that exceeded $4 million for the previous fiscal year, or are expected to exceed that amount during the current fiscal year.

The data are needed to monitor U.S. trade in services, to analyze the impact on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the services component of the U.S. international transactions accounts and national income and product accounts.

The Bureau of Economic Analysis (BEA) is proposing minor additions and modifications to the current BE–125 survey. The effort to keep current reporting requirements generally unchanged is intended to minimize respondent burden while considering the needs of data users. Existing language in the instructions and definitions will be reviewed and adjusted as necessary to clarify survey requirements.

II. Method of Collection

Form BE–125 is a quarterly report that must be filed within 45 days after the end of each fiscal quarter, or within 90 days after the close of the fiscal year. BEA offers its electronic filing option, the eFile system, for use in reporting on Form BE–125. For more information about eFile, go to *www.bea.gov/efile.*

III. Data

OMB Control Number: 0608–0067.

Form Number: BE–125.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations.

Estimated Number of Responses: 8,400 annually (2,100 filed each quarter; 1,600 reporting mandatory data, and 500 that would file other responses).

Estimated Time Per Response: 16 hours is the average for those reporting data and 1 hour is the average for other responses, but hours may vary considerably among respondents because of differences in company size and complexity.

Estimated Total Annual Burden Hours: 104,400.

Estimated Total Annual Cost to Public: $0.

Respondent's Obligation: Mandatory.

LEGAL AUTHORITY: International Investment and Trade in Services Survey Act (Pub. L. 94–472, 22 U.S.C. 3101–3108, as amended).

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: July 28, 2015.

Glenna Mickelson,

Management Analyst, Office of Chief Information Officer.

[FR Doc. 2015–18873 Filed 8–3–15; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

International Trade Administration

Smart Cities Infrastructure Business Development Mission to India; February 8–12, 2016

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: The United States Department of Commerce, International Trade Administration (ITA) is organizing an Executive-led Smart Cities Infrastructure Business Development Mission to India (New Delhi, Mumbai and Chennai, with an optional spin off site visit to Vizag) from February 8–12, 2016.

Today, India's cities account for approximately 60% of the country's Gross Domestic Product (GDP). By 2030, that share is expected to reach 75% and the urban labor force is expected to increase by nearly 200 million workers. The new Indian Government led by Prime Minister Modi assumed office in June 2014 with an overwhelming mandate to focus on economic development. To capture the popular imagination and motivate the people of India, the new government has proposed a dramatic nationwide program to build 100 smart cities. In practice this will mean a wide variety of major infrastructure projects across the country that will be funded by the central and state governments over the next few years along with private sector capital. Infrastructure needs in India are estimated to be in the $1.5–$2 trillion range. The recently launched initiative

will move to define and implement reforms that drive the growth of smart cities. At this stage, the government has highlighted resource management, 24 hour water and power supply, world class transportation systems, state of the art education systems, advanced e-government, and environmental sustainability as pillars of India's smart cities. This initiative offers excellent opportunities for U.S. companies to participate in these projects in selected areas and sectors.

In recognition of cutting-edge U.S. technologies, products and services, the Government of India is encouraging the U.S. Government (USG) and U.S. companies to take the lead in developing smart city projects in three major urban areas: Ajmer in the state of Rajasthan, Allahabad in the state of Uttar Pradesh, Vishakhapatnam (aka Vizag) in the state of Andhra Pradesh. With the support of the U.S. Trade and Development Agency, U.S. companies will be involved in planning and technical assistance for each of these cities. However, U.S. participation is not limited to these three cities. CS India, in partnership with the American Chamber of Commerce and other local commercial chambers, has been staging events throughout the country in cities with additional public and private smart city projects.

SCHEDULE

Day of week	Date	Activity
Sunday	Feb. 7	Participants arrive in Delhi.
Monday	Feb. 8	Country briefing by U.S. Embassy staff on programs and opportunities in the infrastructure sector. B–2–B Business Meetings for delegates in New Delhi. Evening Reception.
Tuesday	Feb. 9	Government meetings. Depart for Mumbai afternoon. Briefing on Western India. Evening Reception.
Wednesday	Feb. 10	B–2–B Business Meetings for delegates in Mumbai. Evening Travel to Chennai.
Thursday	Feb. 11	Briefing on Southern India B–2–B Business Meetings for delegates in Chennai. Evening Reception.
Friday	Feb. 12	Optional smart city site visit to Vizag.* Return to the United States on own itinerary.

* Vizag (aka Vishakhapatnam) has made the most progress in terms of planning for physical infrastructure upgrades and implementation of smart city technologies. Additionally, the US Trade and Development Agency recently awarded a master planning contract to a consortium of US companies to facilitate smart city implementation in Vizag. A spin off visit to Vizag will provide an opportunity for mission participants to visit an up and coming smart city in India and to market their technologies directly to decision makers in Vizag as well as to the US consortium that has the master planning contract.

TARGET SECTORS

IT infrastructure	Water
▪ IT architecture, security solutions, and other Internet of Things applications. ▪ Smart Grid applications, including Demand Management and Demand Response, Distribution Automation, and Distributed Energy Resource Management. ▪ Building Energy Management Systems, LED Lighting, Smart Street Lighting and other energy efficient lighting systems and control technology. ▪ Energy efficient technologies and applications in transportation. ▪ Services for city planning, including Environmental Sustainability Plans, GIS mapping, and financial services.	▪ Engineering, procurement, and construction services. ▪ Operations services. ▪ Advanced Filtration. ▪ Membrane filtration. ▪ Sewage treatment technology. ▪ Waste to energy technology. ▪ Anaerobic digestion. ▪ Nitrification. ▪ Biological denitrification. ▪ Monitoring equipment. ▪ Testing equipment.

Web site: Please visit our official mission Web site for more information: *http://www.export.gov/trademissions/smartcitiesindia2016/index.asp*

Fees:

$4,000 for SME firms.

$4,500 for large firms.

Additional participants: $1,000 per person.

Additional fees for optional trip to Vizag:

SME firms that will be attending the optional Vizag trip will pay $4,100,

Large firms that attend will pay $4,800.

Application: All interested firms and associations may register via the following link, *https://emenuapps.ita.doc.gov/ePublic/TM/6R0Q*.

Application Deadline: November 10, 2015.

Exclusions

The mission fee does not include any personal travel expenses such as lodging, most meals, local ground transportation, and air transportation from the U.S. to the mission sites, between mission sites, and return to the United States. Business visas may be required. Government fees and processing expenses to obtain such visas are also not included in the mission costs. However, the U.S. Department of Commerce will provide instructions to each participant on the procedures required to obtain necessary business visas.

SUPPLEMENTARY INFORMATION: Each applicant must submit a completed and signed mission application and supplemental application materials, including adequate information on the company's products or services primary market objectives, and goals for participation. If the U.S. Department of Commerce receives an incomplete application, the Department may reject the application, request additional

information, or take the lack of information into account when evaluating the applications.

Companies must provide certification of products or services originating from the United States or if manufactured/produced outside of the United States, the product/service is marketed under the name of a U.S. firm and has U.S. content representing at least 51% of the value of the finished good or service. In the case of a trade association or trade organization, the applicant must certify that, for each company to be represented by the trade association or trade organization, the products and services the represented company seeks to export are either produced in the United States or, if not, marketed under the name of a U.S. firm and have at least 51% U.S. content.

Criteria for Application

The following criteria will be evaluated in selecting participants:

- Relevance of the company's (or in the case of a trade association/organization, represented companies') business to the mission goals;
- Company's (or in the case of a trade association/organization, represented companies') market potential for business in India; and
- Provision of adequate information on the company's products and/or services, and communication of the company's (or in the case of a trade association/organization, represented companies') primary objectives.

FOR FURTHER INFORMATION CONTACT:

Ms. Jessica Dulkadir, International Trade Specialist, Trade Missions, U.S. Department of Commerce, Washington, DC 20230, Tel: 202 482 2026, Fax: 202–482–9000, *Jessica.Dulkadir@trade.gov*.

Ms. Camille Richardson, Principal Commercial Officer, U.S. Commercial Service, Mumbai, Tel: +91 22 2672–4215, *Camille.Richardson@trade.gov*.

Frank Spector,

Trade Missions Program.

[FR Doc. 2015–19123 Filed 8–3–15; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–833]

Polyester Staple Fiber From Taiwan: Rescission of Antidumping Duty Administrative Review; 2014–2015

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is rescinding its administrative review of the antidumping duty order on polyester staple fiber (PSF) from Taiwan for the period of review (POR) May 1, 2014, through April 30, 2015.

DATES: *Effective Date:* August 4, 2015.

FOR FURTHER INFORMATION CONTACT: Bryan Hansen at 202–482–3683 or Minoo Hatten at 202–482–1690, AD/CVD Operations Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On May 30, 2015, based on a timely request for review by Far Eastern New Century Corporation (FENC), an exporter of subject merchandise,[1] the Department initiated an administrative review of the antidumping duty order on PSF from Taiwan with respect to FENC.[2]

On July 21, 2015, FENC withdrew its request for an administrative review.[3]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, if a party that requested a review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review. FENC withdrew its request for review within the 90-day time limit. Because no other party requested a review, the Department is rescinding this administrative review of the antidumping duty order on PSF from Taiwan.

Assessment

The Department will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of PSF from Taiwan during the POR at rates equal to the cash deposit rate of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions to CBP 15 days after the publication of this notice in the **Federal Register**.

[1] *See* letter from FENC to the Department, ''Polyester Staple Fiber from Taiwan'' (May 30, 2015).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 80 FR 37588 (July 1, 2015).

[3] *See* letter from FENC to the Department, ''Polyester Staple Fiber from Taiwan'' (July 21, 2015).

Notifications

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

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO, in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: July 28, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2015–19143 Filed 8–3–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules From the People's Republic of China: Partial Rescission of Antidumping Duty Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* August 4, 2015.

FOR FURTHER INFORMATION CONTACT: Jeff Pedersen or Thomas Martin, AD/CVD Operations, Office IV, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, telephone: (202) 482–2769 or (202) 482–3936, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2012 the Department of Commerce (Department) published in the **Federal Register** the antidumping duty order on crystalline silicon photovoltaic cells, whether or not assembled into modules from the People's Republic of China (PRC).[1] On December 3, 2014, the Department published a notice of opportunity to request an administrative review of the order on crystalline silicon photovoltaic cells, whether or not assembled into modules.[2] The Department received multiple timely requests for an administrative review of the order on crystalline silicon photovoltaic cells, whether or not assembled into modules. On February 4, 2015, in accordance with section 751(a) of Tariff Act of 1930, as amended (the Act), the Department published in the **Federal Register** a notice of the initiation of an administrative review of that order.[3] The administrative review was initiated with respect to 78 companies or groups of companies, and covers the period from December 1, 2013, through November 30, 2014. While 32 companies or groups of companies remain under review, the requesting parties have timely withdrawn all review requests for 46 companies or groups of companies, as discussed below.

Rescission of Review, in Part

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if a party that requested the review withdraws its request within 90 days of the date of publication of the notice of initiation of the requested review. All requesting parties withdrew their respective requests for an administrative review of the 46 companies or groups of companies listed in the Appendix within 90 days of the date of publication of *Initiation Notice.* Accordingly, the Department is rescinding this review, in part, with respect to these companies, in accordance with 19 CFR 351.213(d)(1).[4]

Assessment

The Department will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries. For the companies for which this review is rescinded, antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(l)(i).[5] The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of this notice.

Notification to Importers

This notice serves as the only reminder to importers whose entries will be liquidated as a result of this rescission notice, of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's assumption that the reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective orders (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under an APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: July 28, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

- Changzhou NESL Solartech Co., Ltd.
- CSG PVTech Co., Ltd.
- DelSolar Co., Ltd.
- Dongfang Electric (Yixing) MAGI Solar Power Technology Co., Ltd.
- Hengdian Group DMEGC Magnetics Co., Ltd.
- Himin Clean Energy Holdings Co., Ltd.
- Innovosolar
- Jiangsu Green Power PV Co., Ltd.
- Jiawei Solarchina Co., Ltd.
- Jinko Solar Co., Ltd.
- Jinko Solar Import and Export Co., Ltd.
- JinkoSolar International Limited
- Konca Solar Cell Co., Ltd.
- Kuttler Automation Systems (Suzhou) Co., Ltd.
- LDK Solar Hi-Tech (Nanchang) Co., Ltd.
- LDK Solar Hi-Tech (Suzhou) Co., Ltd.
- Leye Photovoltaic Science Tech.
- Luoyang Suntech Power Co., Ltd.
- Magi Solar Technology
- Motech (Suzhou) Renewable Energy Co., Ltd.
- Ningbo ETDZ Holdings, Ltd.
- Ningbo Ulica Solar Science & Technology Co., Ltd.
- Perlight Solar Co., Ltd.
- ReneSola Jiangsu Ltd.
- Renesola Zhejiang Ltd.
- Shenglong PV-Tech
- Shenzhen Suntech Power Co., Ltd.
- ShunFeng PV
- Solarbest Energy-Tech (Zhejiang) Co., Ltd.
- Sopray Energy Co., Ltd.
- Sumec Hardware & Tools Co., Ltd.
- Suntech Power Co., Ltd.
- Suzhou Shenglong PV-Tech Co., Ltd.
- tenKsolar (Shanghai) Co., Ltd.
- Tianwei New Energy (Chengdu) PV Module Co., Ltd.
- Upsolar Group Co., Ltd.
- Wanxiang Import & Export Co., Ltd.
- Wuxi Sunshine Power Co., Ltd.
- Yangzhou Rietech Renewal Energy Co., Ltd.
- Yangzhou Suntech Power Co., Ltd.
- Zhejiang Jiutai New Energy Co., Ltd.
- Zhejiang Shuqimeng Photovoltaic Technology Co., Ltd.
- Zhejiang Xinshun Guangfu Science and Technology Co., Ltd.
- Zhejiang ZG-Cells Co., Ltd.
- Zhenjiang Rietech New Energy Science & Technology Co., Ltd.
- Zhiheng Solar Inc.

[FR Doc. 2015–19161 Filed 8–3–15; 8:45 a.m.]

BILLING CODE 3510–DS–P

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 77 FR 73018 (December 7, 2012).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 79 FR 71382 (December 3, 2014).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 80 FR 6041 (February 4, 2014) (*Initiation Notice*).

[4] *See* Appendix. As stated in *Change in Practice in NME Reviews,* the Department will no longer consider the non-market economy (''NME'') entity as an exporter conditionally subject to administrative reviews. *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013) (''*Change in Practice in NME Reviews*''). The PRC-wide entity is not subject to this administrative review because no interested party requested a review of the entity. *See Initiation Notice.*

[5] For Hengdian Group DMEGC Magnetics Co., Ltd., we shall instruction CBP to assess duties on entries from June 1, 2014 through November 30, 2014 because there in an ongoing new shipper review of this company covering the period December 1, 2013 through May 31, 2014.

DEPARTMENT OF COMMERCE

International Trade Administration

Meeting of the United States Manufacturing Council

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The United States Manufacturing Council (Council) will hold the third meeting of the current members' term by teleconference on Wednesday, August 19, 2015. The Council was established in April 2004 to advise the Secretary of Commerce on matters relating to the U.S. manufacturing industry.

The purpose of the meeting is for Council members to review and deliberate on recommendations developed by the Workforce subcommittee looking at issues of improving the image of manufacturing as a career path and developing skilled workers for consideration by the Manufacturing Council. The agenda may change to accommodate Council business. The final agenda will be posted on the Department of Commerce Web site for the Council at *http://trade.gov/manufacturingcouncil,* at least one week in advance of the meeting.

DATES: Wednesday, August 19, 2015, 12:00 p.m.–1:00 p.m. The deadline for members of the public to register, including requests to make comments during the meetings and for auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5 p.m. EDT on August 4, 2015.

ADDRESSES: The meeting will be held by conference call. The call-in number and passcode will be provided by email to registrants. Requests to register (including to speak or for auxiliary aids) and any written comments should be submitted to: U.S. Manufacturing Council, U.S. Department of Commerce, Room 4043, 1401 Constitution Avenue NW., Washington, DC, 20230, *archana.sahgal@trade.gov*. Members of the public are encouraged to submit registration requests and written comments via email to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT: Archana Sahgal, the United States Manufacturing Council, Room 4043, 1401 Constitution Avenue NW., Washington, DC, 20230, telephone: 202–482–4501, email: *archana.sahgal@trade.gov*.

SUPPLEMENTARY INFORMATION:

Background: The Council advises the Secretary of Commerce on matters relating to the U.S. manufacturing industry.

Public Participation: The meeting will be open to the public and will be accessible to people with disabilities. All guests are required to register in advance by the deadline identified under the DATES caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted, but may be impossible to fill. There will be fifteen (15) minutes allotted for oral comments from members of the public joining the call. To accommodate as many speakers as possible, the time for public comments may be limited to three (3) minutes per person. Individuals wishing to reserve speaking time during the meeting must submit a request at the time of registration along with a brief statement of the general nature of the comments, as well as the name and address of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. on Wednesday, August 5, 2015, for inclusion in the meeting records and for circulation to the members of the Manufacturing Council.

In addition, any member of the public may submit pertinent written comments concerning the Council's affairs at any time before or after the meeting. Comments may be submitted to Archana Sahgal at the contact information indicated above. To be considered during the meeting, comments must be received no later than 5:00 p.m. EDT on August 15, 2015, to ensure transmission to the Council prior to the meeting. Comments received after that date and time will be distributed to the members but may not be considered on the call. Copies of Council meeting minutes will be available within 90 days of the meeting.

Dated: July 29, 2015.

Archana Sahgal,

Executive Secretary, United States Manufacturing Council.

[FR Doc. 2015–19034 Filed 8–3–15; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

Environmental Technologies Trade Advisory Committee Public Meeting

AGENCY: International Trade Administration, DOC.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a meeting of the Environmental Technologies Trade Advisory Committee (ETTAC).

DATES: The meeting is scheduled for Tuesday, September 1, 2015, at 8:30 a.m. Eastern Daylight Time (EDT).

ADDRESSES: The meeting will be held in Room 1414 at the U.S. Department of Commerce, Herbert Clark Hoover Building, 1401 Constitution Avenue NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Kreps, Office of Energy & Environmental Industries (OEEI), International Trade Administration, Room 4053, 1401 Constitution Avenue NW., Washington, DC 20230 (*Phone:* 202–482–3835; *Fax:* 202–482–3835; *email: amy.kreps@trade.gov*.) This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to OEEI at (202) 482–5225 no less than one week prior to the meeting.

SUPPLEMENTARY INFORMATION: The meeting will take place from 8:30 a.m. to 3:30 p.m. EDT. The general meeting is open to the public and time will be permitted for public comment from 3:00–3:30 p.m. EDT. Those interested in attending must provide notification by Friday, August 21, 2015 at 5:00 p.m. EDT, via the contact information provided above. Written comments concerning ETTAC affairs are welcome any time before or after the meeting. Minutes will be available within 30 days of this meeting.

Topics to be considered: The agenda for this meeting will include discussion of priorities and objectives for the committee, trade promotion programs within the International Trade Administration, and subcommittee working meetings.

Background: The ETTAC is mandated by Public Law 103–392. It was created to advise the U.S. government on environmental trade policies and programs, and to help it to focus its resources on increasing the exports of the U.S. environmental industry. ETTAC operates as an advisory committee to the Secretary of Commerce

and the Trade Promotion Coordinating Committee (TPCC). ETTAC was originally chartered in May of 1994. It was most recently re-chartered until August 2016.

Edward A. O'Malley,

Office Director, Office of Energy and Environmental Industries.

[FR Doc. 2015–19089 Filed 8–3–15; 8:45 am]

BILLING CODE 3510–Dr–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Proposed Information Collection; Comment Request; National Voluntary Laboratory Accreditation Program (NVLAP) Information Collection System

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before October 5, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *jjessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to the attention of Vanda R. White, National Voluntary Laboratory Accreditation Program, National Institute of Standards and Technology, 100 Bureau Drive, Stop 2140, Gaithersburg, MD 20899–2140; phone: (301) 975–3592; email: *vanda.white@nist.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request to extend the expiration date of this currently approved information collection.

This information is collected from all testing or calibration laboratories that apply for NVLAP accreditation. Applicants provide the minimum information necessary for NVLAP to evaluate the competency of laboratories to carry out specific tests or calibrations or types of tests or calibrations. The collection is mandated by 15 CFR 285.

II. Method of Collection

Each new or renewal applicant laboratory electronically submits its application for NVLAP accreditation through a self-service, web-based portal called the ''NVLAP Interactive Web System'' (NIWS). This method of collection also gives applicant laboratories the ability to upload document files needed to support the application process and to maintain their own profile information.

III. Data

OMB Control Number: 0693–0003.

Form Number: None.

Type of Review: Regular submission (revision and extension of a currently approved information collection).

Affected Public: Business or other for-profit organizations; not-for-profit institutions; and Federal, State or local government.

Estimated Number of Respondents: 800.

Estimated Time per Response: 3.0 hours.

Estimated Total Annual Burden Hours: 2400.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: July 29, 2015.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2015–19010 Filed 8–3–15; 8:45 am]

BILLING CODE 3510–13–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Proposed Information Collection Activities To Be Submitted to the Office of Management and Budget (OMB); Request for Comments; Annual Representations and Certification Form

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Submission for Office of Management and Budget (OMB) Review; request for comments.

SUMMARY: Committee for Purchase From People Who Are Blind or Severely Disabled (Committee) is submitting to OMB for their review the collection of the Annual Representations and Certification Form as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The agency's 60-day notice informing the public of the intent to replace the existing annual certifications (Committee forms 403 and 404) with the Representations and Certifications form was published in the **Federal Register** of May 15, 2015, in FR Doc. 2015–11754, on page 27930.

DATES: Interested persons are invited to submit comments about the collection on or before August 31, 2015.

ADDRESSES: Comments may be submitted, identified by the title of the information collection activity, to the Office of Information and Regulatory Affairs, ATTN: Ms. Jasmeet K. Seehra, OMB Desk Officer, by any of the following two methods within 30 days from the date of publication in the **Federal Register**: (1) FAX to: (202) 395–6974, ATTN: Ms. Jasmeet K. Seehra, OMB Desk Office; (2) Electronically by email to: *Jasmeet_K._Seehra@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for copies of documents pertaining to the collection should be addressed to Committee for Purchase From People Who Are Blind or Severely Disabled, ATTN: Louis Bartalot, Director of Compliance, 1401 S. Clark Street, Suite 715, Arlington, VA 22202–4149 or emailed to *rulescomment@abilityone.gov.*

SUPPLEMENTARY INFORMATION: The Committee has two annual certification forms, one for nonprofit agencies serving people who are blind (Committee Form 403, OMB Control Number 3037–0001) and one for nonprofit agencies primarily serving people who have other severe disabilities (Committee Form 404, OMB

Control Number 3037–0002). The information included on the forms is required to ensure that nonprofit agencies that participate in the Committee's Program meet the requirements of the Javits-Wagner-O'Day Act (JWOD), 41 U.S.C. 8105–8506. The Committee intends to combine the two current forms in a revised and expanded format, so that the Committee can continue to verify the appropriateness of nonprofit agencies that would like to participate in the AbilityOne Program.

In response to the agency's 60-day notice published in the **Federal Register** of May 15, 2015, in FR Doc. 2015–11754, on page 27930 (informing the public of the intent to revise and expand the current forms), a comment was received with concerns of the ability of board members to be able to certify the information being on the form, objecting to the use of the term competitive placements, objecting to the reference to 2 CFR part 230, and the accuracy of the burden estimate.

Title: Annual Representations and Certifications For AbilityOne Qualified Nonprofit Agency.

OMB Control Number: 3037–0013.

Form Number: Reps and Certs.

Description of Respondents: Nonprofit agencies serving people who are blind or significantly disabled that participate in the AbilityOne Program.

Annual Number of Respondents: About 570 nonprofit agencies serving people who are blind or significantly disabled will annually participate in the AbilityOne Program.

Total Annual Burden Hours: Burden is estimated to average 8 hours per respondent. Total annual burden is 4,560 hours. Note: this burden estimate is only for the reporting of information; a separate burden estimate exists for the recordkeeping requirement.

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2015–18852 Filed 8–3–15; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the procurement list.

SUMMARY: This action adds products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Effective Date:* 8/31/2015.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 6/6/2014 (79 FR 32716–32718); 5/8/2015 (80 FR 26548–26549); 6/5/2015 (80 FR 32096–32097); and 6/19/2015 (80 FR 35320–35321), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and services and impact of the additions on the current or most recent contractors, the Committee has determined that the products and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. The action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products and services are added to the Procurement List:

Products

NSN(s)—Product Names(s):

5340–00–NIB–0160—Safety Padlock, Red, 1.5″ Shackle

5340–00–NIB–0162—Hasp, Steel with Tabs, 1″

5340–00–NIB–0220—6 Lockout Padlocks, Nylon, Red

Distribution: A-List

5340–00–NIB–0163—Large Plug Lockout with Label

5340–00–NIB–0164—Small Plug Lockout with Label

5340–00–NIB–0166—Gate Valve Lockout, 1″ to 2–1/2″

5340–00–NIB–0169—Gate Valve Lockout, 2–1/2″ to 5″

5340–00–NIB–0183—Wall Switch Lockout

5340–00–NIB–0204—Universal Single Circuit Breaker Lockout

5340–00–NIB–0205—Universal Multi-pole Circuit Breaker Lockout

5340–00–NIB–0208—Hasp, 1.5″ Steel with Tabs

5340–00–NIB–0213—Cable/Valve/Hasp Lockout Device

5340–00–NIB–0221—3 Lockout Padlocks, Nylon, Red

Distribution: B-List

Mandatory Source of Supply: Association for the Blind and Visually Impaired—Goodwill Industries of Greater Rochester, Rochester, NY

Mandatory Purchase For: Total Government Requirement

Contracting Activity: Defense Logistics Agency Troop Support, Philadelphia, PA

NSN(s)—Product Names(s):

6135–00–900–2139—9V Alkaline non-rechargeable battery

6135–01–301–8776—3.6V Lithium AA non-rechargeable battery

Mandatory Source of Supply: Eastern Carolina Vocational Center, Inc., Greenville, NC

Mandatory Purchase For: Total Government Requirement

Contracting Activity: Defense Logistics Agency Land and Maritime, Columbus, OH

Distribution: A-List

Services

Service Type: Healthcare Housekeeping and Related Service

Service is Mandatory For: U.S. Army, Reynolds Army Community Hospital & Multiple Medical Treatment Facilities, Fort Sill, OK

Mandatory Source of Supply: Professional Contract Services, Inc., Austin, TX

Contracting Activity: Dept of the Army, W40M USA MEDCOM HCAA JBSA, Fort Sam Houston, TX

Service Type: Base Supply Center Service

Service is Mandatory For: U.S. Air Force, Tyndall Air Force Base, FL

Mandatory Source of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC

Contracting Activity: Dept of the Air Force, FA4819 325TH Contracting SQ, Tyndall AFB, FL

Service Type: Janitorial Service

Service is Mandatory For: Department of Energy, Western Area Power Administration, Sioux Falls Field Office, Brandon, SD

Mandatory Source of Supply: South Dakota

Achieve, Sioux Falls, ID
Contracting Activity: Department Of Energy, Western-Upper Great Plains Region, Billings, MT

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2015–18850 Filed 8–3–15; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the procurement list.

SUMMARY: The Committee is proposing to add products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products previously furnished by such agency.

Comments Must Be Received on or Before: 8/31/2015.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

For Further Information or To Submit Comments Contact: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following products and services are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Products

NSN(s)—Product Names(s):
MR 10681—Bib, Baby, Halloween
MR 10683—Socks, Halloween
MR 10684—Gloves, Halloween
MR 10685—Party Favors, Halloween, Spiders and Webs
MR 10686—Party Favors, Halloween, Witch's Fingers
MR 10687—Party Favors, Halloween, Nose and Glasses
MR 10688—Party Favors, Halloween, Fangs
MR 10689—Party Favors, Halloween, Mini Spiral Note Book
MR 10690—Party Favors, Halloween, Sticky Eyes
Mandatory Source of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC
Mandatory Purchase For: Military commissaries and exchanges in accordance with the Code of Federal Regulations, Chapter 51, 51–6.4.
Contracting Activity: Defense Commissary Agency, Fort Lee, VA
Distribution: C-List

Services

Service Type: Removal/Clean-up Bird Dropping Service
Service is Mandatory For: Defense Logistics Agency, Defense Supply Center Richmond, 8000 Jefferson Davis Highway, Richmond, VA
Mandatory Source of Supply: Richmond Area Association for Retarded Citizens, Richmond, VA
Contracting Activity: Defense Logistics Agency, DLA Contracting Services Office, Richmond, VA

Service Type: Janitorial and Related Service
Service is Mandatory For: U.S. Customs and Border Protection, 1 La Puntilla Street, San Juan, PR
Mandatory Source of Supply: The Corporate Source, Inc., New York, NY
Contracting Activity: U.S. Customs and Border Protection, Border Enforcement Contracting Division

Deletions

The following products are proposed for deletion from the Procurement List:

Products

NSN(s)—Product Names(s):
8440–00–205–2509—Belt, General Officers, Leather, Army, Black, 44
8440–00–205–2510—Belt, General Officers, Leather, Army, Black, 28
8440–00–205–2511—Belt, General Officers, Leather, Army, Black, 29
8440–00–205–2512—Belt, General Officers, Leather, Army, Black, 30
8440–00–205–2513—Belt, General Officers, Leather, Army, Black, 31
8440–00–205–2514—Belt, General Officers, Leather, Army, Black, 32
8440–00–205–2515—Belt, General Officers, Leather, Army, Black, 33
8440–00–205–2516—Belt, General Officers, Leather, Army, Black, 34
8440–00–205–2517—Belt, General Officers, Leather, Army, Black, 35
8440–00–205–2518—Belt, General Officers, Leather, Army, Black, 36
8440–00–205–2519—Belt, General Officers, Leather, Army, Black, 37
8440–00–205–2520—Belt, General Officers, Leather, Army, Black, 38
8440–00–205–2521—Belt, General Officers, Leather, Army, Black, 39
8440–00–205–2522—Belt, General Officers, Leather, Army, Black, 40
8440–00–205–2523—Belt, General Officers, Leather, Army, Black, 41
8440–00–205–2524—Belt, General Officers, Leather, Army, Black, 42
8440–00–205–2525—Belt, General Officers, Leather, Army, Black, 43
Mandatory Source of Supply: Stone Belt ARC, Inc., Bloomington, IN
Contracting Activity: Defense Logistics Agency Troop Support, Philadelphia, PA

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2015–18851 Filed 8–3–15; 8:45 am]

BILLING CODE 6353–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2015–0018]

Petition for Classification of Vacuum Diffusion Technology as an Anti-Entrapment System Under the Virginia Graeme Baker Pool and Spa Safety Act

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: Paul C. McKain, Chief Executive Officer of PSD Industries, LLC, (''Petitioner''), requests that the Commission initiate rulemaking to determine that Vacuum Diffusion Technology is an anti-entrapment system under the Virginia Graeme Baker Pool and Spa Safety Act (''VGBA''). The Commission invites written comments concerning the petition.

DATES: The Office of the Secretary must receive comments on the petition by October 5, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2015–0018, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov.* Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through *www.regulations.gov.* The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions in the following way: mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All

comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: *http://www.regulations.gov,* and insert the docket number, CPSC–2015–0018, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Rocky Hammond, Office of the Secretary, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD, 20814; telephone (301) 504–6833, email: *rhammond@cpsc.gov.*

SUPPLEMENTARY INFORMATION: Section 1404(c)(1)(A)(ii) of the VGBA requires that each public pool and spa in the United States with a single main drain other than an unblockable drain be equipped, at a minimum, with one or more of the following anti-entrapment devices or systems: (I) Safety vacuum release system; (II) Suction-limiting vent system; (III) Gravity drainage system; (IV) Automatic pump shut-off system; (V) Drain disablement; or (VI) any other system determined by the Commission to be equally effective as, or better than, these systems at preventing or eliminating the risk of injury or death associated with pool drainage systems. 15 U.S.C. 8003(c)(1)(A)(ii). Petitioner submitted a petition to the Commission dated June 11, 2015, to initiate rulemaking to determine that the VDT is an anti-entrapment device or system under the VGBA. To include the VDT in the list of anti-entrapment devices or systems in the VGBA, the Commission must determine that the VDT is ''equally effective as, or better than'' the anti-entrapment devices and systems listed in section 1404(c)(1)(A)(ii) of the VGBA at preventing or eliminating the risk of injury or death associated with pool drainage systems.

Petitioner asserts that VDT can help prevent risks of entrapment as a backup layer of protection and serves the same purpose as a safety vacuum release system (''SVRS''). Petitioner defines VDT as ''a system that removes the intense vacuum draw from the intake point of a pumping system by occluding the intake orifice from swimmers and diffusing the vacuum from a potential blockage immediately in multiple directions from the blockage.'' According to Petitioner, ''covering 50% of the Vacuum Diffusion Technology intake device should not raise the normal vacuum draw by more than .4'' Hg.''

Petitioner states that changing technology necessitates new anti-entrapment safety technology. Petitioner provides that some states have mandated the use of variable speed pumps in pools, and, according to Petitioner, SVRSs do not function on variable speed pumps. Petitioner asserts that technicians have learned to bypass SVRSs.

Petitioner states that VDT is only effective when the drain cover is missing and acknowledges that VDT does not protect against full-body entrapment. Petitioner asserts, however, that the devices and systems listed in the VGBA have limitations, and that VDT protects against limb, hair, and mechanical entrapment and mitigates evisceration.

By this notice, the Commission seeks comments concerning this petition to classify VDT as an anti-entrapment system or device under the VGBA. Interested parties may obtain a copy of the petition by writing or calling the Office of the Secretary, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; telephone (301) 504–6833. The petition is also available at: *http://www.regulations.gov* under Docket No. CPSC–2015–XXXX, Supporting and Related Materials.

Dated: July 30, 2015.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2015–19076 Filed 8–3–15; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday August 12, 2015, 9 a.m.–11 a.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East-West Highway, Bethesda, Maryland.

STATUS: Commission Meeting—Open to the Public

MATTER TO BE CONSIDERED: Decisional Meeting: Electronic Filing of Certificates of Compliance—Pilot Program—Federal Register Notice

A live webcast of the Meeting can be viewed at *www.cpsc.gov/live.*

For a recorded message containing the latest agenda information, call (301) 504–7948.

CONTACT PERSON FOR MORE INFORMATION: Todd A. Stevenson, Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, (301) 504–7923.

Dated: July 30, 2015.

Todd A. Stevenson,

Secretariat.

[FR Doc. 2015–19175 Filed 7–31–15; 4:15 pm]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Health Board; Notice of Federal Advisory Committee Meeting

AGENCY: Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Department of Defense is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Health Board will take place.

DATES:

Thursday, August 20, 2015

9:00 a.m.–12:00 p.m. (Open Session)
12:00 p.m.–1:00 p.m. (Administrative Working Meeting)
1:00 p.m.–5:30 p.m. (Open Session)

ADDRESSES: Defense Health Headquarters (DHHQ), Pavilion Salons B–C, 7700 Arlington Blvd., Falls Church, Virginia 22042 (escort required; see guidance in **SUPPLEMENTARY INFORMATION**, ''Public's Accessibility to the Meeting'').

FOR FURTHER INFORMATION CONTACT: The Executive Director of the Defense Health Board is Ms. Christine Bader, 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042, (703) 681–6653, Fax: (703) 681–9539, *christine.e.bader.civ@mail.mil.* For meeting information, please contact Ms. Kendal Brown, 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042, *kendal.l.brown2.ctr@mail.mil,* (703) 681–6670, Fax: (703) 681–9539.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150, and in accordance

with section 10(a)(2) of the Federal Advisory Committee Act.

Additional information, including the agenda and electronic registration, is available at the DHB Web site, *http://www.health.mil/About-MHS/Other-MHS-Organizations/Defense-Health-Board/Meetings*.

Purpose of the Meeting

The purpose of the meeting is to conduct a decision briefing for deliberation and provide progress updates on specific taskings before the DHB. In addition, the DHB will receive information briefings on current issues or lessons learned related to military operational programs, health policy, health research, disease/injury prevention, health promotion, and healthcare delivery.

Agenda

Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165 and subject to availability of space, the DHB meeting is open to the public from 9:00 a.m. to 12:00 p.m. and 1:00 p.m. to 5:30 p.m. on August 20, 2015. The DHB anticipates deliberating a decision briefing regarding Continuing Education for DoD Health Professionals. The DHB also anticipates receiving a progress update from the Neuro/Behavioral Health Subcommittee on Population Normative Values for Post-Concussive Computerized Neurocognitive Assessments. In addition, information briefings will be provided on activities at the U.S. Army Medical Research Institute of Infectious Diseases and the Walter Reed Army Institute of Research, vector control in support of military operations, missions and accomplishments of U.S. Navy hospital ships, and the U.S. Navy medical response to the tsunami in Indonesia.

Public's Accessibility to the Meeting

Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165 and subject to availability of space, this meeting is open to the public. Seating is limited and is on a first-come basis. All members of the public who wish to attend the public meeting must contact Ms. Kendal Brown at the number listed in the section **FOR FURTHER INFORMATION CONTACT** no later than 12:00 p.m. on Wednesday, August 12, 2015 to register and make arrangements for a DHHQ escort, if necessary. Public attendees requiring escort should arrive at the DHHQ Visitor's Entrance with sufficient time to complete security screening no later than 8:30 a.m. on August 20. To complete security screening, please come prepared to present two forms of identification and one must be a picture identification card.

Special Accommodations

Individuals requiring special accommodations to access the public meeting should contact Ms. Kendal Brown at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Written Statements

Any member of the public wishing to provide comments to the DHB may do so in accordance with 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act, and the procedures described in this notice.

Individuals desiring to provide comments to the DHB may do so by submitting a written statement to the DHB Designated Federal Officer (DFO) (see **FOR FURTHER INFORMATION CONTACT**). Written statements should not be longer than two type-written pages and address the following details: the issue, discussion, and a recommended course of action. Supporting documentation may also be included, as needed, to establish the appropriate historical context and to provide any necessary background information.

If the written statement is not received at least five (5) business days prior to the meeting, the DFO may choose to postpone consideration of the statement until the next open meeting.

The DFO will review all timely submissions with the DHB President and ensure they are provided to members of the DHB before the meeting that is subject to this notice. After reviewing the written comments, the President and the DFO may choose to invite the submitter to orally present their issue during an open portion of this meeting or at a future meeting. The DFO, in consultation with the DHB President, may allot time for members of the public to present their issues for review and discussion by the Defense Health Board.

Dated: July 29, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–18981 Filed 8–3–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Record of Decision for the Final Environmental Impact Statement/Overseas Environmental Impact Statement for Mariana Islands Training and Testing

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy (DoN), after carefully weighing the strategic, operational, and environmental consequences of the proposed action, announces its decision to implement Alternative 1, the Navy's preferred alternative, as described in the Mariana Islands Training and Testing (MITT) Final Environmental Impact Statement/Overseas Environmental Impact Statement (EIS/OEIS). Under Alternative 1, the Navy will be able to meet current and future DoN and DoD training and testing requirements, including the use of active sonar and explosives within the MITT Study Area. The MITT study area is composed of established sea-based (at-sea) ranges and land-based training areas on Guam and the Commonwealth of the Mariana Islands, and operating areas and special use airspace in the regions of the Mariana Islands that are part of the Mariana Islands Range Complex (MIRC). The Study Area also includes a transit corridor that connects the MIRC and the Hawaiian Islands Range Complex and pierside sonar maintenance and testing alongside Navy piers located in Inner Apra Harbor.

SUPPLEMENTARY INFORMATION: The complete text of the Record of Decision is available at *https://mitt-eis.com*. Single copies of the Record of Decision are available upon request by contacting: MITT EIS/OEIS Project Manager, Naval Facilities Engineering Command Pacific, 258 Makalapa Drive, Suite 100, Pearl Harbor, HI 96860–3134.

Dated: July 29, 2015.

N.A. Hagerty-Ford,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2015–19050 Filed 8–3–15; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0071]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Evaluation of the Pell Grant Experiments Under the Experimental Sites Initiative

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before September 3, 2015.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2015–ICCD–0071. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E103, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Daphne Garcia, 202–219–2024.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Evaluation of the Pell Grant Experiments Under the Experimental Sites Initiative.

OMB Control Number: 1850–0892.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 3,202.

Total Estimated Number of Annual Burden Hours: 1,066.

Abstract: The Pell Grant Experiments evaluation is a two-part, seven-year demonstration study sponsored by the U.S. Department of Education that focuses on the effects of expanded access to Pell grants on students' educational outcomes, employment and earnings. The primary outcome of interest is (1) educational enrollment and completion, and (2) measures of student debt and financial aid while secondary outcomes include (3) the employment status and earnings of students who participate in the study.

This study consists of two experiments, each of which will examine the impact of a single change to the Pell grant eligibility criteria. The first experiment will relax the prohibition on receipt of Pell grants by students with a bachelors' degree. Individuals eligible for the first experiment must have a bachelor's degree, be unemployed or underemployed, and pursue a vocational training program up to one year in duration. The second experiment will reduce the minimum duration and intensity levels of programs that Pell grant recipients must participate in from 15 weeks with 600 minimum clock hours to 8 weeks with 150 minimum clock hours. Each experiment will operate through a set of PGE schools that provide education and training services that qualify as PGE programs.

Participants in both experiments will be randomly assigned to either (1) a treatment group, which will have expanded access to Pell grants; or (2) a control group, which will not have access. Within both experiments, the treatment group will be very similar to the control at the time of random assignment except for access to Pell grants. Subsequent differences in the employment and earnings outcomes between treatment and control group members can then be attributed to Pell grant access. The first experiment will involve roughly 28 PGE schools with an average of 25 students participating per school. The second experiment will involve roughly 40 PGE schools with an average of 100 participating students per school. The expected sample of both experiments combined is approximately 4,700 students. Data for this evaluation will come from participants' FAFSA applications, PGE school administrative records, and SSA earnings statements. The study participant enrollment period is expected to last from November 2012 to June 2016. A data extracts from FAFSA applications will occur in summer 2015, 2017, and 2018. Administrative data extracts from PGE schools will also occur summer 2015, 2017, and 2018.

Dated: July 30, 2015.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015–19048 Filed 8–3–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2014–ICCD–0154]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Evaluation of the Pell Grant Experiments Under the Experimental Sites Initiative

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before September 3, 2015.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by

searching the Docket ID number ED–2014–ICCD–0154. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E103, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Sara Starke, 202–502–7688.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: International Resource Information System (IRIS).

OMB Control Number: 1850–0892.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals or Households, Private Sector, Federal Government.

Total Estimated Number of Annual Responses: 6,596.

Total Estimated Number of Annual Burden Hours: 35,712.

Abstract: The International Resource Information System (IRIS) is an online performance reporting system for International and Foreign Language Education (IFLE) grantees. IFLE grantees are institutions of higher education, organizations and individuals funded under Title VI of the Higher Education Act of 1965, as amended (HEA) and/or the Mutual Educational and Cultural Exchange Act (Fulbright-Hays Act). Grantees under these programs enter budget and performance measure data for interim, annual and final performance reports via IRIS, as well as submit International Travel Approval Requests and Grant Activation Request. IRIS also includes a public Web site that helps disseminate information about IFLE programs.

Dated: July 29, 2015.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015–19019 Filed 8–3–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Basic Energy Sciences Advisory Committee

AGENCY: Department of Energy, Office of Science.

ACTION: Notice of Renewal.

SUMMARY: Pursuant to Section 14(a)(2)(A) of the Federal Advisory Committee Act, App. 2, and Section 102–3.65(a), Title 41, Code of Federal Regulations, and following consultation with the Committee Management Secretariat, General Services Administration, notice is hereby given that the Basic Energy Sciences Advisory Committee's (BESAC) charter will be renewed for a two-year period.

The Committee will provide advice and recommendations to the Office of Science on the Basic Energy Sciences program.

Additionally, the renewal of the BESAC has been determined to be essential to conduct business of the Department of Energy and to be in the public interest in connection with the performance of duties imposed upon the Department of Energy, by law and agreement. The Committee will continue to operate in accordance with the provisions of the Federal Advisory Committee Act, the rules and regulations in implementation of that Act.

FOR FURTHER INFORMATION CONTACT:

Dr. Harriet Kung at (301) 903–3081.

Issued in Washington DC, on July 29, 2015.

Erica De Vos,

Acting Committee Management Officer.

[FR Doc. 2015–19110 Filed 8–3–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Orders Granting Authority To Import and Export Natural Gas, To Import and Export Liquefied Natural Gas and To Vacate Prior Authorization During June 2015

	FE Docket Nos.
Orion Aviation, Corp	15–51–NG
Orion Aviation, Corp	15–54–LNG
Solensa S.A. de C.V	15–57–LNG
Trans-Peco Pipeline, LLC	15–75–NG
Sandcastle Petroleum Gas & Energy, LLC	15–39–LNG
Venture Global Calcasieu Pass, LLC	15–25–LNG
Cascade Natural Gas Corporation	15–81–NG
Southern California Gas Company	15–82–NG
Hermiston Generating Company, L.P	15–83–NG
SV Global LNG Trading Company, LLC	15–85–LNG
Petrochina International (Canada) Trading LTD	15–87–NG
Gazprom Marketing & Trading USA, Inc	15–23–NG

	FE Docket Nos.
Sabine Pass Liquefaction, LLC	13–30–LNG 13–42–LNG 13–121–LNG
Sithe/Independence Power Partners, L.P	15–86–NG
Logistic Energy And Petroleum Services, Inc	15–89–LNG
Chevron U.S.A. Inc	15–91–NG

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of orders.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that during June 2015, it issued orders granting authority to import and export natural gas, to import and export liquefied natural gas and to vacate prior authority. These orders are summarized in the attached appendix and may be found on the FE Web site at *http://energy.gov/fe/downloads/listing-doefe-authorizationsorders-issued-2015.*

They are also available for inspection and copying in the Office of Fossil Energy, Office of Oil and Gas Global Security and Supply, Docket Room 3E–033, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478. The Docket Room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on July 29, 2015.

John A. Anderson,

Director, Office of Oil and Gas Global Security and Supply, Office of Oil and Natural Gas.

APPENDIX—DOE/FE ORDERS GRANTING IMPORT/EXPORT AUTHORIZATIONS

Order No.	Date issued	FE Docket No.	Authorization holder	Description of action
3657	06/11/15	15–51–NG	Orion Aviation, Corp	Order granting blanket authority to import natural gas from Canada/Mexico.
3658	06/11/15	15–54–LNG	Orion Aviation, Corp	Order granting blanket authority to import LNG from various international sources by vessel and to export LNG to Canada/Mexico by vessel.
3659	06/11/15	15–57–LNG	Solensa S.A. de C.V	Order granting blanket authority to export LNG to Mexico by truck.
3660	06/11/15	15–75–NG	Trans-Peco Pipeline, LLC	Order granting blanket authority to import/export natural gas from/to Mexico.
3661	06/17/15	15–39–LNG	Sandcastle Petroleum Gas & Energy, LLC.	Order granting blanket authorization to export LNG in ISO Containers loaded on vessels and in LNG vessels to Free Trade Agreement nations.
3662	06/17/15	15–25–LNG	Venture Global Calcasieu Pass, LLC.	Order granting long-term, multi-contract authorization to export LNG by vessel from the proposed Venture Global Calcasieu Pass LNG Project in Cameron Parish, Louisiana to Free Trade Agreement nations.
3663	06/24/15	15–81–NG	Cascade Natural Gas Corporation.	Order granting blanket authority to import natural gas from Canada.
3664	06/24/15	15–82–NG	Southern California Gas Company.	Order granting blanket authority to import/export natural gas from/to Mexico.
3665	06/24/15	15–83–NG	Hermiston Generating Company, L.P.	Order granting blanket authority to import natural gas from Canada.
3666	06/24/15	15–85–LNG	SV Global LNG Trading Company, LLC.	Order granting blanket authority to import LNG from various international sources by vessel.
3667	06/24/15	15–87–NG	PetroChina International (Canada) Trading Ltd.	Order granting blanket authority to import/export natural gas from/to Canada and vacating prior authorization.
3668	06/25/15	15–23–NG	Gazprom Marketing & Trading USA, Inc.	Order granting blanket authority to import/export natural gas from/to Canada/Mexico.
3669	06/26/15	13–30–LNG 13–42–LNG 13–121–LNG	Sabine Pass Liquefaction, LLC.	Final Opinion and Order granting long-term, multi-contract authority to export LNG by vessel from the Sabine Pass LNG Terminal located in Cameron Parish, Louisiana, to Non-Free Trade Agreement nations.
3670	06/25/15	15–86–NG	Sithe/Independence Power Partners, L.P.	Order granting blanket authority to import/export natural gas from/to Canada.
3671	06/25/15	15–89–LNG	Logistic Energy and Petroleum Services Inc.	Order granting blanket authority to import LNG from various international sources by vessel.
3672	06/25/15	15–91–NG	Chevron U.S.A. Inc	Order granting blanket authority to import/export natural gas from/to Canada.

[FR Doc. 2015–19108 Filed 8–3–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC15–11–000]

Commission Information Collection Activities (Ferc–914); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission. DOE.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–914 (Cogeneration and Small Power Production—Tariff Filings).

DATES: Comments on the collection of information are due October 5, 2015.

ADDRESSES: You may submit comments (identified by Docket No. IC15–11–000) by either of the following methods:

- *eFiling at Commission's Web site: http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: FERC–914, Cogeneration and Small Power Production—Tariff Filings.

OMB Control No.: 1902–0231.

Type of Request: Three-year extension of the FERC–914 information collection requirements with no changes to the current reporting requirements.

Abstract: Section 205(c) of the Federal Power Act (FPA) requires that every public utility have all of its jurisdictional rates and tariffs on file with the Commission and make them available for public inspection, within such time and in such form as the Commission may designate. Section 205(d) of the FPA requires that every public utility must provide notice to the Commission and the public of any changes to its jurisdictional rates and tariffs, file such changes with the Commission, and make them available for public inspection, in such manner as directed by the Commission. In addition, FPA section 206 requires the Commission, upon complaint or its own motion, to modify existing rates or services that are found to be unjust, unreasonable, unduly discriminatory or preferential. FPA section 207 requires the Commission upon complaint by a state commission and a finding of insufficient interstate service, to order the rendering of adequate interstate service by public utilities, the rates for which would be filed in accordance with FPA sections 205 and 206.

In Orders Nos. 671 and 671–A,[1] the Commission revised its regulations that govern qualifying small power production and cogeneration facilities. Among other things, the Commission eliminated certain exemptions from rate regulation that were previously available to qualifying facilities (QFs). New qualifying facilities may need to make tariff filings if they do not meet the new exemption requirements.

FERC implemented the Congressional mandate of the Energy Policy Act of 2005 (EPAct 2005) to establish criteria for new qualifying cogeneration facilities by: (1) Amending the exemptions available to qualifying facilities from the FPA and from PUHCA [resulting in the burden imposed by FERC–914, the subject of this statement]; (2) ensuring that these facilities are using their thermal output in a productive and beneficial manner; that the electrical, thermal, chemical and mechanical output of new qualifying cogeneration facilities is used fundamentally for industrial, commercial, residential or industrial purposes; and there is continuing progress in the development of efficient electric energy generating technology; (3) amending the FERC Form 556 [2] to reflect the criteria for new qualifying cogeneration facilities; and (4) eliminating ownership limitations for qualifying cogeneration and small power production facilities. The Commission satisfied the statutory mandate and its continuing obligation to review its policies encouraging cogeneration and small power production, energy conservation, efficient use of facilities and resources by electric utilities, and equitable rates for energy customers.

Type of Respondents: New qualifying facilities and small power producers that do not meet Commission exemption criteria.

Estimate of Annual Burden: [3] The Commission estimates the annual public reporting burden for the information collection as:

FERC–914: COGENERATION AND SMALL POWER PRODUCTION—TARIFF FILINGS

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden and cost per response [4]	Total annual burden hours & total annual cost	Cost per respondent ($)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
FPA Section 205 Filings	35	1	35	183 $13,176	6,405 $461,160	$13,176
Electric Quarterly Reports (initial)	0	0	0	230 $16,560	0 $0	0

[1] *Revised Regulations Governing Small Power Production and Cogeneration Facilities,* Order No. 671, 71 FR 7852 (2/15/2006), FERC Stats. & Regs. ¶ 31,203 (2006); and *Revised Regulations Governing Small Power Production and Cogeneration Facilities,* Order 671–A, 71 FR 30585 (5/30/2006), in Docket No. RM05–36.

[2] The FERC–556 is cleared separately as OMB Control No. 1902–0075 and is not a subject of this notice.

[3] The Commission defines burden as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 Code of Federal Regulations 1320.3.

FERC–914: COGENERATION AND SMALL POWER PRODUCTION—TARIFF FILINGS—Continued

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden and cost per response [4] (4)	Total annual burden hours & total annual cost (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
Electric Quarterly Reports (later)	35	4	140	6 $432	840 $60,480	1,728
Change of Status	10	1	10	3 $216	30 $2,160	216
Total			185		7,725 $523,800	$15,120

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: July 24, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19056 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

[4] The estimates for cost per response are derived using the following formula: Average Burden Hours per Response.

* $72.00 per Hour = Average Cost per Response. The hourly cost figure comes from the FERC average salary of $149,489/year.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14447–004]

L.S. Starrett Company; Notice of Application Accepted For Filing, Soliciting Comments, Motions To Intervene, And Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Incorporation of modified 30(c) condition 5 into Appendix A and B of the project exemption order.

b. *Project No:* 14447–004.

c. *Date Filed:* May 28, 2015.

d. *Applicant:* L.S. Starrett Company (exemptee).

e. *Name of Project:* Crescent Street Hydroelectric Project.

f. *Location:* Millers River in the Town of Athol, Worcester County, Massachusetts.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mr. Steve Walsh, L.S. Starrett Company, 121 Crescent Street, Athol, Massachusetts 01331; phone 978–249–3551.

i. *FERC Contact:* Mr. Robert Ballantine at 202–502–6289, *robert.ballantine@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests is 30 days from the issuance of this notice by the Commission. All documents may be filed electronically via the Internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp.* If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and seven copies should be mailed to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. 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.

Please include the project number (P–14447–004) on any comments, motions, or recommendations filed.

k. *Description of Request:* Pursuant to exemption Article 16(d), the exemptee is requesting to amend Appendix A and Appendix B of the Commission's March 1, 2013, Order Granting Exemption From Licensing (5MW or Less) to incorporate a modified condition 5. The appendices contain the mandatory terms and conditions submitted under section 30(c) of the Federal Power Act by the Massachusetts Division of Fisheries and Wildlife (MDFW) and by the U.S. Department of the Interior (Interior). The MDFW and the Interior issued modifications to condition 5 of their terms and conditions and as such, the exemptee is requesting that the Commission amend the exemption order by incorporating the modified terms and conditions. The modification of condition 5 allows the exemptee to operate the project with an approach velocity at the left-side trash rack greater than the 2.0 cubic feet per second as required by the original condition 5, until such time that the MDFW determines that protection for atlantic salmon is necessary. The Interior revision requires additional American eel monitoring during the period of time that the exceedance of the 2.0 cfs approach velocity is allowed.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling 202–502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call 202–502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the

requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS''; ''PROTESTS'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: July 28, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19068 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC15–177–000.

Applicants: DG North Carolina Solar Holding, LLC.

Description: Section 203 Application of DG North Carolina Solar Holding, LLC.

Filed Date: 7/28/15.

Accession Number: 20150728–5214.

Comments Due: 5 p.m. ET 8/18/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–1471–002.

Applicants: Blue Sky West, LLC.

Description: Notice of Change in Status and Request for Confidential Treatment of Blue Sky West, LLC.

Filed Date: 7/29/15.

Accession Number: 20150729–5051.

Comments Due: 5 p.m. ET 8/19/15.

Docket Numbers: ER15–2294–000.

Applicants: Pacific Gas and Electric Company.

Description: Section 205(d) Rate Filing: Transmission Owner Rate Case 2016 (TO17) to be effective 10/1/2015.

Filed Date: 7/29/15.

Accession Number: 20150729–5000.

Comments Due: 5 p.m. ET 8/19/15.

Docket Numbers: ER15–2295–000.

Applicants: Southwest Power Pool, Inc.

Description: Petition of Southwest Power Pool, Inc. For Tariff Waiver.

Filed Date: 7/28/15.

Accession Number: 20150728–5198.

Comments Due: 5 p.m. ET 8/18/15.

Take notice that the Commission received the following land acquisition reports:

Docket Numbers: LA15–2–000.

Applicants: MidAmerican Energy Company.

Description: Quarterly Land Acquisition Report of the MidAmerican Energy Companies.

Filed Date: 7/29/15.

Accession Number: 20150729–5046.

Comments Due: 5 p.m. ET 8/19/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 29, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–19046 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER15–2293–000]

Fair Wind Power Partners, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Fair Wind Power Partners, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 18, 2015.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the

Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 29, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19057 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL15–86–000]

ITC Grid Development LLC; Notice of Petition for Declaratory Order

Take notice that on July 28, 2015, pursuant to rule 207(a) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure and sections 366.3(d) and 366.4(b)(3) of the Commission's regulations, 18 CFR 385.207(a), 366.3(d), and 366.4(b)(3), ITC Grid Development LLC (ITC Grid), filed a petition for declaratory order (petition) seeking a Commission ruling: (1) That binding revenue requirement bids selected as the result of Commission-approved, Order No. 1000-compliant, and demonstrably competitive transmission project selection processes will be deemed just and reasonable when filed at the Commission as a stated rate pursuant to Federal Power Act (FPA) section 205; and (2) that such binding bids are entitled to protection under the *Mobile-Sierra* standard, and may not subsequently be changed by means of a complaint filed under FPA section 206 unless required by the public interest. ITC Grid requests that the Commission rule on this petition within 90 days of when its petition was filed, or by October 26, 2015, in order to facilitate ITC Grid's participation in upcoming competitive project solicitations, as more fully explained in its petition. .

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. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

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 August 27, 2015.

Dated: July 29, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19060 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–523–000]

American Midstream, LLC; Notice of Intent To Prepare an Environmental Assessment for the Proposed Natchez Pipeline Project and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Natchez Pipeline Project involving construction and operation of facilities by American Midstream, LLC (Midla) in Franklin, Catahoula, and Concordia Parishes, Louisiana, and Adams County, Mississippi. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. 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. Your input will help the Commission staff determine what issues they need to evaluate in the EA. 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 August 24, 2015.

If you sent comments on this project to the Commission before the opening of this docket on June 29, 2015, you will need to file those comments in Docket No. CP15–523–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

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 proposed facilities. 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. 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.

Midla provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC Web site (*www.ferc.gov*).

Public Participation

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has expert staff

available to assist you at (202) 502–8258 or *efiling@ferc.gov*. Please carefully follow these instructions so that your comments are properly recorded.

(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 file your comments electronically by 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*.'' If you are filing a comment on a particular project, please select ''Comment on a Filing'' as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (CP15–523–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Summary of the Proposed Project

Midla proposes to construct, own, maintain, and operate the Natchez Pipeline Project consisting of 51.97 miles of 12-inch-diameter pipeline traversing portions of Franklin, Catahoula, and Concordia Parishes, Louisiana and Adams County, Mississippi, pursuant to Section 7(c) of the Natural Gas Act and Section 2.1 of the Stipulation and Agreement (Settlement) approved in Docket Nos. RP14–638, *et al.* on April 16, 2015. The Natchez Pipeline would have three anchor shippers: Atmos Energy Corporation, which serves the cities of Ferriday, Gilbert, and Wisner, Louisiana, and the city of Natchez, Mississippi; the Louisiana Municipal Gas Authority, serving the municipal gas systems of Clayton, Jonesville, Sicily Island, and Vidalia, Louisiana; and BASF, which has an industrial facility located near Vidalia, Louisiana.

As part of the Commission Order of the Settlement, the Commission approved Midla to abandon about 370 miles of varying diameter pipeline along with associated laterals from the Desiard Compressor Station in Ouachita Parish, Louisiana to a point near Scottlandville in East Baton Rogue Parish, Louisiana, either in place, by removal, or by transfer, subject to certain conditions. Among the conditions, Midla would need to continue to serve customers with delivery points from Winnsboro, Louisiana to the Natchez, Mississippi area through the Natchez pipeline, which the Natchez Pipeline Project would accomplish. Once the Natchez pipeline is in service, Midla would be able to abandon its existing pipeline system.

The Natchez Pipeline Project would consist of the following facilities:

- 51.97 miles of 12-inch-diameter pipeline;
- 0.50 mile of 4-inch-diameter delivery lateral at milepost 46.83 in Concordia Parish to serve the City of Vidalia, Louisiana;
- 4 aboveground valve sites;
- 12 meter stations; and
- 2 pig launcher/receivers.[1]

The general location of the project facilities is shown in appendix 1.[2]

Land Requirements for Construction

Construction of the proposed facilities would disturb about 516.55 acres of land for the aboveground facilities and the pipeline, which includes the pipeline permanent right-of-way, temporary workspaces, additional temporary workspaces, above-ground facilities, contractor yards, and access roads. Following construction, Midla would maintain about 193.68 acres for permanent operation of the project's pipeline, aboveground facilities and access roads; the remaining acreage would be restored and revert to former uses. About 41 miles (or 79 percent) of the proposed pipeline route parallels existing pipeline, utility, or road rights-of-way.

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[3] to discover and address concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils;
- land use;
- water resources, fisheries, and wetlands;
- cultural resources;
- vegetation and wildlife;
- air quality and noise;
- endangered and threatened species;
- public safety; and
- cumulative impacts.

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before making our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2.

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.[4] 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 applicable State Historic Preservation Office(s) (SHPO), and to solicit their

[1] A ''pig'' is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

[2] 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.

[3] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

[4] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[5] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPO(s) as the project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Currently Identified Environmental Issues

We have already identified several issues that we think deserve attention based on a preliminary review of the proposed facilities and the environmental information provided by Midla. This preliminary list of issues may be changed based on your comments and our analysis.

- Potential impacts on lands under the Conservation Reserve Program, administered by the U.S. Department of Agriculture;
- potential impacts on the Louisiana black bear; and
- crossing of the Mississippi River.

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 proposed project.

[5] 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.

If we publish and distribute the EA, copies will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the ''Document-less Intervention Guide'' under the ''e-filing'' link on the Commission's Web site. Motions to intervene are more fully described at *http://www.ferc.gov/resources/guides/how-to/intervene.asp.*

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.,* CP15–523). 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: July 24, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19055 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF15–24–000]

WBI Energy Transmission, Inc.; Notice of Intent To Prepare an Environmental Assessment for the Planned Demicks Lake Pipeline Project and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Demicks Lake Pipeline Project (Project) involving construction and operation of facilities by WBI Energy Transmission, Inc (WBI Energy) in McKenzie County, North Dakota. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. 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. Your input will help the Commission staff determine what issues they need to evaluate in the EA. 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 August 27, 2015.

If you sent comments on this project to the Commission before the opening of this docket on May 13, 2015, you will need to file those comments in Docket No. PF15–24–000 to ensure they are considered as part of this proceeding.

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 facilities. 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. 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.

Public Participation

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(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 file your comments electronically by 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.*'' If you are filing a comment on a particular project, please select ''Comment on a Filing'' as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (PF15–24–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Summary of the Planned Project

WBI Energy plans to construct and operate 22.7 miles of 24-inch-diameter natural gas pipeline and appurtenant facilities between a proposed non-jurisdictional gas plant, ONEOK Rockies Midstream LLC's (ONEOK) Demicks Lake Plant, located west of Keene, North Dakota and a tie-in along Northern Border Pipeline Company's (Northern Border) existing mainline located approximately 8 miles southeast of Watford City, North Dakota. The Project would provide approximately 221,500 Mmcf/d (million standard cubic feet per day) of natural gas transportation capacity to Northern Border's mainline, which would transport the gas to the midcontinent region of the United States. The maximum allowable operating pressure of the new pipeline would be 1,650 pounds per square inch gauge.

The Demicks Lake Pipeline Project would consist of the following facilities:

- 22.7 miles of 24-inch-diameter natural gas pipeline;
- a meter station located at milepost (MP) 22.7 at the site of ONEOK's Demicks Lake Plant;
- two pig launcher/receivers at MP 0.0 and MP 22.7; and
- one mid-point block valve located at approximately MP 10.7.

WBI Energy also proposes to construct a 3,300-foot-long, 16- to 24-inch-diameter tie across pipeline between the proposed 24-inch-diameter Demicks Lake pipeline and WBI Energy's existing 16-inch-diameter Garden Creek II pipeline just south of Highway 23. The tie across pipeline facilities would consist of a block valve on both of the Demicks Lake pipeline and the Garden Creek II pipeline, a pig launcher at both ends of the tie across pipeline, and a metering facility at one end of the tie across pipeline.[1]

The general location of the Project facilities is shown in appendix 1.[2]

Land Requirements for Construction

Construction of the planned facilities would disturb about 266 acres of land for the pipeline and aboveground facilities. Following construction, WBI Energy would maintain about 133 acres of land for permanent operation of the Project's facilities; the remaining land would be restored and revert to former uses. About 67 percent of the planned pipeline route parallels existing pipeline, utility, or road rights-of-way.

Non-Jurisdictional Facilities

Construction of ONEOK's proposed Demicks Lake Plant is not subject to FERC jurisdiction. However, in the EA, we will provide available descriptions of the non-jurisdictional facilities and include them under our analysis of cumulative impacts. The plant would be located west of Keene, North Dakota. As proposed, the plant would be constructed on a plot of approximately 160 acres located in the NE ¼ of Section 20, Township 151 North, Range 96 West in McKenzie County. Construction of the plant would include the installation of underground piping, above ground piping, and above ground gas processing facilities.

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[3] 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/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;
- land use;
- water resources, fisheries, and wetlands;
- cultural resources;
- vegetation and wildlife;
- air quality and noise;
- endangered and threatened species;
- public safety; and
- cumulative 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

[1] The decision to construct the tie across pipeline and associated facilities is still under review by WBI Energy and is not shown on Project maps.

[2] 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.

[3] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

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 EA.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Directions for use of eLibrary are provided on page 6 under Additional Information. 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 we make our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2.

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 EA.[4] 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 applicable State Historic Preservation Office(s), 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.[5] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPO(s) as the project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

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 EA 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

Once WBI Energy 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.,* PF15–24). 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: July 28, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19069 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01P

[4] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[5] 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.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL14–22–000]

California Independent System Operator Corporation; Notice of Filing

Take notice that on July 23, 2015, California Independent System Operator Corporation filed a compliance filing in response to the Federal Energy Regulatory Commission's March 20, 2014 Order to Show Cause.[1]

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

[1] *Posting of Offers to Purchase Capacity,* Order to Show Cause, 146 FERC ¶ 61,203 (2014).

serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 18, 2015.

Dated: July 28, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19062 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD15–31–000]

Town of Grand Lake, Colorado; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On July 16, 2015, the Town of Grand Lake, Colorado, filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA), as amended by section 4 of the Hydropower Regulatory Efficiency Act of 2013 (HREA). The proposed Grand Lake WTP Hydro Project would have an installed capacity of 20 kilowatts (kW), and would be located along an existing 12-inch-diameter raw water pipeline within the city's water treatment plant. The project would be located in the Town of Grand Lake, Colorado.

Applicant Contact: Jim White, Town Manager, P.O. Box 99, Grand Lake, CO, Phone No. (970) 627–3435.

FERC Contact: Christopher Chaney, Phone No. (202) 502–6778, email: *christopher.chaney@ferc.gov*.

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) An approximately 360-square-foot powerhouse within the existing water treatment plant building; (2) a short intake receiving water from the existing 12-inch-diameter raw water pipeline; (3) one turbine/generator unit with an installed capacity of 20 kW; (4) a short discharge returning water to the existing 12-inch-diameter raw water pipeline; and (5) appurtenant facilities.

The proposed project would have a total installed capacity of 20 kW.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all of the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A), as amended by HREA	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity	Y
FPA 30(a)(3)(C)(i), as amended by HREA	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit	Y
FPA 30(a)(3)(C)(ii), as amended by HREA	The facility has an installed capacity that does not exceed 5 megawatts	Y
FPA 30(a)(3)(C)(iii), as amended by HREA	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA	Y

Preliminary Determination: Based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 45 days from the issuance date of this notice.

Deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the ''COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY'' or ''MOTION TO INTERVENE,'' as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments 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

[1] 18 CFR 385.2001–2005 (2014).

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. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Locations of Notice of Intent: Copies of the notice of intent can be obtained directly from the applicant or such copies can be viewed and reproduced at the Commission in its Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the ''eLibrary'' link. Enter the docket number (*i.e.,* CD15–31) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

Dated: July 24, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19054 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL14–26–000]

New York Independent System Operator, Inc.; Notice of Filing

Take notice that on July 23, 2015, New York Independent System Operator, Inc. filed a compliance filing in response to the Federal Energy Regulatory Commission's (Commission) March 20, 2014 Order to Show Cause.[1]

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 18, 2015.

Dated: July 28, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19064 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–531–000]

Columbia Gas Transmission, LLC; Notice of Application

Take notice that on July 14, 2015, Columbia Gas Transmission, LLC (Columbia), 5151 San Felipe, Suite 2500, Houston, TX 77056, filed in Docket No. CP15–531–000, an application pursuant to section 7(b) of the Natural Gas Act and Part 157 of the Commission's regulations, seeking authorization to abandon by sale certain natural gas facilities located in various Counties in Ohio to Columbia Gas of Ohio. The facilities consist of 13.1 miles of pipeline, 594 measuring stations, 35 mainline consumer taps and appurtenances. In addition, Columbia further request that the Commission find that following abandonment by sale, the facilities will perform distribution activities and thus be exempt from the Commission's jurisdiction pursuant to Section 1(b) of the NGA, all as more fully set forth in the application, which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding this application should be directed to Tyler R. Brown, Senior Counsel, Columbia Gas Transmission, LLC, 5151 San Felipe, Suite 2500, Houston, TX 77056, phone: (713) 386–3797 or email: *tbrown@cpg.com.*

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 7 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in

[1] *Posting of Offers to Purchase Capacity,* Order to Show Cause, 146 FERC ¶ 61,203 (2014).

the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, 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.

Comment Date: 5:00 p.m. Eastern Time on August 18, 2015.

Dated: July 28, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19061 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–91–000]

East Tennessee Natural Gas, LLC; Supplemental Notice of Intent To Prepare an Environmental Assessment for the Proposed Loudon Expansion Project and Request for Comments on Environmental Issues

On March 24, 2015, the Federal Energy Regulatory Commission (FERC or Commission) issued in Docket No. CP15–91–000 a *Notice of Intent to Prepare an Environmental Assessment for the Proposed Loudon Expansion Project and Request for Comments on Environmental Issues* (NOI). In response to scoping comments and data requested by FERC staff, East Tennessee Natural Gas, LLC (East Tennessee) has developed Route G–1 as its new proposed route for the above-referenced project in Monroe and Loudon Counties, Tennessee. FERC staff is further evaluating Alternative Route B as described in East Tennessee's February 20, 2015 filing, the Eastside Alternate Route as described in its May 8, 2015 filing, Alternate Route G as described in its July 10, 2015 filing, as well as the originally proposed route (Route F). This Supplemental Notice is being issued to seek comments on the new Proposed Route G–1 and the alternatives mentioned above, and opens a new scoping period for interested parties to file comments on environmental issues specific to these routes.

The March 24, 2015 NOI announced that the FERC staff will prepare an environmental assessment (EA) to address the environmental impacts of the Loudon Expansion Project (Project). Please refer to the NOI for more information about the overall facilities proposed by East Tennessee in Tennessee, and FERC staff's EA process. The Commission will use the EA in its decision-making process to determine whether the Project is in the public convenience and necessity.

We [1] are now specifically seeking comments on the new Proposed Route G–1, Alternate Route B, Alternate Route G, and the Eastside Alternate Route to help the Commission staff evaluates all potential environmental impacts. Please note that this supplemental scoping period will close on August 27, 2015.

This Supplemental Notice is being sent to the Commission's current environmental mailing list for this Project, including landowners along the originally proposed route (Route F) and new landowners that would be affected by the new proposed route (Route G–1) or the alternate routes (Alternate Routes B, G, and the Eastside Alternate Route).

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 proposed facilities. 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. Therefore, if the 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.

Public Participation

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission will provide equal consideration to all comments received, whether filed in written form or provided verbally. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(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

[1] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

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.

Summary of the New Proposed Route G–1 and Alternate Routes B, G, and Eastside

Following original Route F until milepost (MP) 1.5, the new Proposed Route G–1 would then turn east, cross under Tennessee State Highway 72 and parallel it until MP 3.1 where it would meet and be collated with East Tennessee's existing Loudon-Lenoir City Lateral pipeline. Alternate Route G and the Eastside Alternate Route would follow similar paths but each route would be located slightly farther east, rejoining and paralleling the Loudon-Lenoir City Lateral pipeline at approximately MP 3.5. All three of these routes would cross Tellico Lake. Alternate Route B would start at the same location as all other routes, but would then proceed west of those routes, avoiding Lake Tellico completely, rejoining and paralleling the Loudon-Lenoir City Lateral pipeline at approximately MP 5.4.

Overview and aerial maps of the previously proposed route, newly proposed route, and the three alternate routes are included in Appendix 1.[2]

Currently Identified Environmental Issues

We have identified several issues that we think deserve attention for our comparison of the new proposed route and three alternatives based on a review of the proposed facilities and the environmental information provided by East Tennessee. This preliminary list of issues may be changed based on your comments and our analysis.

- Waterbodies;
- karst geology, including caves; and
- candidate and listed threatened or endangered species.

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; commenters; and local libraries and newspapers. This list also includes landowners affected by the pipelines as currently proposed, as well as landowners that may be affected by the Kemblesville Loop Alternative Route 2. 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.

Copies of the completed EA 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 a CD version or would like to remove your name from the mailing list, please return the attached Information Request (Appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the User's Guide under the ''e-filing'' link on the Commission's Web site.

Additional Information

Additional information about the Project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*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.,* CP15–91). 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: July 28, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19066 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

[2] The appendices referenced in this notice are not being printed 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.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP15–1135–000.
Applicants: Questar Southern Trails Pipeline Company.
Description: Section 4(d) Rate Filing: Statement of Negotiated Rates Filing to be effective 7/1/2015.
Filed Date: 7/28/15.
Accession Number: 20150728–5091.
Comments Due: 5 p.m. ET 8/10/15.

Docket Numbers: RP15–1136–000.
Applicants: Washington Gas Light Company, Energy Corporation of America.
Description: Petition for Waiver of Washington Gas Light Company and Energy Corporation of America under RP15–1136.
Filed Date: 7/28/15.
Accession Number: 20150728–5103.
Comments Due: 5 p.m. ET 8/5/15.

Docket Numbers: RP15–1137–000.
Applicants: Kern River Gas Transmission Company.
Description: Section 4(d) Rate Filing: 2015 NVE Converted Contracts to be effective 8/1/2015.
Filed Date: 7/28/15.
Accession Number: 20150728–5190.
Comments Due: 5 p.m. ET 8/10/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing

requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 29, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–19047 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC15–5–000]

Commission Information Collection Activities (FERC–552); Comment Request

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Comment request.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(a)(1)(D), the Federal Energy Regulatory Commission (Commission or FERC) is submitting its information collection [FERC–552, Annual Report of Natural Gas Transactions.] to the Office of Management and Budget (OMB) for review of the information collection requirements. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission previously issued a Notice in the **Federal Register** (80 FR 20217, 4/15/2015) requesting public comments. The Commission received no comments on the FERC–552 and is making this notation in its submittal to OMB.

DATES: Comments on the collection of information are due by September 3, 2015.

ADDRESSES: Comments filed with OMB, identified by the OMB Control No. 1902–0242, should be sent via email to the Office of Information and Regulatory Affairs: *oira_submission@omb.gov.* Attention: Federal Energy Regulatory Commission Desk Officer. The Desk Officer may also be reached via telephone at 202–395–4718.

A copy of the comments should also be sent to the Commission, in Docket No. IC15–5–000, by either of the following methods:

- eFiling at Commission's Web site: *http://www.ferc.gov/docs-filing/efiling.asp.*
- Mail/Hand Delivery/Courier: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* by telephone at (202) 502–8663, and by fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: Annual Report of Natural Gas Transactions.

OMB Control No.: 1902–0242.

Type of Request: Three-year extension of the FERC–552 information collection requirements with no changes to the reporting requirements.

Abstract: The Commission uses the information collected within the FERC–552 to provide greater transparency concerning the use of indices to price natural gas and how well index prices reflect market forces. The collection also includes transactions that contribute to, or may contribute to natural gas price indices. Many market participants rely on indices as a way to reference market prices without taking on the risks of active trading.

FERC–552 had its genesis in the Energy Policy Act of 2005,[1] which added section 23 of the Natural Gas Act (NGA). Section 23 of the NGA, among other things, directs the Commission ''to facilitate price transparency in markets for the sale or transportation of physical natural gas in interstate commerce, having due regard for the public interest, the integrity of those markets, and the protection of consumers.'' [2]

Type of Respondents: Wholesale natural gas market participants.

Estimate of Annual Burden: [3] The Commission estimates the annual public reporting burden for the information collection as:

FERC–552—ANNUAL REPORT OF NATURAL GAS TRANSACTIONS

	Number of respondents [6]	Number of responses per respondent	Total number of responses	Average burden hours per response	Estimated total annual burden
	(A)	(B)	(A) × (B) = (C)	(D)	(C) × (D)
Wholesale natural market participants	666	1	666	10	6,660

The total estimated annual cost burden to respondents is $478,652 [6,660 hours ÷ 2,080 [4] hours/year = 3.201923 * $149,489/year [5] = $478,652].

The estimated annual cost of filing the FERC–552 per response is $719 [$478,652 ÷ 666 responses = $719/response].

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use

[1] Pub. L. 109–58.

[2] 15 U.S.C. 717t–2.

[3] The Commission defines burden as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 Code of Federal Regulations 1320.3.

[4] 2080 hours = 40 hours/week * 52 weeks (1 year).

[5] Average annual salary per FERC employee in 2015. We are using FERC cost (salary and benefits) as it fairly reflects an estimate for the industry cost.

[6] Number of respondents as of the 2013 Form 552 survey

of automated collection techniques or other forms of information technology.

Dated: July 28, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19065 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL14–23–000]

ISO New England Inc.; Notice of Filing

Take notice that on July 23, 2015, ISO New England Inc. filed a compliance filing in response to the Federal Energy Regulatory Commission's March 20, 2014 Order to Show Cause.[1]

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 18, 2015.

[1] *Posting of Offers to Purchase Capacity,* Order to Show Cause, 146 FERC ¶ 61,203 (2014).

Dated: July 28, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19063 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice Of Revised Procedural Schedule

	Project Nos.
Clean River Power MR–3, LLC.	P–13404–002
Clean River Power MR–1, LLC.	P–13405–002
Clean River Power MR–5, LLC.	P–13406–002
Clean River Power MR–2, LLC.	P–13407–002
Clean River Power MR–7, LLC.	P–13408–002
Clean River Power MR–6, LLC.	P–13411–002

On October 31, 2012, Clean River Power MR–3, LLC, Clean River Power MR–1, LLC, Clean River Power MR–5, LLC, Clean River Power MR–2, LLC, Clean River Power MR–7, LLC, and Clean River Power MR–6, LLC, filed applications for original licenses to construct, operate, and maintain the 3-megawatt (MW) Beverly Lock and Dam Water Power Project No. 13404, 4–MW Devola Lock and Dam Water Power Project No. 13405, 4–MW Malta/McConnelsville Lock and Dam Water Power Project No. 13406, 5–MW Lowell Lock and Dam Water Power Project No. 13407, 3–MW Philo Lock and Dam Water Power Project No. 13408, and 4–MW Rokeby Lock and Dam Water Power Project No. 13411 (Muskingum River Projects), respectively. On January 14, 2014, the Commission issued a *Notice of Application Ready for Environmental Analysis, and Soliciting Comments, Recommendations, Preliminary Terms and Conditions, and Preliminary Fishway Prescriptions* (REA Notice) for the Muskingum River Projects. The REA Notice included a procedural schedule.

The above applications will be processed according to the following revised procedural schedule.

Milestone	Target date
Issue EA	August 2015.
Comments on EA due	September 2015.

Any questions regarding this notice may be directed to Aaron Liberty at (202) 502–6862, or by email at *aaron.liberty@ferc.gov.*

Dated: July 29, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19059 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–532–000]

Columbia Gas Transmission, LLC; Notice of Application

Take notice that on July 14, 2015, Columbia Gas Transmission, LLC (Columbia), 5151 San Felipe, Suite 2500, Houston, TX 77056, filed in Docket No. CP15–531–000, an application pursuant to section 7(b) of the Natural Gas Act and Part 157 of the Commission's regulations, seeking authorization to abandon by sale certain natural gas facilities located in various Counties in Pennsylvania to Columbia Gas of Pennsylvania. The facilities consist of 3.6 miles of pipeline, 213 measuring stations, 7 mainline consumer taps and appurtenances. In addition, Columbia further request that the Commission find that following abandonment by sale, the facilities will perform distribution activities and thus be exempt from the Commission's jurisdiction pursuant to Section 1(b) of the NGA, all as more fully set forth in the application, which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding this application should be directed to Tyler R. Brown, Senior Counsel, Columbia Gas Transmission, LLC, 5151 San Felipe, Suite 2500, Houston, TX 77056, phone: (713) 386–3797 or email: *tbrown@cpg.com.*

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the

Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 7 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, 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.

Comment Date: 5:00 p.m. Eastern Time on August 18, 2015.

Dated: July 28, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19067 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC15–8–000]

Commission Information Collection Activities (FERC–576); Comment Request

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Comment request.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507(a)(1)(D), the Federal Energy Regulatory Commission (Commission or FERC) is submitting its information collection [FERC–576, Report of Service Interruptions] to the Office of Management and Budget (OMB) for review of the information collection requirements. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission previously issued a Notice in the **Federal Register** (80 FR 28991, 5/20/2015) requesting public comments. The Commission received no comments on the FERC–576 and is making this notation in its submittal to OMB.

DATES: Comments on the collection of information are due by September 3, 2015.

ADDRESSES: Comments filed with OMB, identified by the OMB Control No. 1902–0004, should be sent via email to the Office of Information and Regulatory Affairs: *oira_submission@omb.gov.* Attention: Federal Energy Regulatory Commission Desk Officer. The Desk Officer may also be reached via telephone at 202–395–4718.

A copy of the comments should also be sent to the Commission, in Docket No. IC15–8–000, by either of the following methods:

- *eFiling at Commission's Web site: http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* by telephone at (202) 502–8663, and by fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: FERC–576, Report of Service Interruptions.

OMB Control No.: 1902–0004.

Type of Request: Three-year extension of the FERC–576 information collection requirements with no changes to the reporting requirements.

Abstract: A natural gas company must obtain Commission authorization to engage in the transportation, sale, or exchange of natural gas in interstate commerce under the Natural Gas Act (NGA).[1] The NGA also empowers the Commission to oversee continuity of service in the transportation of natural gas in interstate commerce. The information collected under FERC–576 notifies the Commission of: (1) Damage to jurisdictional natural gas facilities as a result of a hurricane, earthquake, or other natural disaster, or terrorist activity, (2) serious interruptions to service, and (3) damage to jurisdictional natural gas facilities due to natural disaster or terrorist activity, that creates

[1] Public Law 75 688; 15 U.S.C. 717 & 717w.

the potential for serious delivery problems on the pipeline's own system or the pipeline grid.

Filings (in accordance with the provisions of section 4(d) of the NGA)[2] must contain information necessary to advise the Commission when a change in service has occurred. Section 7(d) of the NGA[3] authorizes the Commission to issue a temporary certificate in cases of emergency to assure maintenance of adequate service or to serve particular customers, without notice or hearing.

Respondents to the FERC–576 are encouraged to submit the reports by email to *pipelineoutage@ferc.gov* but also have the option of faxing the reports to the Director of the Division of Pipeline Certificates. 18 CFR 260.9(b) requires that a report of service interruption or damage to natural gas facilities state: (1) The location of the service interruption or damage to natural gas pipeline or storage facilities; (2) The nature of any damage to pipeline or storage facilities; (3) Specific identification of the facilities damaged; (4) The time the service interruption or damage to the facilities occurred; (5) The customers affected by the service interruption or damage to the facilities; (6) Emergency actions taken to maintain service; and (7) Company contact and telephone number. The Commission may contact pipelines reporting damage or other pipelines to determine availability of supply, and if necessary, authorize transportation or construction of facilities to alleviate constraints in response to these reports.

A report required by 18 CFR 260.9(a)(1)(i) of damage to natural gas facilities resulting in loss of pipeline throughput or storage deliverability shall be reported to the Director of the Commission's Division of Pipeline Certificates at the earliest feasible time when pipeline throughput or storage deliverability has been restored.

In any instance in which an incident or damage report involving jurisdictional natural gas facilities is required by Department of Transportation (DOT) reporting requirements under the Natural Gas Pipeline Safety Act of 1968, a copy of such report shall be submitted to the Director of the Commission's Division of Pipeline Certificates, within 30 days of the reportable incident.[4]

If the Commission failed to collect these data, it would lose the ability to monitor and evaluate transactions, operations, and reliability of interstate pipelines and perform its regulatory functions. These reports are kept by the Commission Staff as non-public information and are not made part of the public record.

Type of Respondents: Natural gas companies.

Estimate of Annual Burden[5]: The Commission estimates the annual public reporting burden for the information collection as:

FERC–576—REPORT OF SERVICE INTERRUPTIONS

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden & cost per response[6] (4)	Total annual burden hours & total annual cost (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
Submittal of Original Email/Fax	22	2	44	1 $72	44 $3,168	72
Submittal of Damage Report	22	2	44	0.25 $18	11 $198	18
Submittal of DOT Incident Report	22	1	22	0.25 $18	5.5 $99	18
Total					60.5 $3,465	108

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: July 29, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–19058 Filed 8–3–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2015–0500; FRL–9931–68–OAR]

Notice of Availability of the Environmental Protection Agency's Updated Ozone Transport Modeling Data for the 2008 Ozone National Ambient Air Quality Standard (NAAQS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of data availability (NODA); request for public comment.

[2] (15 U.S.C. 717c).

[3] (15 U.S.C. 717f).

[4] 18 CFR 260.9(d).

[5] The Commission defines burden as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 Code of Federal Regulations 1320.3.

[6] The estimates for cost per response are derived using the following formula: Average Burden Hours per Response * $72.00 per Hour = Average Cost per Response. The hourly cost figure comes from the FERC average salary ($149,489/year). Commission staff believes the FERC average salary to be representative wage for industry respondents.

SUMMARY: The Environmental Protection Agency (EPA) is providing notice that interstate ozone transport modeling and associated data and methods are available for public review and comment. These data and methods will be used to inform a rulemaking proposal that the EPA is developing and expects to release later this year to address interstate ozone transport for the 2008 ozone national ambient air quality standards (NAAQS). This notice also meets the EPA's expressed intent to update the air quality modeling data that were released on January 22, 2015, and to share the updated data with states and other stakeholders. The information available includes: (1) Emission inventories for 2011 and 2017, supporting data used to develop those emission inventories, methods and data used to process emission inventories into a form that can be used for air quality modeling; and (2) base year 2011 and projected 2017 ozone concentrations and projected 2017 ozone state contribution data at individual ozone monitoring sites based on air quality modeling, supporting data including 2009–2013 base period and 2017 projected ozone design values, and methods used to process air quality model outputs to calculate 2017 ozone concentrations and contributions at individual monitoring sites. A docket has been established to facilitate public review of the data and to track comments.

DATES: Comments must be received on or before September 23, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2015–0500, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* (202)566–9744. Attention Docket ID No. EPA–HQ–OAR–2015–0500.
- *Mail:* EPA Docket Center, WJC West Building, Attention Docket ID No. EPA–HQ–OAR–2015–0500, U.S. Environmental Protection Agency, Mailcode: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460. Please include a total of 2 copies.
- *Hand Delivery:* U.S. Environmental Protection Agency, WJC West Building, 1301 Constitution Avenue NW., Room 3334, Washington, DC 20004, Attention Docket ID No. EPA–HQ–OAR–2015–0500. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2015–0500. 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. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD–ROM that you mail to the EPA docket office, 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. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. 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.

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.

When submitting comments, remember to:

1. Identify the notification by docket number and other identifying information (subject heading, **Federal Register** date and page number).
2. Explain your comments, why you agree or disagree; suggest alternatives and substitute data that reflect your requested changes.
3. Describe any assumptions and provide any technical information and/or data that you used.
4. Provide specific examples to illustrate your concerns, and suggest alternatives.
5. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
6. Make sure to submit your comments by the comment period deadline identified.

For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

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 in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. 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 Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions on the emissions data and on how to submit comments on the emissions data and related methodologies, contact Alison Eyth, Air Quality Assessment Division, Environmental Protection Agency, C339–02, 109 T.W. Alexander Drive, Research Triangle Park, NC 27709; telephone number: (919)541–2478; fax number: (919)541–1903; email: *eyth.alison@epa.gov.* For questions on the air quality modeling and ozone contributions and how to submit comments on the air quality modeling data and related methodologies, contact Norm Possiel, Air Quality Assessment Division, Environmental Protection Agency, C439–01, 109 T.W. Alexander Drive, Research Triangle Park, NC 27709; telephone number: (919)541–5692; fax number: (919)541–0044; email: *possiel.norm@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On January 22, 2015, the EPA issued a memo and preliminary air quality modeling data that would help states as

they develop State Implementation Plans to address cross-state transport of air pollution under the ''Good Neighbor'' Provision of the Clean Air Act (CAA), section 110(a)(2)(D)(i)(I), as it pertains to the 2008 ozone NAAQS.[1] That information included the EPA's preliminary air quality modeling data that applies the Cross-State Air Pollution Rule (CSAPR—76 FR 48208) approach to contribution projections for the year 2018 for the 2008 8-hour ozone NAAQS. Specifically, the EPA provided data identifying ozone monitoring sites that are projected to be nonattainment or have maintenance problems for the 2008 ozone NAAQS in 2018. The EPA also provided the projected contribution estimates from 2018 anthropogenic oxides of nitrogen (NO_X) and volatile organic compound (VOC) emissions in each state to ozone concentrations at each of these sites. The year 2018 was used as the analytic year for the preliminary modeling because at the onset of the modeling assessment, that year aligned with the December 2018 attainment date for Moderate ozone nonattainment areas. However, subsequent to the completion of the 2018 modeling, the EPA issued the final 2008 Ozone NAAQS SIP Requirements Rule,[2] which revised the attainment deadline for ozone nonattainment areas currently designated as Moderate for the 2008 ozone NAAQS to July 2018. The EPA established this deadline in the 2015 Ozone SIP Requirements Rule after previously establishing a deadline of December 31, 2018, that was vacated by the DC Circuit in *Natural Resources Defense Council* v. *EPA.* In order to demonstrate attainment by the revised attainment deadline, the demonstration would have to be based on design values calculated using 2015 through 2017 ozone season data, since the July 2018 deadline does not afford a full ozone season of measured data. Therefore, the EPA has adopted 2017 as the analytic year for the updated ozone transport modeling information being released as part of this NODA.

The 2011 and 2018 emissions inventory data used for the preliminary air quality modeling were released for public review on November 27, 2013 (78 FR 70935), and January 14, 2014 (79 FR 2437), respectively. Based in part on comments received from the public review process, the EPA updated the 2011 emissions inventory data, developed emissions inventory data for 2017, and used these data in air quality modeling to develop updated projections of future year ozone concentrations and contributions.

In the January 22, 2015 memo, the EPA expressed its intent to update the preliminary air quality modeling data and to share the updated data with states and other stakeholders. This notice meets this intent. Additionally, the EPA, together with its state partners, is assessing the next steps to address interstate air pollution transport for the 2008 ozone NAAQS under the CAA. The EPA recognizes its backstop role to develop and promulgate federal implementation plans, as appropriate. We are planning to take this action, if necessary, by issuing a proposal for a federal rule later this year. This notice provides an opportunity to review and comment on the agency's ozone transport modeling data that EPA intends to use in this forthcoming proposal.

II. Air Quality Modeling Data and Methodologies

Using the updated emissions inventories, the EPA performed photochemical air quality modeling to project ozone concentrations at air quality monitoring sites to 2017, and to estimate state-by-state contributions to those 2017 concentrations. We then used the air quality modeling results to identify nonattainment or maintenance sites for the 2008 ozone NAAQS in 2017, consistent with the CSAPR approach to identify such sites. We used the contribution information to quantify projected interstate contributions from emissions in each upwind state to ozone concentrations at each of the projected 2017 nonattainment and maintenance sites in downwind states.

The EPA's air quality modeling used the updated version of the 2011-based air quality modeling platform. This platform includes emissions for the 2011 base year and a 2017 future base case as well as meteorology for 2011. The 2011 meteorology was used in air quality model simulations for both 2011 and 2017. The 2011 and 2017 emissions data are described in more detail in Section III.

The EPA used the Comprehensive Air Quality Model with Extensions (CAMx version 6.11) for modeling the 2011 base year and 2017 future base case emissions scenarios to identify sites with projected nonattainment and maintenance problems in 2017. The air quality model runs were performed for a modeling domain that covers the 48 states in the contiguous U.S. along with adjacent portions of Canada and Mexico. The spatial resolution (*i.e.,* grid size) for this modeling domain is 12 km x 12 km. The 2011 and 2017 scenarios were both modeled for the full year with 2011 meteorology. The meteorological data used as input to the air quality modeling was obtained from an annual simulation of version 3.4 of the Weather Research Forecast Model (WRF) for 2011. The initial and boundary concentration inputs to the air quality modeling were derived from an annual simulation of the Goddard Earth Observing System global chemical transport model (GEOS-Chem). The CAMx predictions for 2011 were compared to corresponding measurements as part of a model performance evaluation. Information on the development of the 2011 meteorological and initial and boundary concentration inputs to the CAMx simulations and the model performance evaluation methodologies and results are described in the ''Updated Air Quality Modeling Technical Support Document'' (AQM TSD) for the 2008 Ozone NAAQS Interstate Transport Assessment, which is available in the docket for this notice. Also in this docket is a report on the performance evaluation for the annual 2011 WRF meteorological model simulation.

A. Identification of Projected 2017 Nonattainment and Maintenance Sites

The ozone predictions from the 2011 and 2017 CAMx model runs were used to project measured ozone design values to 2017 following the approach described in the EPA's draft guidance for attainment demonstration modeling.[3] We selected 2011 as the base year to reflect the most recent National Emissions Inventory (NEI). In addition, the meteorological conditions during the summer of 2011 were generally conducive for ozone formation across much of the U.S., particularly the eastern U.S. We selected 2017 as the projected analysis year to coincide with the attainment date for Moderate nonattainment areas under the 2008 ozone NAAQS. The draft attainment modeling guidance recommends using 5-year weighted average ambient design values[4] centered on the base year as the starting point for projecting design values to the future. Because 2011 is the

[1] Memorandum from Stephen D. Page, Information on the Interstate Transport ''Good Neighbor'' Provision for the 2008 Ozone National Ambient Air Quality Standards (NAAQS) under CAA section 110(a)(2)(D)(i)(I), January 22, 2015, *available at http://www.epa.gov/airtransport/GoodNeighborProvision2008NAAQS.pdf.*

[2] 80 FR 12264, 12268 (Mar. 6, 2015); 40 CFR 51.1103.

[3] The December 3, 2014, draft ozone, fine particulate matter and regional haze SIP modeling guidance is available at *http://www.epa.gov/ttn/scram/guidance/guide/Draft_O3–PM–RH_Modeling_Guidance-2014.pdf.*

[4] The air quality design value for a site is the 3-year average annual fourth-highest daily maximum 8-hour average ozone concentration.

base year of emissions, we started with the average ambient 8-hour ozone design values for the period 2009 through 2013 (*i.e.,* the average of design values for 2009–2011, 2010–2012, and 2011–2013). The 5-year weighted average ambient design value at each site was projected to 2017 using model-predicted Relative Response Factors (RRFs) [5] that were calculated based on procedures described in the draft attainment demonstration modeling guidance. The 2017 projected average ozone design values were evaluated to identify those sites with design values that exceed the 2008 ozone NAAQS.[6] Consistent with the approach used in CSAPR, those sites with 2017 average design values that exceed the NAAQS are projected to be in nonattainment in 2017.

As noted above, we followed the CSAPR approach to identify sites with projected maintenance problems in 2017. As part of the approach for identifying sites with projected future maintenance problems, the highest (*i.e.,* maximum) ambient design value from the 2011-centered 5-year period (*i.e.,* the maximum of design values from 2009–2011, 2010–2012, and 2011–2013) was projected to 2017 for each site using the site-specific RRFs. Following the CSAPR approach, monitoring sites with a maximum design value that exceeds the NAAQS, even if the average design value is below the NAAQS, are projected to have a maintenance problem in 2017. In this regard, nonattainment sites are also maintenance sites because the maximum design value at nonattainment sites is always greater than or equal to the 5-year weighted average. Monitoring sites with a 2017 average design value below the NAAQS, but with a maximum design value that exceeds the NAAQS, are considered maintenance-only sites. These sites are projected to have a maintenance problem, but not a nonattainment problem in 2017.

The base period ambient and projected 2017 average and maximum design values at individual nonattainment sites and maintenance-only sites are provided in Tables 1 and 2, respectively.

TABLE 1—2009–2013 AND 2017 AVERAGE AND MAXIMUM DESIGN VALUES AT PROJECTED NONATTAINMENT SITES IN THE EAST (TOP) AND WEST (BOTTOM)

[Units are ppb]

Monitor ID	State	County	2009–2013 average design value	2009–2013 maximum design value	2017 average design value	2017 maximum design value
90013007	Connecticut	Fairfield	84.3	89.0	77.1	81.4
90019003	Connecticut	Fairfield	83.7	87.0	78.0	81.1
90099002	Connecticut	New Haven	85.7	89.0	77.2	80.2
240251001	Maryland	Harford	90.0	93.0	81.3	84.0
360850067	New York	Richmond	81.3	83.0	76.3	77.8
361030002	New York	Suffolk	83.3	85.0	79.2	80.8
390610006	Ohio	Hamilton	82.0	85.0	76.3	79.1
480391004	Texas	Brazoria	88.0	89.0	81.4	82.3
481210034	Texas	Denton	84.3	87.0	76.9	79.4
482011034	Texas	Harris	81.0	82.0	76.8	77.8
482011039	Texas	Harris	82.0	84.0	78.2	80.2
484392003	Texas	Tarrant	87.3	90.0	79.6	82.1
484393009	Texas	Tarrant	86.0	86.0	78.6	78.6
551170006	Wisconsin	Sheboygan	84.3	87.0	77.0	79.4
.						
60190007	California	Fresno	94.7	95.0	89.0	89.3
60190011	California	Fresno	93.0	96.0	87.6	90.4
60190242	California	Fresno	91.7	95.0	87.1	90.3
60194001	California	Fresno	90.7	92.0	84.2	85.4
60195001	California	Fresno	97.0	99.0	90.6	92.5
60251003	California	Imperial	81.0	82.0	79.3	80.3
60290007	California	Kern	91.7	96.0	86.2	90.2
60290008	California	Kern	86.3	88.0	80.6	82.2
60290011	California	Kern	80.0	81.0	76.2	77.1
60290014	California	Kern	87.7	89.0	82.8	84.0
60290232	California	Kern	87.3	89.0	82.2	83.8
60295002	California	Kern	90.0	91.0	84.5	85.5
60296001	California	Kern	84.3	86.0	79.7	81.3
60311004	California	Kings	87.0	90.0	81.1	83.9
60370002	California	Los Angeles	80.0	82.0	79.0	81.0
60370016	California	Los Angeles	94.0	97.0	92.8	95.8
60371002	California	Los Angeles	80.0	81.0	77.1	78.1
60371201	California	Los Angeles	90.0	90.0	87.9	87.9
60371701	California	Los Angeles	84.0	85.0	82.2	83.2
60372005	California	Los Angeles	79.5	82.0	78.1	80.6
60376012	California	Los Angeles	97.3	99.0	94.5	96.2
60379033	California	Los Angeles	90.0	91.0	86.0	86.9
60392010	California	Madera	85.0	86.0	79.8	80.8
60470003	California	Merced	82.7	84.0	78.1	79.3
60610006	California	Placer	84.0	86.0	78.2	80.0

[5] In brief, the RRF for a particular location is the ratio of the 2017 ozone model prediction to the 2011 ozone model prediction. The RRFs were calculated using model outputs for the May through September period.

[6] In determining compliance with the NAAQS, ozone design values are truncated to integer values. For example, a design value of 75.9 ppb is truncated to 75 ppb which is attainment. In this manner, design values at or above 76.0 ppb are considered nonattainment.

TABLE 1—2009–2013 AND 2017 AVERAGE AND MAXIMUM DESIGN VALUES AT PROJECTED NONATTAINMENT SITES IN THE EAST (TOP) AND WEST (BOTTOM)—Continued

[Units are ppb]

Monitor ID	State	County	2009–2013 average design value	2009–2013 maximum design value	2017 average design value	2017 maximum design value
60650004	California	Riverside	85.0	85.0	82.3	82.3
60650012	California	Riverside	97.3	99.0	93.5	95.1
60651016	California	Riverside	100.7	101.0	95.7	96.0
60652002	California	Riverside	84.3	85.0	79.8	80.5
60655001	California	Riverside	92.3	93.0	87.6	88.2
60656001	California	Riverside	94.0	98.0	88.1	91.9
60658001	California	Riverside	97.0	98.0	93.3	94.3
60658005	California	Riverside	92.7	94.0	89.2	90.4
60659001	California	Riverside	88.3	91.0	82.7	85.2
60670012	California	Sacramento	93.3	95.0	85.7	87.3
60675003	California	Sacramento	86.3	88.0	80.5	82.0
60710005	California	San Bernardino	105.0	107.0	103.6	105.6
60710012	California	San Bernardino	95.0	97.0	91.8	93.8
60710306	California	San Bernardino	83.7	85.0	81.2	82.4
60711004	California	San Bernardino	96.7	98.0	94.3	95.6
60712002	California	San Bernardino	101.0	103.0	99.5	101.5
60714001	California	San Bernardino	94.3	97.0	92.3	95.0
60714003	California	San Bernardino	105.0	107.0	101.8	103.8
60719002	California	San Bernardino	92.3	94.0	88.0	89.6
60719004	California	San Bernardino	98.7	99.0	95.7	96.0
60731006	California	San Diego	81.0	82.0	76.6	77.6
60990006	California	Stanislaus	87.0	88.0	83.0	83.9
61070006	California	Tulare	81.7	85.0	77.0	80.1
61070009	California	Tulare	94.7	96.0	87.3	88.5
61072002	California	Tulare	85.0	88.0	78.6	81.4
61072010	California	Tulare	89.0	90.0	82.7	83.6
61112002	California	Ventura	81.0	83.0	78.3	80.2
80350004	Colorado	Douglas	80.7	83.0	76.0	78.1
80590006	Colorado	Jefferson	80.3	83.0	76.3	78.8

TABLE 2—2009–2013 AND 2017 AVERAGE AND MAXIMUM DESIGN VALUES AT PROJECTED MAINTENANCE-ONLY SITES IN THE EAST (TOP) AND WEST (BOTTOM)

[Units are ppb]

Monitor ID	State	County	2009–2013 average design value	2009–2013 maximum design value	2017 average design value	2017 maximum design value
90010017	Connecticut	Fairfield	80.3	83.0	75.8	78.4
211110067	Kentucky	Jefferson	82.0	85.0	75.8	78.6
211850004	Kentucky	Oldham	82.0	86.0	73.7	77.3
240053001	Maryland	Baltimore	80.7	84.0	73.2	76.2
260050003	Michigan	Allegan	82.7	86.0	75.5	78.5
261630019	Michigan	Wayne	78.7	81.0	74.0	76.2
340071001	New Jersey	Camden	82.7	87.0	74.2	78.1
340150002	New Jersey	Gloucester	84.3	87.0	75.1	77.5
340230011	New Jersey	Middlesex	81.3	85.0	73.0	76.3
340290006	New Jersey	Ocean	82.0	85.0	73.9	76.6
360810124	New York	Queens	78.0	80.0	75.7	77.6
420031005	Pennsylvania	Allegheny	80.7	82.0	75.3	76.5
421010024	Pennsylvania	Philadelphia	83.3	87.0	75.1	78.4
480850005	Texas	Collin	82.7	84.0	74.9	76.0
481130069	Texas	Dallas	79.7	84.0	74.0	78.0
481130075	Texas	Dallas	82.0	83.0	75.8	76.7
481211032	Texas	Denton	82.7	84.0	75.1	76.3
482010024	Texas	Harris	80.3	83.0	75.9	78.5
482010026	Texas	Harris	77.3	80.0	73.5	76.1
482010055	Texas	Harris	81.3	83.0	75.4	77.0
482011050	Texas	Harris	78.3	80.0	74.6	76.2
484390075	Texas	Tarrant	82.0	83.0	75.5	76.4
484393011	Texas	Tarrant	80.7	83.0	74.5	76.6
40131004	Arizona	Maricopa	79.7	81.0	75.0	76.2
60170020	California	El Dorado	82.7	84.0	75.1	76.3
60390004	California	Madera	79.3	81.0	75.3	76.9
60610003	California	Placer	83.0	85.0	75.4	77.2

TABLE 2—2009–2013 AND 2017 AVERAGE AND MAXIMUM DESIGN VALUES AT PROJECTED MAINTENANCE-ONLY SITES IN THE EAST (TOP) AND WEST (BOTTOM)—Continued

[Units are ppb]

Monitor ID	State	County	2009–2013 average design value	2009–2013 maximum design value	2017 average design value	2017 maximum design value
60670006	California	Sacramento	78.7	81.0	74.0	76.1
60773005	California	San Joaquin	79.0	80.0	75.9	76.8
80050002	Colorado	Arapahoe	76.7	79.0	74.4	76.6
80590011	Colorado	Jefferson	78.7	82.0	75.8	78.9

B. Quantification of Interstate Ozone Contributions

The EPA performed nationwide, state-level ozone source apportionment modeling using the CAMx Ozone Source Apportionment Technology/Anthropogenic Precursor Culpability Analysis (OSAT/APCA) technique [7] to quantify the contribution of 2017 base case NO_X and VOC emissions from all sources in each state to projected 2017 ozone concentrations at each air quality monitoring site. In the source apportionment model run, we tracked the ozone formed from each of the following contribution categories (*i.e.,* ''tags''):

- States—anthropogenic NO_X and VOC emissions from each state tracked individually (emissions from all anthropogenic sectors in a given state were combined);
- Biogenics—biogenic NO_X and VOC emissions domain-wide (*i.e.,* not by state);
- Boundary Concentrations—concentrations transported into the modeling domain;
- Tribes—the emissions from those tribal lands for which we have point source inventory data in the 2011 NEI (we did not model the contributions from individual tribes);
- Canada and Mexico—anthropogenic emissions from sources in the portions of Canada and Mexico included in the modeling domain (we did not model the contributions from Canada and Mexico separately);
- Fires—combined emissions from wild and prescribed fires; and
- Offshore—combined emissions from offshore marine vessels and offshore drilling platforms.

The CAMx OSAT/APCA model run was performed for the period May 1 through September 30 using the 2017 future base case emissions and 2011 meteorology for this time period. The hourly contributions [8] from each tag were processed to obtain the 8-hour average contributions corresponding to the time period of the 8-hour daily maximum concentration on each day in the 2017 model simulation. This step was performed for those model grid cells containing monitoring sites in order to obtain 8-hour average contributions for each day at the location of each site. The model-predicted contributions were then applied in a relative sense to quantify the contributions to the 2017 average design value at each site. Additional details on the source apportionment modeling and the procedures for calculating contributions can be found in the AQM TSD.

The average contribution metric is intended to provide a reasonable representation of the contribution from individual states to the projected 2017 design value, based on modeled transport patterns and other meteorological conditions generally associated with modeled high ozone concentrations in the vicinity of the monitoring site. An average contribution metric constructed in this manner is beneficial since the magnitude of the contributions is directly related to the magnitude of the design value at each site.

The resulting 2017 contributions from each tag to each monitoring site are provided in the AQM TSD. The largest contributions from each state to projected 2017 downwind nonattainment sites and to projected downwind maintenance-only sites are provided in Table 3.

TABLE 3—LARGEST OZONE CONTRIBUTIONS FROM EACH STATE TO DOWNWIND 2017 PROJECTED NONATTAINMENT AND TO 2017 PROJECTED MAINTENANCE-ONLY SITES

[Units are ppb]

Upwind state	Largest contribution to a 2017 nonattainment site in downwind states	Largest contribution to a 2017 maintenance-only site in downwind states
Alabama	0.79	1.28
Arizona	1.78	0.41
Arkansas	1.24	2.15
California	1.75	3.44
Colorado	0.36	0.34
Connecticut	0.46	0.41
Delaware	0.68	2.23
District of Columbia	0.73	0.64
Florida	0.57	0.72
Georgia	0.58	0.56
Idaho	0.23	0.35

[7] As part of this technique, ozone formed from reactions between biogenic VOC and NO_X with anthropogenic NO_X and VOC are assigned to the anthropogenic emissions.

[8] Contributions from anthropogenic emissions under ''NO_X-limited'' and ''VOC-limited'' chemical regimes were combined to obtain the net contribution from NO_X and VOC anthropogenic emissions in each state.

TABLE 3—LARGEST OZONE CONTRIBUTIONS FROM EACH STATE TO DOWNWIND 2017 PROJECTED NONATTAINMENT AND TO 2017 PROJECTED MAINTENANCE-ONLY SITES—Continued

[Units are ppb]

Upwind state	Largest contribution to a 2017 nonattainment site in downwind states	Largest contribution to a 2017 maintenance-only site in downwind states
Illinois	17.48	23.17
Indiana	7.15	14.95
Iowa	0.61	0.85
Kansas	0.80	1.03
Kentucky	11.17	2.14
Louisiana	3.81	4.23
Maine	0.00	0.08
Maryland	2.39	7.11
Massachusetts	0.10	0.37
Michigan	2.69	1.79
Minnesota	0.40	0.47
Mississippi	0.78	1.48
Missouri	1.63	3.69
Montana	0.15	0.17
Nebraska	0.51	0.36
Nevada	0.84	0.73
New Hampshire	0.02	0.07
New Jersey	12.38	11.48
New Mexico	1.05	0.54
New York	16.96	17.21
North Carolina	0.55	0.93
North Dakota	0.14	0.28
Ohio	3.99	7.92
Oklahoma	1.70	2.46
Oregon	0.65	0.65
Pennsylvania	13.51	15.93
Rhode Island	0.02	0.08
South Carolina	0.19	0.21
South Dakota	0.08	0.12
Tennessee	1.67	0.90
Texas	2.44	2.95
Utah	1.59	1.66
Vermont	0.01	0.05
Virginia	5.29	4.70
Washington	0.22	0.09
West Virginia	2.99	3.11
Wisconsin	0.56	2.59
Wyoming	1.22	1.22

In CSAPR, the EPA used a contribution screening threshold of 1 percent of the NAAQS to identify upwind states in the eastern U.S. that may significantly contribute to downwind nonattainment and/or maintenance problems and which warrant further analysis. The EPA will take comment on the appropriate threshold to be applied for purposes of the 2008 ozone NAAQS in the upcoming rulemaking proposal to address interstate ozone transport for that standard. The EPA is not proposing or taking comment on this threshold as part of this NODA.

C. Air Quality Modeling Information Available for Public Comment

The EPA is requesting comment on the components of the 2011 air quality modeling platform, the air quality model applications and model performance evaluation, and the projected 2017 ozone design value concentrations and contribution data. The EPA is also seeking comment on the methodology for calculating contributions at individual monitoring sites. The EPA encourages all states and sources to review and comment on the information provided in this NODA.

The EPA has placed key information related to the air quality modeling into the electronic docket for this notice (EPA–HQ–OAR–2015–0500) which is available at *www.regulations.gov.* This includes the AQM TSD, an Excel file which contains the 2009–2013 base period and 2017 projected average and maximum ozone design values at individual monitoring sites, and an Excel file with the ozone contributions from each state and all other source tags to each monitoring site. However, the air quality modeling input and output data files are too large to be directly uploaded into the electronic docket and/or are not in formats accepted by that docket. These air quality modeling files have been placed on a data drive in the docket office. Electronic copies of the non-emissions air quality modeling input files and the air quality modeling output files can also be obtained prior to the end of the comment period by contacting Norm Possiel at *possiel.norm@epa.gov.* A detailed description of the 2011 and 2017 emissions data and procedures for accessing and commenting on these data are provided below.

III. Emissions Data and Methodologies

The EPA is requesting comment on the updated 2011 and 2017 emission

inventories; supporting ancillary files used to allocate emissions temporally, spatially, and by emissions species; and on the emissions modeling methods used to develop the emission inventories, including but not restricted to, the activity data, model input databases, and the projection, control, and closure data used to develop projected 2017 emissions. Summaries of the emission inventories are provided to aid in the review of the data, but comments are sought on the actual inventories, model inputs, data, and methods used to develop the projected emissions.

A. Instructions for Submitting Emissions Comments and Alternative Emissions Data

The EPA can most effectively use comments on emissions data that provide specific alternative values to those in the EPA data sets, and for which accompanying documentation supports the alternative values. Commenters should provide the alternative data at a level of detail appropriate to the data set into which it will be incorporated, thereby including all key fields needed to substitute the old data with the new. For example, any data provided as an alternative to the EPA's point source emissions data should include all key fields used to identify point source data such as facility, unit, release point, process, and pollutant, along with alternative emissions values. If a commenter were to provide a new set of county total emissions as an alternative to detailed point source emissions data, the EPA would not be able to use that new data. Commenters should also include documentation that describes methods for development of any alternative values and relevant references supporting the alternative approach.

Any alternative emission inventory or ancillary data provided should be compatible with the formats used by the Sparse Matrix Operator Kernel Emissions (SMOKE) modeling system version 3.6.5, which is used by the EPA to process emission inventories into a format that can be used for air quality modeling. Formats are defined in the SMOKE Version 3.6.5 User's Manual available from *http://www.cmascenter.org/smoke/.* Only the rows of data that have changed from those provided by the EPA should be included in the alternative data sets. Alternative data that are not an input to SMOKE, such as model input databases for mobile source models, should be provided in a format in which it could be directly input to the model.

Commenters wishing to comment on inventory projection methods should submit to the docket comments that describe an alternative approach to the existing methods, along with documentation describing why that method is an improvement over the existing method.

B. Emissions Information Available for Public Comment

The released data include emission inventories that represent projected emissions into the atmosphere of criteria and some hazardous air pollutants in the years 2011 and 2017, additional ancillary data files that are used to convert the NEI emissions into a form that can be used for air quality modeling, and methods used to prepare the air quality model inputs and to develop projections of emissions for the year 2017. The platform includes emission inventories for sources at specific locations called point sources; emissions from fire events; and county-level emissions of onroad mobile sources, nonroad mobile sources, and nonpoint stationary sources.

The provided emission inventories are split into categories called modeling sectors. For example, facility-specific point emission sources are split into electric generating units (EGUs), oil and gas point sources, and other point sources. Nonpoint emission sources are split into agricultural ammonia sources, area fugitive dust sources, non-Category 3 commercial marine and locomotive sources, residential wood sources, oil and gas nonpoint sources, agricultural burning sources, and other nonpoint sources. Additional modeling sectors are onroad and nonroad mobile sources, Category 3 commercial marine sources, and emissions from wild and prescribed fires.

The emission inventories for the future year of 2017 have been developed using projection methods that are specific to the type of emission source. Future emissions are projected from the 2011 base case either by running models to estimate future year emissions from specific types of emission sources (*i.e.,* EGUs, and onroad and nonroad mobile sources), or for other types of sources by adjusting the base year emissions according to the best estimate of changes expected to occur in the intervening years (*i.e.,* non-EGU point and nonpoint sources).

For some sectors, the same emissions are used in the base and future years, such as biogenic emissions, wild and prescribed fire emissions, and Canadian emissions. For all other sectors, rules and specific legal obligations that go into effect in the intervening years, along with changes in activity for the sector, are considered when possible. Documentation of the methods used for each sector is provided in the TSD *Preparation of Emissions Inventories for the Version 6.2, 2011 Emissions Modeling Platform,* which can be found in the docket for this notice.

Emission projections for EGUs for 2017 were developed using the Integrated Planning Model (IPM). The National Electric Energy Data System (NEEDS) database contains the generation unit records used for the model plants that represent existing and planned/committed units in EPA modeling applications of IPM. The NEEDS database includes basic geographic, operating, air emissions, and other data on these generating units and is updated for the EPA's version 5.14 power sector modeling platform. The EGU emission projections included in this data release are reported in an air quality modeling-ready flat file taken from the EPA Base Case v.5.14, developed using IPM. The 2017 EGU emission projections in the flat file format, the corresponding NEEDS database, and user guides and documentation are available in the docket for this notice, and at *http://www.epa.gov/powersectormodeling.*

To project future emissions from onroad and nonroad mobile sources, the EPA uses the Motor Vehicle Emissions Simulator (MOVES) and the National Mobile Inventory Model (NMIM), respectively. Development of the future year onroad and nonroad emissions requires a substantial amount of lead time and resources. The EPA had already prepared the emissions projections for 2018 when the attainment deadline for Moderate nonattainment areas was revised to July 2018 in the 2008 Ozone SIP Requirements Rule, as discussed above, effectively requiring the agency to adjust its projection year to 2017. Thus, for purposes of this NODA, the EPA calculated the 2017 emissions from mobile sources using post-modeling adjustments to 2018 emissions, but the agency anticipates that it will directly generate the mobile source emissions for 2017 that will be used in the air quality modeling for the final rule to address interstate transport for the 2008 ozone standard. The EPA obtained 2018 projections by running the MOVES and NMIM models using year-specific information about fuel mixtures, activity data, and the impacts of national and state-level rules and control programs. The input databases and future year activity data for onroad mobile sources are provided with the 2011v6.2 platform available at *http://www.epa.gov/ttn/*

chief/emch/index.html#2011. The 2018 onroad and nonroad mobile source emissions were adjusted for 2017 using factors derived from national scale runs of MOVES and NMIM, respectively.

For non-EGU point and nonpoint sources, projections of 2017 emissions were developed by starting with the 2011 emissions inventories and applying adjustments that represent the impact of national, state, and local rules coming into effect in the years 2012 through 2017, along with the impacts of planned shutdowns, the construction of new plants, specific information provided by states, and specific legal obligations resolving alleged environmental violations, such as consent decrees. Changes in activity are considered for sectors such as oil and gas, residential wood combustion, cement kilns, livestock, aircraft, commercial marine vessels and locomotives. Data files that include factors that represent the changes are provided, along with summaries that quantify the emission changes resulting from the projections at a state and national level.

The provided data include relevant emissions inventories for neighboring countries used in our modeling, specifically the 2010 emissions inventories for Canada and the 2008 and 2018 emissions inventories for Mexico. Canadian emissions for a future year were not available.

Ancillary data files used to allocate annual emissions to the hourly, gridded emissions of chemical species used by the air quality model are also provided. The types of ancillary data files include temporal profiles that allocate annual and monthly emissions down to days and hours, spatial surrogates that allocate county-level emissions onto the grid cells used by the AQM, and speciation profiles that allocate the pollutants in the NEI to the chemical species used by the air quality model. In addition, there are temporal, spatial, and speciation cross-reference files that map the emission sources in the emission inventories to the appropriate profiles based on their location, emissions source classification code (SCC), and, in some cases, the specific facility or unit. With the exception of some speciation profiles and temporal profiles for EGUs and mobile sources, the same ancillary data files are used to prepare the 2011 and 2017 emissions inventories for air quality modeling.

Information related to this section is located in the docket. However, as mentioned above, some of the emissions data files are too large to be directly uploaded into the electronic docket and/or are not in formats accepted by that docket. Therefore, the information placed in the electronic docket, associated detailed data, and summaries to help with interpretation of the data are available for public review with the 2011v6.2 platform available on the Emissions Modeling Clearinghouse on the EPA's Web site at *http://www.epa.gov/ttn/chief/emch/index.html#2011.* Requests for electronic copies of pre-merged, intermediate and air quality model-ready emissions files for input to air quality modeling can be obtained by contacting Alison Eyth at *eyth.alison@epa.gov.*

The emissions inventories, along with many of the ancillary files, are provided in the form of flat files that can be input to SMOKE. Flat files are comma-separated values-style text files with columns and rows that can be loaded into spreadsheet or database software. The columns of interest in the emission inventory files are specified in each subsection below. The EPA specifically requests comment on the following components of the provided emissions modeling inventories and ancillary files:

• *Emissions values and supporting data for EGUs.* The EPA requests comment on the IPM version 5.14 input assumptions, NEEDS database, 2018 unit-level parsed files because 2017 parsed files are not available, 2017 flat file inputs and outputs (including modifications to the IPM 2018 Base Case to inform 2017 NO_X emissions), temporal profiles use to allocate seasonal emissions to hours, and cross references and matching between IPM and NEI.

• *Emission values for non-EGU sources.* The EPA requests comment on the criteria air pollutant projected 2017 emissions in the modeling inventories, such as NO_X, VOC, sulfur dioxide, particulate matter less than 2.5 micrometers, particulate matter less than 10 micrometers, and ammonia, with a focus on the ozone precursors NO_X and VOC. The EPA will also accept comments on 2017 projections of hazardous air pollutants (HAPs), as they are included in the outputs of models used to develop 2017 emission projections. However, HAPs are not the focus of this effort. The annual emissions values are located in the ANN_VALUE column of emission inventory files in the Flat File 2010 (FF10) format. Some emission inventories (*e.g.,* nonroad) may also have values filled in to the monthly value columns (*e.g.,* JAN_VALUE, FEB_VALUE, . . ., DEC_VALUE). The EPA requests comment on both the annual and monthly emissions values, where applicable. Summaries of emissions by state and county are provided to aid in the review of emissions values.

• *Model inputs and activity data used to develop mobile source emission inventories.* The EPA requests comment on the mobile source model input data used to develop the projected future mobile source emission inventories. These include both the databases used to create emission factors and the vehicle miles traveled and vehicle population activity data used to compute the emissions. Of particular interest are county total vehicle miles traveled, the mixture of vehicle types in 2017, hoteling hours of combination long-haul trucks, and changes to the inspection and maintenance programs. Alternative activity data should be provided in the SMOKE FF10 activity data format.

• *Projection data and methods.* The EPA seeks comment on the data used to project point and nonpoint source emissions from 2011 to 2017, and on the methods and assumptions used to implement the projections. In this context, nonpoint source emissions are inclusive of commercial marine vessel, railroad, oil and gas, and other nonpoint emissions. In particular, the EPA seeks comment on its assumptions regarding the manner in which specific consent decrees and state- or locality-specific control programs will be implemented.

• *Existing control techniques.* The emission inventories include information on emissions control techniques listed in terms of control codes submitted to the EIS. These are listed in the CONTROL_IDS and CONTROL_MEASURES columns in the emission inventory flat files, with levels of reduction in the ANN_PCT_RED column. Projection of non-EGU point source emissions to future years is dependent on this information. The EPA seeks comment on whether data on existing controls given in the inventory flat files are incomplete or erroneous. The flat files must be consulted for details of control techniques by pollutant.

• *Emissions modeling methods.* The EPA is using SMOKE version 3.6.5 to prepare data for air quality modeling. The EPA requests comment on the methods by which SMOKE is used to develop air quality model-ready emissions, as illustrated in the scripts provided with the modeling platform and as described in the TSD *Preparation of Emissions Inventories for the Version 6.2, 2011 Emissions Modeling Platform,* available with the 2011v6.2 platform at *http://www.epa.gov/ttn/chief/emch/index.html#2011.*

• *Temporal allocation.* Annual emission inventories must be allocated

to hourly values prior to air quality modeling. This may be done with temporal profiles in several steps, such as annual-to-month, month-to-day, and day-to-hour. The exact method used depends on the type of emissions being processed. The EPA seeks comment on the allocation of the emission inventories to month, day, and hour for all types of emission processes. In particular, the EPA seeks information that could help improve the temporal allocation in 2017 of emissions from EGUs, nonroad mobile sources, residential wood combustion sources, and the temporal allocation of vehicle miles traveled needed to model onroad mobile sources. The EPA seeks local- and region-specific data that can be used to improve the temporal allocation of emissions data.

• *Spatial surrogates.* Spatial surrogates are used to allocate county-level emissions to the grid cells used for air quality modeling. The EPA requests comment on the spatial surrogates used to spatially allocate the 2011 and 2017 emissions. The same spatial surrogates are used in the base and future years.

• *Chemical speciation.* Prior to air quality modeling, the pollutants in the emission inventories must be converted into the chemical species used by the air quality model using speciation profiles. The speciation profiles provided are consistent with version 4.4 of the SPECIATE database. The EPA requests comment on the provided speciation profiles, as well as any information that could help improve the speciation of oil and gas emissions in both the eastern and western U.S. in 2017. Oil and gas speciation information, along with VOC to TOG adjustment factors that are used to compute methane emissions, would be of the most use at the county or oil/gas basin level of detail and also for each distinct process at oil and gas drilling/production facilities (*e.g.,* glycol dehydrators).

To aid in the interpretation of the provided data files and how they relate to the aspects of the data on which the EPA is requesting comment, the EPA has provided a summary document in the docket that describes in more detail the provided data and summary files.

Dated: July 23, 2015.

Stephen D. Page,

Director, Office of Air Quality Planning and Standards.

[FR Doc. 2015–18878 Filed 8–3–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2014–0170; FRL—9931–67–OW]

RIN 2040–ZA24

Final 2014 Effluent Guidelines Program Plan and 2014 Annual Effluent Guidelines Review Report

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of the Environmental Protection Agency's (EPA) Final 2014 Effluent Guidelines Program Plan and EPA's 2014 Annual Effluent Guidelines Review Report. Section 304(m) of the Clean Water Act requires EPA to biennially publish a plan for new and revised effluent guidelines, after public notice and comment. The Plan identifies any new or existing industrial categories selected for effluent guidelines and provides a schedule. EPA typically publishes a preliminary plan upon which the public is invited to comment, and then publishes a final plan thereafter. EPA published the Preliminary 2014 Plan on September 16, 2014, and received public comment on it.

FOR FURTHER INFORMATION CONTACT: Mr. William F. Swietlik, Engineering and Analysis Division, Office of Water, 4303T, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC., 20460; telephone number: (202) 566–1129; fax number: (202) 566–1053; email address: *swietlik.william@epa.gov*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Supporting Documents—Key documents providing additional information about EPA's 2014 annual review and the Final 2014 Plan include the 2014 Effluent Guidelines Review Report and the Final 2014 Effluent Guidelines Program Plan.

B. *How can I get copies of these documents and other related information?*

1. *Docket.* EPA has established official public dockets for these actions under Docket ID No. EPA–HQ–OW–2014–0170. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301Constitution Ave. NW., Washington, DC 20460.

2. *Electronic Access.* You can access this **Federal Register** document electronically through the United States government online source for Federal regulations at *http://www.regulations.gov*.

3. *Internet access.* Copies of the supporting documents are available at *http://water.epa.gov/lawsregs/lawsguidance/cwa/304m/index.cfm*

II. How Is This Document Organized?

The outline of this notice follows.

A. Legal Authority
B. Summary of the Final 2014 Effluent Guidelines Program Plan

A. Legal Authority

This notice is published under the authority of the CWA, 33 U.S.C. 1251, *et seq.,* and in particular sections 301(d), 304(b), 304(g), 304(m), 306, 307(b) and 308 of the Act, 33 U.S.C. 1311(d), 1314(b), 1314(g), 1314(m), 1316, 1317(b), and 1318.

B. Summary of the Final 2014 Effluent Guidelines Program Plan

EPA prepared the *Final 2014 Effluent Guidelines Program Plan* (the Plan) pursuant to Clean Water Act section 304(m). The Plan provides a summary of EPA's review of effluent guidelines and pretreatment standards, consistent with CWA sections 301(d), 304(b), 304(g), 304(m), and 307(b). It includes EPA's evaluation of indirect discharge categories that do not have categorical pretreatment standards for the purpose of identifying potential new categories for which pretreatment standards under CWA section 307(b) might be warranted. From these reviews, the Plan identifies any new or existing industrial categories selected for effluent guidelines, and provides a schedule. In addition, the Plan presents any new or existing categories of industry selected for further review and analysis. The Final 2014 Plan and the 2014 Annual Review Report can be found at *http://water.epa.gov/lawsregs/lawsguidance/cwa/304m/index.cfm*

Dated: July 24, 2015.

Kenneth J. Kopocis,

Deputy Assistant Administrator for Water.

[FR Doc. 2015–18877 Filed 8–3–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention—Health Disparities Subcommittee (HDS)

Notice of Cancellation: This notice was published in the **Federal Register** on July 20, 2015, Volume 80, Number 138, page 42820. The meeting previously scheduled to convene on August 11, 2015 has been cancelled.

Contact Person for more Information: Leandris Liburd, Ph.D., M.P.H., M.A., Designated Federal Officer, Health Disparities Subcommittee, Advisory Committee to the Director, CDC, 1600 Clifton Road NE., M/S K–77, Atlanta, GA 30333; telephone (770) 488–8200, Email: *LEL1@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015–19040 Filed 8–3–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Nominations of Candidates To Serve on the Breast and Cervical Cancer Early Detection and Control Advisory Committee (BCCEDCAC)

The Centers for Disease Control and Prevention (CDC) is soliciting nominations for membership on The Breast and Cervical Cancer Early Detection and Control Advisory Committee. The committee provides advice and guidance to the Secretary, HHS, and the Director, CDC, regarding the early detection and control of breast and cervical cancer. The committee makes recommendations regarding national program goals and objectives; implementation strategies; program priorities, including surveillance, epidemiologic investigations, education and training, information dissemination, professional interactions and collaborations, and policy.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives. The Secretary, HHS, acting through the Director, CDC, shall appoint to the advisory committee nominees with expertise in breast cancer, cervical cancer, medicine, public health, behavioral science, epidemiology, radiology, pathology, clinical medical care, health education, and surveillance. Two members may be representatives of the general public with personal experience in issues related to breast or cervical cancer early detection and control. Members may be invited to serve for up to four years.

The next cycle of selection of candidates will conclude in the Fall of 2015, for selection of potential nominees to replace members whose terms will end on March 31, 2016. Selection of members is based on candidates' qualifications to contribute to the accomplishment of BCCEDCAC objectives (*http://www.cdc.gov/maso/FACM/facmBCCEDCAC.htm*). The U.S. Department of Health and Human Services will give close attention to equitable geographic distribution and to minority and female representation so long as the effectiveness of the Committee is not impaired. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, HIV status, disability, and cultural, religious, or socioeconomic status. Consideration is given to a broad representation of geographic areas within the U.S., with diverse representation of both genders, all ethnic and racial groups, and persons with disabilities. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government.

Candidates should submit the following items:

- Current curriculum vitae or resume, including complete contact information (name, affiliation, mailing address, telephone numbers, fax number, email address)
- A 150 word biography for the nominee;
- At least one letter of recommendation from a person(s) not employed by the U.S. Department of Health and Human Services. Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by HHS.

Nominations should be submitted ((postmarked or received)) by September 25, 2015.

- *Electronic submissions:* You may submit nominations, including attachments, electronically to *bccedcac@cdc.gov*.
- *Regular, Express or Overnight Mail:* Written nominations may be submitted to the following addressee only: Ms. Jameka Reese Blackmon, M.B.A., C.M.P., c/o BCCEDCAC Secretariat, Centers for Disease Control and Prevention, 3719 North Peachtree Road, Bldg. 100 Chamblee, GA 30341. Telephone and facsimile submissions cannot be accepted.

Nominations may be submitted by the candidate or by the person/organization recommending the candidate.

Candidates invited to serve will be asked to submit the ''Executive Branch Confidential Financial Disclosure Report, OGE 450'' for Special Government Employees Serving on Federal Advisory Committees at the Centers for Disease Control and Prevention. This form allows CDC to determine whether there is a conflict of interest between that person's public responsibilities as a Special Government Employee and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal regulation. The form may be viewed and downloaded at *http://www.usoge.gov/forms/oge450_pdf/oge450_accessible.pdf*. This form should not be submitted as part of the nomination.

Contact Person for More Information: Jameka R. Blackmon, MBA, CMP, Designated Federal Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Hwy., NE., Mailstop F76, Atlanta, Georgia, 30341, Telephone (770) 488–4880; Fax (770) 488–4760; Email: *bccedcac@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and the Agency for Toxic Substances and Disease Registry.

Catherine Ramadei,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015–19041 Filed 8–3–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–15–1006; Docket No. CDC–2015–0061]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, 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. This notice invites comment on a proposed information collection extension for the CDC Work@Health® Program: Phase 2 Training and Technical Assistance Evaluation. The Work@Health® Program is a comprehensive workplace training program designed to improve employer knowledge and skills related to effective, science-based workplace health programs, and support the adoption of these programs in the workplace.

DATES: Written comments must be received on or before October 5, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0061 by any of the following methods:

Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov.*

Please note: *All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

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.

Proposed Project

CDC Work@Health® Program: Phase 2 Training and Technical Assistance Evaluation (OMB No. 0920–1006, exp. date 1/31/2016)—Extension—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In the United States, chronic diseases, such as heart disease, obesity, and diabetes are among the leading causes of death and disability. Although chronic diseases are among the most common and costly health problems, they are also among the most preventable. Adopting healthy behaviors—such as eating nutritious foods, being physically active and avoiding tobacco use—can prevent the devastating effects and reduce the rates of these diseases.

Employers are recognizing the role they can play in creating healthy work environments and providing employees with opportunities to make healthy lifestyle choices. To support these efforts, the Centers for Disease Control and Prevention (CDC) developed the Work@Health® Program, a comprehensive worksite health training program which includes the development of a worksite health training curriculum and delivery of training to employers nationwide to improve the health of workers and their families. The Work@Health® Program is authorized by the Public Health Service Act and funded through the Prevention and Public Health Fund of the Patient Protection and Affordable Care Act (ACA). The Work@Health® curriculum uses a problem-solving approach to improve employer knowledge and skills related to effective, science-based workplace health programs, and support the adoption of these programs in the workplace. Topics covered in the Work@Health® curriculum include principles, strategies, and tools for leadership engagement; how to make a business case for workplace health programs; how to assess the needs of organizations and individual employees; how to plan, implement, and evaluate sustainable workplace health programs; and how to partner with community organizations for additional support.

CDC began the full-scale implementation and evaluation of the Work@Health® Program in Winter/Spring 2014 (Work@Health® Program: Phase 2 Training and Technical Assistance Evaluation, OMB No. 0920–1006, exp. date 1/31/2016). During the initial two-year clearance period, the

target number of trainees was 1,200. Information was collected from trainees and employers to support program recruitment, implementation, and evaluation.

CDC is requesting OMB approval to extend information collection for three years. There are no changes to information collection methods or instruments. The target number of new trainees is 1,200. There are minor changes to the burden table as a result of annualizing responses over a three-year period instead of a two-year period. The expansion of the Work@Health® program will foster the creation of far-reaching networks to help develop a sustainable worksite wellness network.

CDC will offer training in four models (formats): (1) A ''Hands-on'' instructor-led workshop model; (2) a self-paced ''Online'' model; (3) a combination or ''Blended'' model; and (4) a ''Train-the-Trainer'' model designed to prepare qualified individuals to train other employers using the Work@Health® curricula. Employers who complete the Hands-on, Online, and Blended model trainings will be invited to participate in peer learning networks and receive technical assistance from coaches to support their efforts to implement or enhance their workplace health programs. Technical assistance will also be provided to the individuals who complete the Train-the-Trainer model to help prepare them to provide the Work@Health® training to employers. Training graduates may be eligible for advanced technical assistance and training from CDC at a later date, through the expanded Work@Health® Advance Program.

To be eligible for the Hands-on, Online, and Blended model trainings, employers must have a minimum of 20 employees, a valid business license, and have been in business for at least one year. In addition, they must offer health insurance to their employees and have at least minimal workplace health program knowledge and experience. Applicants for the Train-the-Trainer model must have previous knowledge, training and experience with workplace health programs and an interest in becoming instructors for the Work@Health® program. They may be referred by employers, health departments, business coalitions, trade associations, or other organizations.

CDC will collect a combination of qualitative and quantitative data elements for analysis. These analyses will be supplemented with interview data collected for approximately six case studies. Outcome evaluation will therefore include a descriptive component as well as statistical models to assess the extent to which the program affected the target outcomes. Employers will be recruited to participate in the Work@Health® training and evaluation scheduled to begin in the Winter of 2016. The training models will be evaluated by assessing the participating employers' changes in readiness to develop or enhance a worksite health program; environmental elements of the physical worksite such as facilities; aggregate employee participation in programs and community partnership activities; and elements of worksite structure, practices, and policies related to health and safety. CDC will also assess trainees' knowledge, attitudes, and behaviors related to worksite health and their reaction to the Work@Health® training, including their satisfaction with the training and opinions about whether it met their needs. CDC will not collect individual-level health data for this project.

Participation is voluntary and 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	Avg. burden per response (in hrs.)	Total burden (in hrs.)
Interested Employer	Employer Application Form	400	1	20/60	133
Employers Participating in Work@Health®.	CDC Worksite Health Scorecard	320	1	30/60	160
	Organizational Assessment	320	1	15/60	80
	Employer Follow-up Survey	160	1	15/60	40
	Case Study Interviews with Senior Leadership.	2	1	1	2
	Case Study Interviews with Employees.	4	1	1	4
Trainees Participating in the Work@Health® Program (Hands-on, Online, Blended models).	Trainee KAB Survey	640	1	20/60	213
	Trainee Reaction Survey—Hands-On Model.	100	1	15/60	25
	Trainee Reaction Survey—Online Model.	120	1	15/60	30
	Trainee Reaction Survey—Blended Model.	100	1	15/60	25
	Trainee Technical Assistance Survey.	640	1	15/60	160
	Case Study Interviews with Selected Trainees.	10	1	1	10
	Trainee Focus Group Discussion Guide.	7	1	1.5	14
Interested Train-the-Trainer Participants.	Train-the-Trainer Application Form	120	1	30/60	60
Trainees Participating in the Work@Health® Program (Train-the-Trainer model).	Train-the-Trainer Participant Survey	80	1	20/60	27
	Trainee Reaction Survey—Train-the-Trainer Model.	40	1	15/60	10
	Train-the-Trainer Trainee Technical Assistance Survey.	80	1	15/60	20

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)	Total burden (in hrs.)
Trainees participating in the Work@Health® Program Wave 2.	Wave 2 Trainee Reaction Survey	200	1	15/60	50
Work@Health® Instructors/Coaches	Instructor/Coach Group Discussion Guide.	7	1	30/60	4
Total	.....	.....	.....	.....	1,064

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. 2015–19042 Filed 8–3–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–224–14]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's 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.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by September 3, 2015.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 or, Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*
3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. The term ''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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Federally Qualified Health Center Cost Report Form; *Use:* Providers of services participating in the Medicare program are required under sections 1815(a) and 1861(v)(1)(A) of the Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. The form CMS–224–14 cost report is needed to determine a provider's reasonable costs incurred in furnishing medical services to Medicare beneficiaries and reimbursement due to or from a provider. *Form Number:* CMS–224–14 (OMB control number 0938—New); *Frequency:* Yearly; *Affected Public:* Private sector—For-profit and Not-for-profit institutions; *Number of Respondents:* 1,296; *Total Annual Responses:* 1,296; *Total Annual Hours:* 75,168. (For policy questions regarding this collection contact Julie Stankivic at 410–786–5725).

Dated: July 30, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–19075 Filed 8–3–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Initial Medical Exam Form and Initial Dental Exam Form.

OMB No.: 0970–NEW.

Description: The Administration for Children and Families' Office of Refugee Resettlement (ORR) places unaccompanied minors in their custody in licensed care provider facilities until reunification with a qualified sponsor. Care provider facilities are required to provide children with services such as

classroom education, mental health services, and health care. Pursuant to Exhibit 1, part A.2 of the *Flores* Settlement Agreement (*Jenny Lisette Flores, et al.,* v. *Janet Reno, Attorney General of the United States, et al.,* Case No. CV 85–4544–RJK (C.D. Cal. 1996), care provider facilities, on behalf of ORR, shall arrange for appropriate routine medical and dental care, family planning services, and emergency health care services, including a complete medical examination (including screening for infectious disease) within 48 hours of admission, excluding weekends and holidays, unless the minor was recently examined at another facility; appropriate immunizations in accordance with the U.S. Public Health Service (PHS), Center for Disease Control; administration of prescribed medication and special diets; appropriate mental health interventions when necessary for each minor in their care.

The forms are to be used as worksheets for clinicians, medical staff, and the health department to compile information that would otherwise have been collected during the initial medical or dental exam. Once completed, the forms will be given to shelter staff for data entry into ORR's electronic data repository known as the 'UAC Portal'. Data will be used to record UC health on admission and for case management of any identified illnesses/conditions.

Respondents: Clinicians, Health Department staff, Office of Refugee Resettlement Grantee staff.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Estimated Respondent Burden for Responding				
Initial Medical Exam Form (including Appendix A: Supplemental TB Screening Form)	150	270	0.17	6,885
Initial Dental Exam Form	150	27	0.08	324

Estimated Total Burden Hours: 7,209.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Estimated Respondent Burden for Recordkeeping				
Initial Medical Exam Form (including Appendix A: Supplemental TB Screening Form)	150	270	0.08	3,240
Initial Dental Exam Form	150	27	0.08	324

Estimated Total Annual Burden 3,564.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–19001 Filed 8–3–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Trafficking Victim Assistance Program Data.

OMB No.: 0970—NEW.

Description: The Trafficking Victims Protection Act of 2000 (TVPA), as amended, authorizes the Secretary of Health and Human Services (HHS) to expand benefits and services to foreign nationals in the United States who are victims of severe forms of trafficking in persons. Such benefits and services may include services to assist potential victims of trafficking. (Section 107(b)(1)(B) of the TVPA, 22 U.S.C. 7105(b)(1)(B)).

The Administration for Children and Families (ACF) intends to award cooperative agreements in fiscal year 2015 to approximately three organizations that will ensure national coverage. The awarded organization must provide comprehensive case management and referrals to qualified persons, either directly through its own organization or by partnering with other organizations through contracts or both.

Persons qualified for services under this grant are victims of a severe form of trafficking in persons who have received certification from HHS; potential victims of a severe form of trafficking who are actively seeking to achieve HHS certification; family members with derivative T visas, and minor dependent children of foreign

victims of severe forms of trafficking in persons or potential victims of trafficking.

To help measure each grant project's performance and the success of the program in assisting participants, to assist grantees to assess and improve their projects over the course of the project period, and to fulfill instructions for a consolidated report to several committees of the House of Representatives, ACF proposes to collect information from TVAP grant project participants through the grantees on a monthly, quarterly, or annual basis, including participant demographics (age, sex, and country of origin), type of trafficking experienced (sex, labor, or both), immigration status during participation, types of health screening and medical services received, the names of the entities providing medical services, and the amount of money expended on each type of medical service provided.

This information will help ACF assess the project's performance in assisting victims of trafficking and will better enable TVAP grantees to meet the program objectives and to monitor and evaluate the quality of case management services provided by any subcontractors. ACF will also include aggregate information in reports to Congress to help inform strategies and policies to assist victims of human trafficking.

Respondents: Individual participants in TVAP projects.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Request for Information	1250	1	.25	312.5

Estimated Total Annual Burden Hours: 312.5.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the Information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, *Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–19035 Filed 8–3–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: 45 CFR 303.7—Provision of Services in Intergovernmental IV–D; Federally Approved Forms.

OMB No.: 0970–0085.

Description: Public Law 104–193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, amended 42 U.S.C. 666 to require State Child Support Enforcement (CSE) agencies to enact the Uniform Interstate Family Support Act (UIFSA) into State law by January 1, 1998. Section 311(b) of UIFSA requires the States to use forms mandated by Federal law. 45 CFR 303.7 also requires child support programs to use federally-approved forms in intergovernmental IV–D cases unless a country has provided alternative forms as a part of its chapter in a Caseworker's Guide to Processing Cases with Foreign Reciprocating Countries.

Respondents: State agencies administering a child support program under title IV–D of the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Transmittal #1—Initial Request	54	19,440	0.17	178,459.20
Transmittal #1—Initial Request Acknowledgement*	54	19,440	0.05	52,488.00
Transmittal #2—Subsequent Action	54	14,580	0.08	62,985.60
Transmittal #3—Request for Assistance/Discovery	54	2,700	0.08	11,664.00
Uniform Support Petition	54	6,480	0.05	17,496.00
General Testimony	54	6,480	0.33	115,473.60
Declaration in Support of Establishing Parentage	54	2,700	0.15	21,870.00
Locate Data Sheet	54	388	0.05	1,047.60
Notice of Determination of Controlling Order	54	54	0.25	729.00
Letter of Transmittal Requesting Registration	54	14,310	0.08	61,819.20
Personal Identifiable Information (PII) Form*	54	37,584	0.05	101,476.80
Request for Change of Support Payment Location Pursuant to UIFSA 319(b)*	54	27,000	0.05	72,900.00
Estimated Total Annual Burden Hours:				698,409.00

*—New Forms

In compliance with the requirements of Section 506(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: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–18987 Filed 8–3–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2390]

Evidentiary Considerations for Integration of Biomarkers in Drug Development; Notice of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the University of Maryland's Center of Excellence in Regulatory Science and Innovation and the Critical Path Institute, is announcing a public workshop entitled ''Evidentiary Considerations for Integration of Biomarkers in Drug Development.'' The purpose of the meeting is to discuss current scientific approaches to biomarker development, acceptance, and utility in drug and biologic (hereafter referred to as therapeutic product) development programs.

DATES: The meeting will be held on August 21, 2015, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the University of Maryland, Pharmacy Hall, 20 North Pine St., Baltimore, MD 21201. For additional travel and hotel information, please refer to *www.pharmacy.umaryland.edu/cersibiomarkers.* (FDA has verified the Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**).

FOR FURTHER INFORMATION CONTACT: Ann Anonsen, University of Maryland, Fischell Dept. of Bioengineering, 2207 Jeong H. Kim Bldg., College Park, MD 20742, 301–405–0285, FAX: 304–405–9953, *aanonsen@umd.edu.*

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this public workshop is to facilitate a unique opportunity for relevant stakeholders from industry, academia, and FDA to discuss biomarker development and provide a framework for evidentiary considerations required for biomarker qualification. The objective of the workshop is to discuss evidentiary considerations for use of clinical safety and enrichment biomarkers in drug development.

A. Registration

There is a registration fee to attend this meeting. The registration fee is charged to help defray the costs for facilities, materials, and food. Seats are limited, and registration will be on a first-come, first-served basis.

To register, please complete registration online at *http://www.pharmacy.umaryland.edu/cersibiomarkers.* (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**). The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representatives	$50
Charitable Nonprofit/Academic	50
Government	0

B. Accommodations

Attendees are responsible for their own hotel accommodations. If you need special accommodations due to a disability, please contact Ann Anonsen (see **FOR FURTHER INFORMATION CONTACT**).

II. Comments

Interested persons may submit electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify all comments with the corresponding 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: July 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–19037 Filed 8–3–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[Funding Announcement Number: HHS–2016–IHS–SDPI–0001; Catalog of Federal Domestic Assistance Number: 93.237]

Special Diabetes Program for Indians; Community-Directed Grant Program; Announcement Type: New and Competing Continuation

Key Dates

Application Deadline Date: October 7, 2015.

Review Date: October 19–November 6, 2015.

Earliest Anticipated Start Date: January 1, 2016.

Signed Tribal Resolution(s) Due Date: October 16, 2015.

Proof of Non-Profit Status Due Date: October 7, 2015.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Special Diabetes Program for Indians (SDPI) is accepting new and competing continuation cooperative agreement applications for the Community-Directed Grant Program. This program is authorized by Section 330C of the Public Health Service Act, codified at 42 U.S.C. 254c–3, as amended, and by the Snyder Act, 25 U.S.C. 13. This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.237.

Background

Diabetes is a complex and costly chronic disease that requires tremendous long-term efforts to prevent and treat. Although diabetes is a nationwide public health problem, American Indian/Alaska Native (AI/AN) people are disproportionately affected. In 2012, 15.9% of AI/AN people aged 20 years or older had diagnosed diabetes, compared to 7.6% of non-Hispanic white people [CDC, 2014 (*http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf*)]. In addition, AI/AN people have higher rates of diabetes-related morbidity and mortality than the general U.S. population [O'Connell, 2012 (*http://care.diabetesjournals.org/content/33/7/1463.full?sid=f3c75e2c-5b22-479b-ac82-6e96b5f7576c*); Cho, 2014 (*http://ajph.aphapublications.org/doi/full/10.2105/AJPH.2014.301968*)]. Strategies to address the prevention and treatment of diabetes in AI/AN communities are urgently needed.

In response to the burgeoning diabetes epidemic among AI/AN people, Congress established the SDPI through the Balanced Budget Act of 1997. SDPI is a $150 million per year program that provides grants for diabetes treatment and prevention services. SDPI is administered by IHS, with programmatic oversight provided by the IHS Division of Diabetes Treatment and Prevention (Division of Diabetes).

Over 330 programs have received SDPI Community-Directed grants annually since 1998. A Congressional re-authorization in 2015 extended SDPI through FY 2017.

Purpose

The purpose of this IHS cooperative agreement is to provide diabetes treatment and/or prevention activities and/or services (also referred to as ''activities/services'') for AI/AN communities. Grantees will implement one SDPI Diabetes Best Practice (also referred to as ''Best Practice'') and report data on its Required Key Measure. Grantees may also implement other activities/services based on diabetes-related community needs and develop an evaluation plan. Activities/services will be aimed at reducing the risk of diabetes in at-risk individuals, providing high quality care to those with diagnosed diabetes, and/or reducing the complications of diabetes.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for fiscal year (FY) 2016 is approximately $130.2 million. Individual award amounts are anticipated to be between $12,500 and $6.5 million with an average award amount of approximately $300,000.

The funding formula which determines the funds available to each IHS area has been determined through Tribal consultation. Within each area, grantee Tribes provide input on the formula which determines the amount of funding available for each successful applicant.

- Current SDPI Community-Directed grantees should budget for the same amount as they received in FY 2015. However, funding amounts may change. See the paragraph below for additional information.
- New SDPI Community-Directed grant applicants should apply for a $12,500 base amount.

The amount of funding available for competing and continuation awards issued under this announcement are subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 325–450 awards will be issued under this program announcement.

Project Period

January 1, 2016 to December 31, 2020.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as a grant. The funding agency (IHS) is required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both IHS and the grantee. IHS will be responsible for activities listed under section A and the grantee will be responsible for activities listed under section B as stated:

Substantial Involvement Description for Cooperative Agreement

A. IHS Involvement

1. IHS Division of Diabetes Treatment and Prevention (Division of Diabetes): The Division of Diabetes will provide general programmatic oversight, coordination, leadership, and resources. Detailed responsibilities include:

a. Communication and technical assistance

i. Maintain a Community-Directed grantee email list and provide updates and announcements via email.

ii. Maintain and update the Division of Diabetes Web site: *www.diabetes.ihs.gov*

iii. Maintain and update SDPI Community-Directed Grant Program Web pages (*http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=sdpi_hub*), which provide information and resources regarding the cooperative agreement, including:

(1) Information sessions—Recorded webinars available to view on demand and provide a review of the programmatic Terms and Conditions and overview of application or report-specific resources.

(2) Frequently Asked Questions (FAQs)—Updated annually, this Web page provides answers to common questions about SDPI Community-Directed grants.

(3) Additional resources—Documents and links from the Division of Diabetes and the Division of Grants Management (DGM).

(4) New to SDPI—Provides information for new grantees and/or staff.

b. Provide Question and Answer (Q&A) Sessions: The Division of Diabetes will hold regular Q&A sessions regarding application and report processes via live webinars. Sessions will be held regularly one month before the due date for each application and report. These sessions will provide the following:

i. Review of programmatic Terms and Conditions.

ii. Overview of report or application instructions, templates and resources.

iii. Opportunity for attendees to ask questions.

c. Create and provide instructions and templates for the Semi-Annual and Annual Progress Reports.

d. Create and provide instructions and Project Narrative template(s) for continuation applications.

e. Maintain and update the SDPI Diabetes Best Practices.

f. Provide resources, tools, support, and training for facilities to conduct IHS Diabetes Care and Outcomes Audits.

g. Create and provide support for the SDPI Outcomes System (SOS) which grantees will use to track and report on Required Key Measure (RKM) data.

h. Establish SDPI grantee training requirements.

i. Provide or coordinate SDPI grantee training sessions and record them.

2. Area Diabetes Consultant (ADC): Diabetes expert located in each IHS area with the following responsibilities:

a. Serves as the project officer for the SDPI Community-Directed Grant Programs in their IHS area. The project officer is a federal program staff person who is responsible for managing and monitoring the progress of grantees.

b. Serves as a liaison between the SDPI grant programs, Division of Diabetes, and DGM.

c. Helps coordinate an extensive Indian health system diabetes network to facilitate information flow between local and national levels.

d. Provides diabetes training and resources to health care and wellness professionals and paraprofessionals in the Indian health system.

e. Works with the Division of Diabetes to translate and disseminate the latest scientific findings on diabetes treatment and prevention to AI/AN communities.

3. IHS Division of Grants Management: Official grants management office. Provides complete monitoring and oversight for all financial business management and administration for the life cycle of the grant award. First contact for all financial grants operations and policy requirements for compliance of the grant award terms and conditions. Contact office for the Grants Management Specialist (GMS), Grants Management Officer, Chief Grants Management Officer and Acting Director of Grants Management Operations and Policy. Works on a daily basis with all grants award recipients to provide guidance on all grants management questions and concerns.

B. Grantee Cooperative Agreement Award Activities

All awardees (grantees) will need to meet the following requirements. All requirements, including these programmatic requirements, will also be provided as an attachment in the Notice of Award.

1. Diabetes Treatment and Prevention Activities and Services: Grantees must provide activities/services that:

a. Meet the purpose of this FOA (see section I above) which is to provide diabetes treatment and/or prevention services and activities/services for AI/AN communities.

b. Are targeted at reducing risk factors for diabetes and related conditions.

c. Address diabetes-related issues as identified in the grantee's needs assessment.

d. Implement a selected Best Practice and its RKM (see item 2 directly below).

e. Utilize SDPI funds as outlined in the grantee's Budget Narrative.

2. SDPI Diabetes Best Practices (Best Practices): The Best Practices (*http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=programsSDPIcommunityDirectedApp*) were updated for FY 2016 to include the latest scientific findings and recommendations. Grantees must select one Best Practice and implement activities/services aimed at improving the RKM from their selected Best Practice. Grantees will report on RKM data via the SDPI Outcomes System.

3. SDPI Outcomes System (SOS): Data for the RKM will be reported using the new SOS. Grantees will enter results for the RKM for their selected Best Practice into this system at the start and end of the budget period, with the option to enter more frequently. The system will generate reports of these results to meet the SDPI outcomes reporting requirements. These results will be stored in the system and accessible to program staff as needed. Grantees will need to appoint at least one person in their program to get access to and add RKM data into the SOS.

4. IHS Diabetes Care and Outcomes Audit (Diabetes Audit): SDPI Community-Directed grantees are required to participate in the Annual Diabetes Audit (*http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=resourcesAudit*). Grantees must review the results and submit a copy of the Annual Diabetes Audit Report with their continuation applications. Non-clinical or community-based grantees that are not able to directly participate in the Diabetes Audit will need to acquire a copy of the Annual Diabetes Audit Report from their local facility or ADC.

5. Collaboration: Grantee must agree to:

a. Consult with and accept guidance from the Division of Diabetes, the DGM, and their ADC/Federal project officer(s) and/or designated assignee(s). In addition, sub-grantees must agree to consult with and accept guidance from their primary grantee.

b. Respond promptly to requests for information.

c. Attend required meetings and trainings.

d. Provide short presentations on their processes and successes, as requested.

e. Keep the above entities (see item a. above) informed of emerging issues, developments, and challenges that may affect the grantee's ability to comply with the grant Terms and Conditions and/or any requirements.

6. Program Coordinator: Grantees must have an officially approved (by the IHS project officer) program coordinator with the following qualifications:

a. Relevant health or wellness education and/or experience.

b. Experience with grant program management, including skills in program coordination, budgeting, reporting, and supervision of staff.

c. Working knowledge of diabetes.

The program coordinator will also be the primary email contact to entities listed in item B.5. above under ''Collaboration.'' All SDPI grant program staff should be routinely updated by the program coordinator with information and requirements related to their program's activities/services.

7. Hardware/software requirements: The hardware and software items listed below are required in order for grantees to access application and report materials, Web sites, and training forums relevant to this grant:

a. Desktop or laptop computer (recommended: Purchased in 2010 or later).

b. Internet access (recommended: High speed).

c. Internet browser software (recommended: Microsoft® Internet Explorer, version 10.0 or higher).

d. Adobe software compatibility for using Grants.gov. For more information: *http://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html*

e. Adobe Connect webinar capability. For more information: *https://na1cps.adobeconnect.com/common/help/en/support/meeting_test.htm*

In addition to the requirements above, it is recommended that grantees have Microsoft Office software, version 2010 or higher.

8. Semi-Annual Progress Report: Grantees must adhere to reporting

requirements as specified by grants policy. See section VI.4 for details. In addition, a programmatic Semi-Annual Progress Report will be required in the middle of the grantee's budget period. Details, instructions, and a report template will be made available on the following Web page: *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=programsSDPIcommunityDirectedMidReportingReq*

9. Required Trainings: Grantees must participate in SDPI required trainings offered by the Division of Diabetes. Training sessions will be primarily live webinars that will be recorded for those not able to attend the live sessions. Grantees will be expected to:

a. Participate in interactive discussion or chats during conference calls or webinars.

b. Share activities, tools, and results.

c. Share problems encountered and how barriers are overcome.

d. Keep track of participation whether live or recorded.

The SDPI grantee training requirements will be provided on the following Division of Diabetes Web page: *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=programsSDPIcommunityDirectedTraining*

10. Grantees that propose sub-grantees: A sub-grantee is an entity that has an arrangement between a primary grantee institution and one or more participating institutions in support of a project. Primary grantee responsibilities include:

a. Providing oversight and coordination to ensure sub-grantees adhere to the grant requirements as listed in this cooperative agreement.

b. Serving as a liaison between the sub-grantees and the entities provided in item 5.a. above.

I. Eligibility Information

1. Eligibility

To be eligible for this ''New/Competing Continuation Announcement'' under this cooperative agreement announcement, applicants must be one of the following:

i. A Federally-recognized Indian Tribe as defined by 25 U.S.C. 1603(14), operating an Indian health program operated pursuant to a contract, grant, cooperative agreement, or compact with IHS pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), (Pub. L. 93–638).

ii. A Tribal organization as defined by 25 U.S.C. 1603(26), operating an Indian health program operated pursuant to a contract, grant, cooperative agreement, or compact with the IHS pursuant to the ISDEAA, (Pub. L. 93–638).

iii. An urban Indian organization, as defined by 25 U.S.C. 1603(29), operating a Title V urban Indian health program that currently has a grant or contract with the IHS under Title V of the Indian Health Care Improvement Act, (Pub. L. 93–437). Applicants must provide proof of non-profit status with the application, *e.g.* 501(c)(3).

iv. Indian Health Service facilities: Under this announcement, only one SDPI Community-Directed diabetes grant will be awarded per entity. If a Tribe submits an application, their local IHS facility cannot apply; if the Tribe does not submit an application, the IHS facility can apply. Tribes that are awarded grant funds may sub-contract with local IHS facilities to provide specific clinical services. In this case, the Tribe would be the primary SDPI grantee and the Federal entity would have a sub-contract within the Tribe's SDPI grant.

Current SDPI Community-Directed grantees are eligible to apply for competing continuation funding under this announcement and must demonstrate that they have complied with previous terms and conditions of the SDPI grant in order to receive funding under this announcement.

Note: Please refer to section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

If application budgets exceed the highest dollar amount outlined under the ''Estimated Funds Available'' section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the DGM of this decision.

Documentation of Support

Tribes and Tribal organizations

These entities must submit documentation of support *from each* of the Indian Tribes served by the project. This documentation of support must be either of the following for each Tribe served:

1. *Tribal Resolution:* Tribes and Tribal organizations should submit an official signed Tribal resolution from each of the Indian Tribes served by the project. Applications by Tribal organizations will not require a specific Tribal resolution if the current Tribal resolution(s) under which they operate would encompass the proposed grant activities/services.

Official signed Tribal resolution(s) should be submitted along with the electronic application submission by the Application Deadline Date (see Key Dates). If an official signed Tribal resolution is not available by the Application Deadline Date, a draft Tribal resolution(s) should be submitted along with the electronic application submission by the Application Deadline Date. Then, the official signed Tribal resolution(s) must be received by the Signed Tribal Resolution(s) Due Date (see Key Dates); otherwise, the application will be considered incomplete and ineligible.

2. *Letter of Support:* If it is not possible to obtain a signed official Tribal resolution by the Signed Tribal Resolution(s) Due Date for a Tribe served by the project, then a letter of support signed by a senior Tribal official may be submitted instead of a Tribal resolution for that Tribe. Letter(s) of support must be submitted along with the electronic application submission by the Application Deadline Date (see Key Dates).

Title V Urban Indian Health Programs

These entities must submit a letter of support from their organization's board of directors.

IHS Hospitals and Clinics

These entities must submit a letter of support from their chief executive officer. In addition, letter(s) of support from Tribe(s) served by the IHS SDPI program are highly recommended but not required.

Documentation of support as required above must be submitted with the electronic application.

It is highly recommended that all application materials not submitted via grants.gov be sent by a delivery method that includes confirmation of receipt. Materials should be mailed to 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852 (attention to the assigned GMS, see section VII). Please contact the assigned GMS by telephone prior to the Review Date (see Key Dates) regarding material submission questions.

Proof of Non-Profit Status

Organizations claiming non-profit status must also submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the Application Deadline Date listed under the Key Dates section on the cover page of this announcement.

IHS Diabetes Care and Outcomes Audit

The IHS Diabetes Care and Outcomes Audit is a process to assess care and health outcomes for AI/AN people with diagnosed diabetes. IHS, Tribal, and urban Indian health care facilities nationwide participate in this process each year by auditing medical records for their patients with diabetes. Applicants that are able to must submit copies of their local facility's 2014 and 2015 Annual Diabetes Audit Reports.

1. Most applicants can obtain their 2014 and 2015 Annual Diabetes Audit Reports in one of following ways:

a. Via the WebAudit: *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=resourcesAudit.*

b. By requesting these Reports from their local facility.

c. By requesting these Reports from their ADC: *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=peopleADC Directory.*

2. If the applicant is unable to obtain their local facility's 2014 and 2015 Annual Diabetes Audit Reports, they must provide an explanation in the Project Narrative (Part B).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at *http://www.Grants.gov* or *https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_funding.*

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

The applicant must include the Project Narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
  - SF–424, Application for Federal Assistance.
  - SF–424A, Budget Information—Non-Construction Programs.
  - SF–424B, Assurances—Non-Construction Programs.
- Budget Justification and Narrative (must be single spaced and not exceed five pages). See section IV.2.B for details.
- Project Narrative—a PDF-fillable template will be provided. See section [section IV.2.A] for details and a link to the template.
- 2014 and 2015 Annual Diabetes Audit Reports or an explanation as to why these reports cannot be submitted. See section III.3 for details.
- Tribal Resolution(s) (Tribes and/or Tribal organizations). See section III.3 for details.
- Letter(s) of Support (See section III.3) from one of the following:
  - Board of Directors (Title V urban Indian health programs).
  - Chief Executive Officer (IHS facilities).
  - Tribes served (highly recommended for IHS facilities)
- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all Key Personnel.
- Key contacts form for diabetes program coordinator.
- Contractor/Consultant resumes or qualifications and scope of work (if applicable).
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (not applicable to IHS facilities).
- Organizational chart or written information that shows where the SDPI Program fits into the larger organization.
- Documentation of current Office of Management and Budget (OMB) A–133 required Financial Audit or other required audit for FY 2014 (not applicable to IHS facilities).

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
- Face sheets from audit reports. These can be found on the FAC Web site: *http://harvester.census.gov/sac/dissem/accessoptions.html?submit=Go+To+Database.*

Mandatory Documents for Programs That Propose Sub-Grantees

A sub-grantee is an entity that has an arrangement between a grantee institution and one or more participating institutions in support of a project.

A complete application package including all mandatory documents listed above must be completed, signed, and submitted to the primary grantee to be included in their application in response to this announcement. Sub-grantees cannot submit applications directly to Grants.gov.

The primary grantee's application must reflect the total budget for the entire cost of the project. Total budget for the sub-grantees should be accounted for under the contractual/consultant category.

Mandatory Documents for Programs That Propose Sub-Contracts With Local IHS Facilities

A sub-contract is between two entities to provide services or supplies. Programs that propose sub-contracts with IHS facilities to provide clinical services must submit a separate budget for the sub-contract, but the grantee's application must reflect the total budget for the entire cost of the project.

While not required for this grant application, it is highly recommended that the grantee obtain a Memorandum of Agreement that is signed by the grantee, the IHS facility, the IHS area director, and the Tribal chairperson.

Public Policy Requirements

All Federal-wide public policies apply to organizations that receive IHS grants and cooperative agreements with exception of the Discrimination policy: *http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html.*

Requirements for Project and Budget Narratives

A. Project Narrative: This narrative will be provided using a PDF fillable template that will be available on the SDPI Community-Directed Application Web page at *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=programsSDPIcommunityDirectedApp.*

Be sure to answer succinctly all applicable questions in the Project Narrative, being mindful of the evaluation criteria (see section V.1). The Project Narrative will provide reviewers with critical information about the applicant's resources, capabilities, and proposed activities/services.

There are seven parts to the Project Narrative:

1. Part A—Program Identifiers
2. Part B—Needs Assessment
3. Part C—Program Support
4. Part D—SDPI Diabetes Best Practice
5. Part E—Activities/Services not related to selected Best Practice (Optional)
6. Part F—Additional Information

B. Budget Narrative: The Budget Narrative provides additional explanation to support the information provided on the SF–424A (Budget

Information for Non-Construction Programs). The Budget Narrative consists of two parts:

(1) Budget Line Items.

(2) Budget Justification that provides a brief justification for each budget item, including why it is necessary and relevant to the proposed project and how it supports project activities/services.

The Budget Narrative must include a line item budget with a justification for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the Project Narrative. Budget should match the scope of work described in the Project Narrative. The page limitation should not exceed five pages.

The list of budget categories and items below is provided for ideas about what might be included in the budget. The applicant does not need to include all the categories and items below and may include others not listed. The budget is specific to the applicant's program, objectives, and activities/services. A sample Budget Narrative is also provided in Appendix 2.

A. Personnel

For each position to be funded by the grant, including program coordinator and others, provide the information below. Include ''in-kind'' positions if applicable.

- Position name.
- Individual's name or enter ''To be named.''
- Brief description of role and/or responsibilities.
- Percentage of annual salary that will be paid for by SDPI funds OR hourly rate and hours worked per year that will be paid for by SDPI funds.

B. Fringe Benefits

List the fringe rate for each position separately. DO NOT list a lump sum fringe benefit amount for all personnel combined.

C. Travel and Training

- Staff travel necessary to provide project activities/services.
- Staff travel to meetings planned during budget period.
- Staff travel for training as needed to provide services related to goals and objectives of the grant, such as continuing clinical education courses, IHS SDPI Meetings, etc.

D. Equipment

- Capital Equipment—Tangible property having a useful life of more than one year and acquisition cost which equals or exceeds $5,000 per item.

E. Supplies

- General office supplies.
- Computers.
- Software purchases or upgrades and other computer supplies.
- Supplies needed for activities/services related to the project.
- File/storage cabinets.

F. Contractual/Consultant

May include partners, collaborators, and/or technical assistance consultants procured to help with project activities/services. Include direct costs and indirect costs for any subcontracts.

G. Alterations and Renovations (A&R)

Major A&R exceeding $150,000 is not allowable under this project without prior approval from the program office.

H. Other

- Participant incentives—list all types of incentives and specify amount per item. See the IHS Grant Programs Incentive Policy at *http://www.ihs.gov/IHM/index.cfm?module=dsp_ihm_circ_main&circ=ihm_circ_0506* for more information including restrictions.
- Marketing, advertising, and promotional items.
- Internet access.
- Medications and lab tests—be specific; list all medications and lab tests.
- Miscellaneous services: rent, telephone, conference calls, computer support, shipping, copying, printing, and equipment maintenance.

I. Indirect Costs

Line item consists of facilities and administrative cost (include IDC agreement computation)

3. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by 11:59 p.m. Eastern Daylight Time (EDT) on the application deadline date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. Grants.gov will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact Grants.gov Customer Support via email to *support@grants.gov* or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Paul Gettys (*Paul.Gettys@ihs.gov*), DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a Grants.gov tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

If the applicant needs to submit a paper application instead of submitting electronically through Grants.gov, a waiver must be requested. Prior approval must be requested and obtained from Ms. Tammy Bagley, Acting Director of DGM, (see Section IV.6 below for additional information). The waiver must: (1) Be documented in writing (emails are acceptable), *before* submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process. A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Tammy.Bagley@ihs.gov.* Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval *must* be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Acting Director of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the application deadline date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant/cooperative agreement will be awarded per applicant.
- IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the *http://www.Grants.gov* Web site to submit an application electronically and select the

''Find Grant Opportunities'' link on the homepage. Download a copy of the application package, complete it offline, and then upload and submit the completed application via the *http://www.Grants.gov* Web site. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

If the applicant receives a waiver to submit paper application documents, they must follow the rules and timelines that are noted above. The applicant must seek assistance at least ten days prior to the application deadline date listed in the Key Dates section on page one of this announcement.

Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or *http://www.Grants.gov* registration or that fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in *http://www.Grants.gov* by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact Grants.gov Support directly at: *support@grants.gov* or (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting Grants.gov, note the tracking number provided as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver to submit paper application documents from the agency must be obtained.
- If it is determined that a waiver is needed, the applicant must submit a request in writing (emails are acceptable) to *GrantsPolicy@ihs.gov* with a copy to *Tammy.Bagley@ihs.gov.* Please include a clear justification for the need to deviate from the standard electronic submission process.
- If the waiver is approved, the application should be sent directly to the DGM by the application deadline date listed in the Key Dates section on page one of this announcement.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through Grants.gov, as the registration process for SAM and Grants.gov could take up to fifteen working days.
- Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this Funding Announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. DGM will download the application from Grants.gov and provide necessary copies to the appropriate agency officials. Neither DGM nor the Division of Diabetes will notify the applicant that the application has been received.
- Email applications will not be accepted under this announcement.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access it through *http://fedgov.dnb.com/webform,* or to expedite the process, call (866) 705–5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended (''Transparency Act''), to report information on subawards. Accordingly, all IHS grantees must notify potential first-tier subrecipients that no entity may receive a first-tier subaward unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that were not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at *https://www.sam.gov* (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with the SAM is free of charge. Applicants may register online at *https://www.sam.gov.*

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy Web site: *https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics.*

V. Application Review Information

The evaluation criteria for reviewing and scoring the application are provided below. Weights assigned to each section are noted in parentheses. Ensure that this Project Narrative and other submitted application documents provide a clear and complete, but succinct, overview of your program. Anticipate that reviewers know nothing about your program and little about IHS and Tribal systems. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 60 points is required for funding. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (15 Points)

(i) Program Identifiers (Project Narrative Part A)

(1) Was the Project Narrative Template used?

(2) Was program identifier information adequately completed?

(3) Was an appropriate abstract provided?

(ii) Needs Assessment (Project Narrative Part B)

(1) Did the applicant adequately describe the key diabetes-related health issues identified by their community/leadership?

(2) Were numbers provided for applicant's local user population and people with diagnosed diabetes?

(3) Was the 2014 Annual Diabetes Audit Report provided? If not, was an adequate statement included regarding why it was not provided?

(4) Was the 2015 Annual Diabetes Audit Report provided? If not, was an adequate statement included regarding why it was not provided?

(5) Did the applicant appropriately identify Diabetes Audit items (or diabetes-related issues if Audit Reports

were not provided) that need to be improved?

(6) Did the applicant adequately describe how they will address the Diabetes Audit items or diabetes-related issues that need to be improved?

(7) Did the applicant adequately describe challenges?

B. Project Objective(s), Work Plan and Approach (30 Points)

(iii) SDPI Diabetes Best Practice (Project Narrative Part D)

(1) Did the applicant provide an adequate description of activities/services to improve the RKM?

(2) Are the activities/services proposed appropriate for the selected Best Practice and Target Group?

(3) Are the planned activities/services realistic given the constraints of timeframe, resources, and staff?

(iv) If Applicable: Activities/Services Not Related to Selected Best Practice (Project Narrative Part E)

(1) Do activities/services address diabetes-related issues identified in the needs assessment in Part B?

(2) Are activities/services aimed at reducing risk factors for diabetes and/or related conditions?

(3) Are activities/services adequately described?

(4) Are the planned activities/services realistic given the constraints of timeframe, resources, and staff?

C. Program Evaluation (15 Points)

(v) SDPI Diabetes Best Practice (Project Narrative Part D)

(1) Was one Best Practice selected?

(2) Was the number of patients/participants in the Target Group provided?

(3) Was the Target Group adequately described?

(4) Are the Target Group and number of patients/participants appropriate given the information the applicant provided in their needs assessment and program resources sections?

(vi) If Applicable: Activities/Services Not Related to Selected Best Practice (Project Narrative Part E)

(1) Was an appropriate target group identified for each activity/service?

(2) Did the applicant specify how improvement and reduction in risk factors will be evaluated?

D. Organizational Capabilities, Key Personnel, and Qualifications (20 Points)

(vii) Program Support (Project Narrative Part C)

(1) Was a completed Key Contact form submitted for the program coordinator?

(2) Were appropriate biographical sketches, resumes, or curricula vitae provided for all key personnel?

(3) Was an appropriate organizational chart or description provided?

(4) Were appropriate Tribal Resolution(s) and/or Letter(s) of Support provided?

(5) Did the applicant identify at least one organization administrator or Tribal leader, other than the Program Coordinator, to support their SDPI program?

(6) Did the applicant describe how this leader will be involved with the SDPI Community-Directed grant program?

(7) Did the applicant provide appropriate and adequate information about key personnel in the Project Narrative?

(8) Did the applicant provide appropriate and adequate information about partnerships and collaborations in the Project Narrative?

(viii) Additional Information (Project Narrative Part F)

(1) Did the applicant adequately complete this part of the Project Narrative?

E. Categorical Budget and Budget Justification (20 Points)

(i) Does the budget match the scope of work described in the Project Narrative?

(ii) Was each line item adequately specified and justified?

(iii) Was the Budget Narrative within the five-page limit?

(iv) Do funding totals match between the SF–424A, budget line item, and justification?

(v) Is the budget reasonable and realistic?

Additional Documents Can Be Uploaded as Appendix Items in Grants.gov

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants may be notified by DGM, via email, to provide minor missing components (*e.g.,* fiscal audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) is a legally binding document signed by the grants management officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in the following grant system, GrantSolutions (*https://www.grantsolutions.gov*). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period.

Disapproved Applicants

Applicants who receive a score less than the recommended funding level for approval, (60 points), and are deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of the application submitted. The IHS program office will also provide additional contact information as needed to address questions and concerns.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be ''Approved.'' but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2016, the approved but unfunded application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of IHS.

2. Administrative Requirements

Cooperative agreements are administered in accordance with the following regulations, policies, and OMB cost principles:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements HHS Awards, located at 45 CFR Part 75.

C. Grants policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost principles:

Uniform Administrative Requirements for HHS Awards, ''Cost Principles,'' located at 45 CFR part 75, subpart E.

E. Audit requirements:

- Uniform Administrative Requirements for HHS Awards, ''Audit Requirements,'' located at 45 CFR part 75, subpart F.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs (IDC) in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities/services under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *https://rates.psc.gov/* and the Department of Interior (Interior Business Center) *http://www.doi.gov/ibc/services/Indirect_Cost_Services/index.cfm.* For questions regarding the indirect cost policy, please call the GMS listed under ''Agency Contacts'' or the main DGM office at (301) 443–5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities/services. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Reports must be submitted electronically via GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required semi-annually, once during the budget period with a due date to be determined by the Division of Diabetes and once within 90 days after the budget period ends. These reports must include a brief summary of progress to date for the period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final annual report must be submitted within 90 days of expiration of the budget/project period.

For SDPI Community-Directed grant programs, the following programmatic reports will be required:

i. *Semi-Annual Progress Report:* Instructions, templates, and other information will be posted on the Division of Diabetes Web site at *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=programsSDPIcommunityDirectedMidReportingReq.* Report will be submitted by attaching as a ''Grant Note'' in GrantSolutions. The due date will be determined by the Division of Diabetes and will fall within the grant program's budget period.

ii. *Annual Progress Report:* Instructions, template(s), and other information will be posted on the Division of Diabetes Web site at *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=programsSDPIcommunityDirectedReportingReq.* Per DGM policy, the report will be submitted by attaching as a ''Grant Note'' in GrantSolutions within 90 days after the end of the grant program's budget period.

Refer to the SDPI Community-Directed Grant Program Web page (*http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=sdpi_hub*) for the latest information on report templates, due dates, Q&A sessions and submission instructions.

B. Financial Reports

Federal Financial Report FFR (SF–425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at: *http://www.dpm.psc.gov.* It is recommended that the applicant also send a copy of the FFR (SF–425) report to the GMS. Failure to submit timely reports may cause a disruption in timely payments to the organization.

Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report.

Federal Subaward Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000

sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and (2) the primary awardee will have a $25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting. For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy Web site at: *https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics*.

Telecommunication for the hearing impaired is available at: TTY (301) 443–6394.

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to:

- Applicant's Area Diabetes Consultant: *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=peopleADCDirectory.*
- IHS Division of Diabetes Treatment and Prevention, 801 Thompson Avenue, Suite 300, Rockville, MD 20852, Phone: 1–844–IHS–DDTP (1–844–447–3387), Fax: 301–594–6213, Email: *IHSDDTPSDPICommunity@ihs.gov*, Division of Diabetes Web site: *www.diabetes.ihs.gov*.

2. Questions on grants management and fiscal matters may be directed to DGM:

For IHS Areas: Albuquerque, Nashville, Navajo, Phoenix, and Tucson GMS: John Hoffman.

Email: *John.Hoffman@ihs.gov,* phone: 301–443–2116.

For IHS Areas: California, Great Plains, Oklahoma City, and Portland GMS: Cherron Smith.

Email: *Cherron.Smith@ihs.gov,* phone: 301–443–2192.

For IHS Areas: Alaska, Bemidji, and Billings GMS: Patience Musikikongo.

Email: *Patience.Musikikongo@ihs.gov,* phone: 301–443–2059.

For urban programs:

GMS: Pallop Chareonvootitam.

Email: *Pallop.Chareonvootitam@ihs.gov,* phone: 301–443–2195, 801 Thompson Avenue, TMP 360, Rockville, MD 20852, Phone: 301–443–5204, Fax: 301–443–9602.

3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852, Phone: 301–443–2114; or the DGM main line 301–443–5204, Fax: 301–443–9602, Email: *Paul.Gettys@ihs.gov*.

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Pub. L. 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Date: July 28, 2015.

Robert G. McSwain,

Deputy Director, Indian Health Service.

VIII. Appendix 1: Commonly Used Abbreviations

ADC = Area Diabetes Consultant
AI/AN = American Indian/Alaska Native
DGM = Division of Grants Management
FOA = Funding Opportunity Announcement
FY = Fiscal Year
GMS = Grants Management Specialist
HHS = Health and Human Services
IHS = Indian Health Service
NOA/NGA = Notice of (Grant) Award
ORC = Objective Review Committee
PDF = Portable Document Format (Access using Adobe Acrobat Reader or Pro)
RKM = Required Key Measure (Pertains to Best Practice requirement)
SDPI = Special Diabetes Program for Indians
SOS = SDPI Outcomes System

IX. Appendix 2: Sample Budget Narrative

Note: This information is included for sample purposes only. Each program's Budget Narrative must include only their budget items and a justification that is relevant to the program's activities/services.

Line Item Budget—SAMPLE

A. Personnel:	
Program Coordinator	40,000
Administrative Assistant	6,373
CNA/Transporter	6,552
Mental Health Counselor	5,769
Total Personnel	58,694
B. Benefits:	
Program Coordinator	14,000
Administrative Assistant\	2,231
CNA/Transporter	2,293
Mental Health Counselor\	2,019
Total Fringe Benefits	20,543
C. Supplies:	
Desk Top Computers and Software (2)	3,000
Exercise Equipment	3,300
Laptop Computer	1,500
LCD Projector	1,200
Educational/Outreach	3,000
Office Supplies	1,200
Food Supplies for Wellness Luncheons	2,400
Medical Supplies (Clinic)	3,000
Total Supplies	18,600
D. Training and Travel:	
Local Mileage	1,350
Staff Training & Travel—Out of State	2,400
Total Travel	3,750
E. Contractual:	
Fiscal Officer	16,640
Consulting Medical Doctor	14,440
Registered Dietitian/Diabetes Educator	18,720
Exercise Therapist	33,250
Total Contractual	83,050
F. Equipment:	
Heavy Duty Printer/Scanner/Copier	9,000
Total Equipment	9,000
G. Other Direct Costs:	
Rent	20,805
Utility	4,000
Postage	500
Telephone	2,611
Audit Fees	2,500
Professional Fees	2,400
Insurance Liability	1,593
Office Cleaning	1,680
Storage Fees	240
Biohazard Disposal	154
Marketing/Advertising	2,010
Total Other Direct Costs	38,493
H. Indirect Costs (15%)	$34,819
TOTAL DIRECT COSTS	$232,130
TOTAL DIRECT COST AND INDIRECT COSTS	$266,949

Budget Justification—SAMPLE

A. Personnel: $58,694.00

Program Coordinator: George Smith

A full-time employee responsible for the implementation of the program goals as well as overseeing financial and grant application aspects of the agency.

(100% Annual Salary = $40,000/year)

Administrative Assistant: Susan Brown

A part-time employee responsible for providing assistance to the Program Coordinator.

(416 hours × $15.32/hour = $6,373.12)

CAN/Transporter/Homemaker: To Be Named

A full-time employee working 8 hours per week on this grant providing transportation services and in-home health care to clients.

(416 hours × $15.75/hour = $6,552.00)

Mental Health Counselor: Lisa Green

A part-time employee works 6 hours per week in the ADAPT/Mental Health Program providing counseling and workshops to clients.

(6 hours × 52 weeks × $18.49/hour = $5,768.88)

B. Fringe Benefits: $20,543.00

Fringe benefits are calculated at 35% for both salaried and hourly employees. Fringe is composed of health, dental, life and vision insurance (20%), FICA/Medicare (7.65%), worker's compensation (1.10%), State

unemployment insurance (1.25%), and retirement (5%).

Program Coordinator: $14,000.

Administrative Assistant: $2,230.59.

CAN/Transporter/Homemaker: $2293.20.

Mental Health Coordinator: $2019.11.

C. Supplies: $18,600.00

Desk Top Computers and Software (2)

Needed by our Diabetes Educator, Exercise Specialist, and Medical Director in order to access and update information on client's records. (2 × $1,500.00 = $3,000.00).

Exercise Equipment

Elliptical cross trainer equipment (creates less impact on the knees), body fat analyzer, 8 dumbbell weights, 4 exercise balls, 4 exercise mats, step stretch, adjustable bench, bow flex plates kit, 2 dance pads, ball stacker set, and exercise video. Total for all exercise equipment is $3,300.00.

Laptop Computer

This type of computer is needed to be used in conjunction with the LCD projector that will be used by the Diabetes Educator for presentations. Cost is $1,500.00.

LCD Projector

This equipment will be used by the Diabetes Educator for presentations. Cost is $1,200.00.

Educational & Outreach Supplies

Various printed literature, books, videos, pamphlets, pens, bottled water, little promotional items will be needed to hand out at various health fairs, events, and to various groups to educate and promote health. Funds allocated are $3,000.00.

Office Supplies

General office supplies are essential in order to properly maintain client records, financial records, and all reporting requirements. General office supplies include file folders, labels, writing pads, pens, paper clips, toner, etc. $1,200.00 will be included in this budget.

Supplies for Monthly Wellness Meetings

An allocation of $200.00 has been made towards teaching tools that will be used by the Diabetes Educator during the monthly wellness classes.

($200.00 × 12 months = $2,400.00)

Medical Supplies—Clinic

An allocation has been made for purchasing medical supplies for our clinic such as alcohol wipes, strips for glucometers, paper sheets, gloves, gowns, etc., in the amount of $3,000.00.

D. Training and Travel: $3,750.00

Local Mileage—Mileage for transportation of clients and outreach services. Estimated at 300 miles/month × 12 months × $0.375 = $1,350.00.

Staff Travel & Training—Expenses in this category are associated with attending conference and seminars associated with diabetes for 2 staff: The budget covers the cost of registration fees ($250 × 2 = $500.00), lodging ($175/night × 2 people × 2 days = $700.00), airfare ($450.00 × 2 people = $900.00), per diem allowance ($50.00 × 2 days × 2 people = $200.00), and ground transportation ($25.00 × 2 × 2 people = $100.00). A total of $2,400.00 for staff travel and training.

E. Contractual: $83,050.00

Fiscal Officer

An independent contractor to perform payroll, accounts payable, financial and grant reporting, and budgetary duties.

(416 hours × $40.00 per hour = $16,640.00)

Consulting Medical Doctor

A medical doctor is contracted to provide medical care to our clients with diabetes.

(12 hours per month × 12 mos. × $100.00 per hour = $14,400.00)

Registered Dietitian/Diabetes Educator

A Registered Dietitian/diabetes educator is contracted to provide diabetes related meal planning and instruction and facilitate one-on-one consultation with clients.

(8 hours per week × 52 weeks × $45 per hour = $18,720.00)

Exercise Specialist

An exercise specialist is contracted to conduct and monitor the exercise program necessary for each client.

(950 hours × $35 per hour = $33,250.00)

F. Equipment: $9,000.00

Heavy Duty Printer/Scanner/Copier

High Performance, high volume printer/scanner/copier to produce materials for diabetes wellness classes. $9,000.00

G. Other Direct Costs: $38,493.00

Rent

This program rents two office locations for a total cost of $83,220.00 per year. Special Diabetes grant program will cover $20,805.00 which is 25% of the rent cost.

Utility

This program will cover 25% of the total utility cost of $16,000.00 per year.

($16,000.00 × 25% = $4,000.00)

Postage

The Diabetes Program postage is estimated at $500.00.

Telephone

This program currently has eight telephone lines at two separate offices as well as pager service and a toll-free number for clients. Diabetes Program will cover $2,611.00 of this expense which is 25% of the annual cost of $10,445.00.

Audit Fees

An annual audit is conducted for this program's financial statements. Funding agencies require audit financial statements of grant funds. Diabetes will cover $2,500.00 of audit expenses which is 25% of the $10,000.00 proposal.

Professional Fees

A computer consultant is needed to fix computer problems. $200.00 per month × 12 mos. = $2,400.00 will cover the expenses.

Insurance Liability

General liability insurance is required to protect the organization against fire and property damage. Diabetes portion of this expense is $1,593.00.

Office Cleaning

Office cleanings are required to keep the agency clean. Diabetes will cover 20% of the contract cost of $8,400.00 = $1,680.00.

Storage Fees

This program stores its records in a storage facility. Diabetes grant will fund $240.00 of this cost.

Biohazard Disposal

A special handling fee for biohazard disposal will cost $154.00 for this program.

Marketing/Advertising

Newspaper advertising will be used to promote Diabetes events. Three (3) ads × $670.00 = $2,010.00

I. Indirect Costs (15%): $34,819

The most recent Indirect Rate Cost Agreement was approved by the Department of the Interior on June 16, 2014. A copy of this agreement is attached separately in the application. The Indirect Rate Cost Agreement for FY2015 will be negotiated after completion of the FY2014 Single Audit.

TOTAL DIRECT COSTS—$232,130.00

TOTAL DIRECT COST AND INDIRECT COSTS—$266,949.00

BILLING CODE 4165–16–P

X. Appendix 3: Sample 2014 Diabetes Audit Report

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2014 (Audit Period 01/01/2013 - 12/31/2013)
Facility: Test02 (known as Test 02 in 2014)

Annual Audit

124 charts were audited from 130 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Gender					
Male	46	124	**37%**	1%	43%
Female	78	124	**63%**	2%	57%
Age					
< 15 years	0	124	**0%**	3%	0%
15-44 years	31	124	**25%**	4%	20%
45-64 years	63	124	**51%**	5%	51%
65 years and older	30	124	**24%**	6%	29%
Diabetes Type					
Type 1	0	124	**0%**	7%	1%
Type 2	124	124	**100%**	8%	99%
Duration of Diabetes					
Less than 1 year	3	124	**2%**	9%	4%
Less than 10 years	54	124	**44%**	10%	47%
10 years or more	69	124	**56%**	11%	40%
Diagnosis date not recorded	1	124	**1%**	12%	13%
Weight Control (BMI)					
Normal (BMI < 25.0)	16	124	**13%**	13%	8%
Overweight (BMI 25.0-29.9)	35	124	**28%**	14%	23%
Obese (BMI 30.0 or above)	73	124	**59%**	15%	67%
Height or weight missing	0	124	**0%**	16%	2%
Blood Sugar Control					
HbA1c < 7.0	20	124	**16%**	17%	36%
HbA1c 7.0-7.9	18	124	**15%**	18%	18%
HbA1c 8.0-8.9	12	124	**10%**	19%	12%
HbA1c 9.0-9.9	19	124	**15%**	20%	9%
HbA1c 10.0-10.9	14	124	**11%**	21%	7%
HbA1c 11.0 or higher	23	124	**19%**	22%	11%
Not tested or no valid result	18	124	**15%**	23%	6%
Mean Blood Pressure (of last 2, or 3 if available)					
<140/<90	79	124	**64%**	24%	67%
140/90 - <160/<95	25	124	**20%**	25%	20%
160/95 or higher	14	124	**11%**	26%	5%
BP category undetermined	6	124	**5%**	75%	8%

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Facility: Test02 (known as Test 02 in 2014)

Annual Audit

124 charts were audited from 130 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Tobacco use					
Current tobacco user	62	124	**50%**	27%	27%
In current users, counseled?					
Yes	46	62	**74%**	28%	62%
No	16	62	**26%**		
Not a current tobacco user	62	124	**50%**	29%	72%
Tobacco use not documented	0	124	**0%**	30%	1%
Diabetes Treatment					
Diet and exercise alone	22	124	**18%**	31%	19%
Diabetes meds currently prescribed, alone or in combination:					
Insulin	47	124	**38%**	32%	33%
Sulfonylurea (glyburide, glipizide, others)	45	124	**36%**	33%	29%
Glinide (Prandin®, Starlix®)	0	124	**0%**	34%	1%
Metformin (Glucophage®, others)	80	124	**65%**	35%	56%
Acarbose (Precose®)/Miglitol (Glyset®)	0	124	**0%**	36%	0%
Pioglitazone (Actos®) or rosiglitazone (Avandia®)	0	124	**0%**	37%	8%
GLP-1 med (Byetta®, Bydureon®, Victoza®)	0	124	**0%**	38%	1%
DPP4 inhibitor (Januvia®, Onglyza®, Tradjenta®)	14	124	**11%**	39%	11%
Amylin analog (Symlin®)	0	124	**0%**	40%	0%
Bromocriptine (Cycloset®)	0	124	**0%**	41%	0%
Colesevelam (Welchol®)	0	124	**0%**	42%	0%
SGLT-2 inhibitor (Invokana®)	0	124	**0%**	43%	0%
Number of diabetes meds currently prescribed:					
One med	40	124	**32%**	44%	38%
Two meds	42	124	**34%**	45%	29%
Three meds	18	124	**15%**	46%	11%
Four or more meds	2	124	**2%**	47%	2%
Ace Inhibitor or ARB Prescribed (See Renal Preservation report for additional info)					
In patients with known hypertension[1]	12	16	**75%**	48%	79%
In patients with increased urine albumin excretion[2]	14	17	**82%**	49%	78%

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	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Aspirin or Other Antiplatelet Therapy Prescribed					
In patients with diagnosed CVD	41	47	**87%**	50%	75%
Lipid Lowering Agent Prescribed					
Single lipid agent	50	124	**40%**	51%	46%
Two or more lipid agents	22	124	**18%**	52%	9%
None	65	124	**52%**	53%	45%
In patients prescribed one or more lipid agents:					
Statin (simvastatin/Zocor®, others)	59	72	**82%**	54%	90%
Statin prescribed in patients with diagnosed CVD:	27	47	**57%**	61%	59%
Fibrate (gemfibrozil/Lopid®, others)	2	72	**3%**	55%	12%
Niacin (Niaspan®, OTC niacin)	4	72	**6%**	56%	3%
Bile Acid Sequestrant (cholestyramine/Questran®, others)	0	72	**0%**	57%	1%
Ezetimibe (Zetia®)	1	72	**1%**	58%	5%
Fish oil	29	72	**40%**	59%	7%
Lovaza®	0	72	**0%**	60%	2%
Exams					
Foot Exam - Neuro & Vasc	77	124	**62%**	62%	59%
Eye Exam - Dilated or Retinal Camera	86	124	**69%**	63%	58%
Dental Exam	42	124	**34%**	64%	40%
Diabetes-Related Education					
Nutrition - by any provider	51	124	**41%**	65%	50%
Nutrition - by RD	39	124	**31%**	66%	23%
Physical activity	90	124	**73%**	67%	54%
Other	90	124	**73%**	68%	65%
Any of above topics	109	124	**88%**	69%	78%
Immunizations					
Flu vaccine during Audit period	70	124	**56%**	70%	62%
Refused - Flu Vaccine	26	124	**21%**	71%	8%
Pneumovax - ever	83	124	**67%**	72%	81%
Refused - Pneumovax	12	124	**10%**	73%	3%
Tetanus/diphtheria - past 10 years	118	124	**95%**	74%	87%
Refused - Tetanus/diphtheria	3	124	**2%**	75%	2%
Hepatitis B 3-dose series complete - ever	22	124	**18%**	76%	22%
Refused - Hepatitis B	2	124	**2%**	77%	1%

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Audit Report for 2014 (Audit Period 01/01/2013 - 12/31/2013)
Facility: Test02 (known as Test 02 in 2014)

Annual Audit

124 charts were audited from 130 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Depression An Active Problem					
Yes	25	124	**20%**	78%	22%
No	99	124	**80%**	79%	78%
In patients without active depression, screened for depression during Audit period:					
Screened	94	99	**95%**	80%	80%
Not screened	5	99	**5%**		
Laboratory Exams					
eGFR to assess kidney function (In age 18 and above)	112	124	**90%**	81%	90%
eGFR ≥60 ml/min	95	124	**77%**	82%	73%
eGFR 30-59 ml/min	14	124	**11%**	83%	14%
eGFR 15-29 ml/min	1	124	**1%**	84%	2%
eGFR <15 ml/min	2	124	**2%**	85%	1%
Not tested or no valid result	12	124	**10%**	86%	10%
Non-HDL cholesterol	64	124	**52%**	87%	77%
Non-HDL <130 mg/dl	25	124	**20%**	88%	46%
Non-HDL 130-159 mg/dl	27	124	**22%**	89%	17%
Non-HDL 160-190 mg/dl	8	124	**6%**	90%	9%
Non-HDL >190 mg/dl	4	124	**3%**	91%	5%
Not tested or no valid result	60	124	**48%**	92%	23%
LDL cholesterol	101	124	**81%**	93%	80%
LDL <100 mg/dl	74	124	**60%**	94%	50%
LDL 100-129 mg/dl	17	124	**14%**	95%	20%
LDL 130-160 mg/dl	7	124	**6%**	96%	7%
LDL >160 mg/dl	3	124	**2%**	97%	3%
Not tested or no valid result	23	124	**19%**	98%	20%
HDL cholesterol	66	124	**53%**	99%	78%
In females					
HDL ≤50 mg/dl	31	78	**40%**	100%	53%
HDL >50 mg/dl	7	78	**9%**	101%	25%
Not tested or no valid result	40	78	**51%**	102%	22%
In males					
HDL ≤40 mg/dl	16	46	**35%**	103%	45%
HDL >40 mg/dl	12	46	**26%**	104%	33%
Not tested or no valid result	18	46	**39%**	105%	22%
Triglycerides	66	124	**53%**	106%	78%
TG ≤400 mg/dl	59	124	**48%**	107%	73%
TG >400 mg/dl	7	124	**6%**	108%	5%
Not tested or no valid result	58	124	**47%**	109%	22%

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2014 (Audit Period 01/01/2013 - 12/31/2013)
Facility: Test02 (known as Test 02 in 2014)

Annual Audit

124 charts were audited from 130 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Laboratory Exams					
Urine Albumin:Creatinine Ratio (UACR)					
Yes	0	124	**0%**	110%	59%
No	0	124	**0%**	111%	41%
In patients with UACR:					
Urine albumin excretion - Normal: <30 mg/g	0	0	**0%**	112%	62%
Urine albumin excretion - Increased:					
30-300 mg/g	0	0	**0%**	113%	29%
>300 mg/g	0	0	**0%**	114%	8%
In patients age 18 and above with eGFR ≥30, UACR done	0	109	**0%**	115%	64%
Cardiovascular Disease					
Diagnosed CVD	47	124	**38%**	116%	33%
Tuberculosis Status					
TB test +, untreated or tx unknown	10	124	**8%**	118%	9%
TB test +, INH treatment complete	27	124	**22%**	117%	2%
TB test -, placed after DM diagnosis	52	124	**42%**	119%	25%
TB test -, placed before DM diagnosis	13	124	**10%**	120%	12%
TB test -, date of DM Dx or TB test date unknown	0	124	**0%**	122%	3%
TB test status unknown	22	124	**18%**	121%	49%
Combined Outcomes Measures					
Records meeting ALL of the following criteria: A1c <8.0, LDL <100, and mean BP <140/<90	16	124	**13%**	123%	22%
In age 18 and above, records with both an eGFR and a UACR	0	124	**0%**	124%	57%

Definitions

[1]Known hypertension: Has hypertension listed as an active problem, or three visits with a diagnosis of hypertension ever (prior to the end of the Audit period).
[2]Increased urine albumin excretion: UACR≥30 mg/g.

Date run: 04/24/2015

Page 5 of 5

XI. Appendix 4: Sample 2015 Diabetes Audit Report

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2015 (Audit Period 01/01/2014 - 12/31/2014)
Facility: Test02

Annual Audit

125 charts were audited from 125 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Gender					
Male	50	125	**40%**	1%	43%
Female	75	125	**60%**	2%	57%
Age					
< 15 years	1	125	**1%**	3%	0%
15-44 years	23	125	**18%**	4%	20%
45-64 years	69	125	**55%**	5%	50%
65 years and older	32	125	**26%**	6%	30%
Diabetes Type					
Type 1	1	125	**1%**	7%	1%
Type 2	124	125	**99%**	8%	99%
Duration of Diabetes					
Less than 1 year	7	125	**6%**	9%	4%
Less than 10 years	56	125	**45%**	10%	48%
10 years or more	67	125	**54%**	11%	40%
Diagnosis date not recorded	2	125	**2%**	12%	12%
BMI Category					
Normal (BMI < 25.0)	6	125	**5%**	13%	8%
Overweight (BMI 25.0-29.9)	23	125	**18%**	14%	22%
Obese (BMI 30.0 or above)	93	125	**74%**	15%	67%
Height or weight missing	3	125	**2%**	16%	3%
Blood Sugar Control					
A1C < 7.0	40	125	**32%**	30%	35%
A1C 7.0-7.9	17	125	**14%**	18%	18%
A1C 8.0-8.9	14	125	**11%**	19%	12%
A1C 9.0-9.9	22	125	**18%**	20%	9%
A1C 10.0-10.9	14	125	**11%**	21%	7%
A1C 11.0 or higher	15	125	**12%**	22%	11%
Not tested or no valid result	3	125	**2%**	23%	8%
Mean Blood Pressure (of last 2, or 3 if available)					
<140/<90	59	125	**47%**	24%	65%
140/90 - <160/<95	39	125	**31%**	25%	21%
160/95 or higher	21	125	**17%**	26%	5%
BP category undetermined	6	125	**5%**	75%	9%

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2015 (Audit Period 01/01/2014 - 12/31/2014)
Facility: Test02

Annual Audit

125 charts were audited from 125 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Gender					
Male	50	125	**40%**	1%	43%
Female	75	125	**60%**	2%	57%
Age					
< 15 years	1	125	**1%**	3%	0%
15-44 years	23	125	**18%**	4%	20%
45-64 years	69	125	**55%**	5%	50%
65 years and older	32	125	**26%**	6%	30%
Diabetes Type					
Type 1	1	125	**1%**	7%	1%
Type 2	124	125	**99%**	8%	99%
Duration of Diabetes					
Less than 1 year	7	125	**6%**	9%	4%
Less than 10 years	56	125	**45%**	10%	48%
10 years or more	67	125	**54%**	11%	40%
Diagnosis date not recorded	2	125	**2%**	12%	12%
BMI Category					
Normal (BMI < 25.0)	6	125	**5%**	13%	8%
Overweight (BMI 25.0-29.9)	23	125	**18%**	14%	22%
Obese (BMI 30.0 or above)	93	125	**74%**	15%	67%
Height or weight missing	3	125	**2%**	16%	3%
Blood Sugar Control					
A1C < 7.0	40	125	**32%**	30%	35%
A1C 7.0-7.9	17	125	**14%**	18%	18%
A1C 8.0-8.9	14	125	**11%**	19%	12%
A1C 9.0-9.9	22	125	**18%**	20%	9%
A1C 10.0-10.9	14	125	**11%**	21%	7%
A1C 11.0 or higher	15	125	**12%**	22%	11%
Not tested or no valid result	3	125	**2%**	23%	8%
Mean Blood Pressure (of last 2, or 3 if available)					
<140/<90	59	125	**47%**	24%	65%
140/90 - <160/<95	39	125	**31%**	25%	21%
160/95 or higher	21	125	**17%**	26%	5%
BP category undetermined	6	125	**5%**	75%	9%

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2015 (Audit Period 01/01/2014 - 12/31/2014)
Facility: Test02

Annual Audit

125 charts were audited from 125 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Ace Inhibitor or ARB Prescribed (See Renal Preservation report for additional info)					
In patients with known hypertension[1]	62	92	**67%**	50%	78%
In patients with increased urine albumin excretion[2]	35	48	**73%**	51%	78%
Aspirin or Other Antiplatelet Therapy Prescribed					
In patients with diagnosed CVD	17	34	**50%**	52%	72%
Statin Prescribed					
Yes	36	125	**29%**	53%	50%
Allergy or intolerant	0	125	**0%**	54%	3%
In patients with diagnosed CVD:					
Yes	10	34	**29%**	55%	58%
Allergy or intolerant	0	34	**0%**	56%	3%
In patients aged 40-75:					
Yes	32	102	**31%**	57%	53%
Allergy or intolerant	0	102	**0%**	58%	3%
Exams					
Foot Exam - Complete	109	125	**87%**	59%	55%
Eye Exam - Dilated or Retinal Camera	98	125	**78%**	60%	55%
Dental Exam	72	125	**58%**	61%	38%
Diabetes-Related Education					
Nutrition - by any provider	115	125	**92%**	62%	50%
Nutrition - by RD	34	125	**27%**	63%	22%
Physical activity	108	125	**86%**	64%	54%
Other	119	125	**95%**	65%	60%
Any of above topics	121	125	**97%**	66%	77%
Immunizations					
Flu vaccine during Audit period	96	125	**77%**	67%	61%
Refused - Flu Vaccine	9	125	**7%**	68%	8%
Pneumovax - ever	118	125	**94%**	69%	81%
Refused - Pneumovax	1	125	**1%**	70%	4%
Tetanus/diphtheria - past 10 years	121	125	**97%**	71%	89%
Refused - Tetanus/diphtheria	1	125	**1%**	72%	1%
Tdap - ever	120	125	**96%**	73%	84%
Refused - Tdap	1	125	**1%**	74%	2%
Hepatitis B 3-dose series complete - ever	73	124	**59%**	75%	25%
Refused - Hepatitis B	9	124	**7%**	76%	2%
Immune - Hepatitis B	1	125	**1%**	77%	1%

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2015 (Audit Period 01/01/2014 - 12/31/2014)
Facility: Test02

Annual Audit

125 charts were audited from 125 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Depression An Active Problem					
Yes	30	125	**24%**	78%	24%
No	95	125	**76%**	79%	76%
In patients without active depression, screened for depression during Audit period:					
Screened	93	95	**98%**	80%	80%
Not screened	2	95	**2%**		
Laboratory Exams					
Non-HDL cholesterol	116	125	**93%**	87%	74%
Non-HDL <130 mg/dl	43	125	**34%**	88%	45%
Non-HDL 130-159 mg/dl	32	125	**26%**	89%	16%
Non-HDL 160-190 mg/dl	22	125	**18%**	90%	8%
Non-HDL >190 mg/dl	19	125	**15%**	91%	5%
Not tested or no valid result	9	125	**7%**	92%	26%
LDL cholesterol	105	125	**84%**	93%	77%
LDL <100 mg/dl	54	125	**43%**	94%	47%
LDL 100-129 mg/dl	30	125	**24%**	95%	19%
LDL 130-160 mg/dl	15	125	**12%**	96%	8%
LDL >160 mg/dl	6	125	**5%**	97%	3%
Not tested or no valid result	20	125	**16%**	98%	23%
HDL cholesterol	116	125	**93%**	99%	75%
In females					
HDL ≤50 mg/dl	53	75	**71%**	100%	50%
HDL >50 mg/dl	17	75	**23%**	101%	25%
Not tested or no valid result	5	75	**7%**	102%	25%
In males					
HDL ≤40 mg/dl	24	50	**48%**	103%	42%
HDL >40 mg/dl	22	50	**44%**	104%	34%
Not tested or no valid result	4	50	**8%**	105%	25%
Triglycerides	116	125	**93%**	106%	75%
TG ≤400 mg/dl	101	125	**81%**	107%	70%
TG >400 mg/dl	15	125	**12%**	108%	5%
Not tested or no valid result	9	125	**7%**	109%	25%
eGFR to assess kidney function (In age 18 and above)	116	124	**94%**	81%	89%
eGFR ≥60 ml/min	94	124	**76%**	82%	72%
eGFR 30-59 ml/min	19	124	**15%**	83%	14%
eGFR 15-29 ml/min	1	124	**1%**	84%	2%
eGFR <15 ml/min	2	124	**2%**	85%	1%
Not tested or no valid result	8	124	**6%**	86%	11%

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2015 (Audit Period 01/01/2014 - 12/31/2014)
Facility: Test02

Annual Audit

125 charts were audited from 125 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Laboratory Exams					
Urine Albumin:Creatinine Ratio (UACR)					
Yes	111	125	**89%**	110%	61%
No	14	125	**11%**	111%	39%
In patients with UACR:					
Urine albumin excretion - Normal: <30 mg/g	63	111	**57%**	112%	63%
Urine albumin excretion - Increased:					
30-300 mg/g	30	111	**27%**	113%	27%
>300 mg/g	18	111	**16%**	114%	9%
In patients age 18 and above with eGFR ≥30, UACR done	108	113	**96%**	115%	68%
Cardiovascular Disease					
Diagnosed CVD	34	125	**27%**	116%	37%
Tuberculosis Status					
TB test done (skin or blood)	102	125	**82%**	117%	49%
If test done, skin test	102	102	**100%**	118%	99%
If test done, blood test	0	102	**0%**	119%	1%
If TB test done, positive result	11	102	**11%**	120%	17%
If positive TB test, treatment completed	2	11	**18%**	121%	25%
If negative TB test, after DM diagnosis	84	91	**92%**	122%	61%
Combined Outcomes Measures					
Patients meeting ALL of the following criteria: A1C <8.0, LDL <100, and mean BP <140/<90	18	125	**14%**	123%	20%
In age 18 and above, patients with both an eGFR and a UACR	109	124	**88%**	124%	59%

Definitions

[1]Known hypertension: Has hypertension listed as an active problem, or three visits with a diagnosis of hypertension ever (prior to the end of the Audit period).
[2]Increased urine albumin excretion: UACR≥30 mg/g.

[FR Doc. 2015–19088 Filed 8–3–15; 8:45 am]
BILLING CODE 4165–16–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Bench to Bassinet Administrative Coordinating Center.

Date: August 25, 2015.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7182, .Bethesda, MD 20892

Contact Person: Susan Wohler Sunnarborg, Ph.D. Scientific Review Officer, Office of Scientific Review/DERA, National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, *sunnarborgsw@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and

Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: July 29, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–19030 Filed 8–3–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases: Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Endocrinology Ancillary Studies.

Date: August 13, 2015.

Time: 4:30 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Maria E. Davila-Bloom, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7637, *davila-bloomm@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Sensitive Obesity.

Date: August 31, 2015.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Biomarkers for TID and Kidney Disease (PAR–13–228: Biomarkers for Diabetes, Digestive and Kidney and Urologic Diseases using Repository Biosamples (R01).

Date: October 1, 2015.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK: Digestive Diseases Program Projects (P01).

Date: October 14, 2015.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR–12–265: NIDDK Ancillary Studies on CKD and Diabetic Nephropathy (R01).

Date: October 15, 2015.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: July 28, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–19026 Filed 8–3–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases: Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: September 9, 2015.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Closed: 3:45 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes And Digestive and Kidney Diseases, 6707 Democracy Blvd. Room 715, Msc 5452, Bethesda, MD 20892, (301) 594–8843, *stanfibr@niddk.nih.gov.*

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Diabetes, Endocrinology and Metabolic Diseases Subcommittee.

Date: September 9, 2015.

Closed: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Open: 2:00 p.m. to 3:30 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes And Digestive and Kidney Diseases, 6707 Democracy Blvd. Room 715, MSC 5452, Bethesda, MD 20892, (301) 594–8843, *stanfibr@niddk.nih.gov.*

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Kidney, Urologic and Hematologic Diseases Subcommittee.

Date: September 9, 2015.

Open: 1:00 p.m. to 3:00 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 7, Bethesda, MD 20892.

Closed: 3:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 7, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes And Digestive and Kidney Diseases, 6707 Democracy Blvd. Room 715, MSC 5452, Bethesda, MD 20892, (301) 594–8843, *stanfibr@niddk.nih.gov.*

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Digestive Diseases and Nutrition Subcommittee.

Date: September 9, 2015.

Open: 1:00 p.m. to 3:00 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Closed: 3:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division Of Extramural Activities, National Institutes of Diabetes And Digestive and Kidney Diseases, 6707 Democracy Blvd. Room 715, MSC 5452, Bethesda, MD 20892 (301) 594–8843, *stanfibr@niddk.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.niddk.nih.gov/fund/divisions/DEA/Council/coundesc.htm.,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: July 29, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–19024 Filed 8–3–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Interferon Alpha Hybrids

Description of Technology: Available for licensing are hybrid interferon alpha (INF-alpha) polypeptides constructed by combinations of INFalpha21b and INFalpha2c, and mutants of these hybrids. These hybrid constructs have resulted in novel IFNs that either combine different biological properties from the parent proteins or have significantly different biological activity from both the parents in anti-proliferative, anti-viral, or competitive binding properties. For instance, the hybrid designated HY–3 has higher anti-proliferative activity in Daudi, WISH, and primary human lymphocyte cells exhibiting approximately 6 times higher anti-proliferative activity than either parent IFN. These IFN hybrids provide a powerful tool for studying the structure-function relationship of these molecules. The engineered IFN-alpha proteins may have important new therapeutic applications and may provide greater insights into understanding of the clinical activities of existing IFN-alphas.

Also available for licensing are hybrid INF-alpha nucleic acids encoding the hybrid polypeptides as well as cells, vectors, pharmaceutical compositions with these nucleic acid sequences.

Potential Commercial Applications

- Anti-viral and cancer therapeutics
- Research tool to study IFN-alpha functions

Competitive Advantages

- Ease of manufacture
- Strong anti-viral activity

Development Stage: In vitro data available.

Inventors: Kathryn C. Zoon (NIAID), Joseph B. Bekisz (NIAID), Mark P. Hayes (FDA), Renqiu Hu (FDA).

Publications

1. Hu R, *et al.* Protein engineering of interferon alphas. Methods Mol Med. 2005;116:69–80. [PMID 16000855]
2. Hu R, *et al.* Human IFN-alpha protein engineering: the amino acid residues at positions 86 and 90 are important for antiproliferative activity. J Immunol. 2001 Aug 1;167(3):1482–9. [PMID 11466368]
3. Hu R, *et al.* Divergence of binding, signaling, and biological responses to recombinant human hybrid IFN. J Immunol. 1999 Jul 15;163(2):854–60. [PMID 10395679]

Intellectual Property: HHS Reference No. E–068–1998/0—

- US Patent No. 6,685,933 issued 03 Feb 2004
- US Patent No. 7,235,232 issued 26 Jun 2007

Licensing Contact: Peter Soukas; 301–435–4646; *ps193c@nih.gov.*

Novel Treatment for Anemia and Polycythemia: AVPR1B Molecules Modulating Erythropoiesis

Description of Technology: Anemia can be caused by chronic diseases, chemotherapy, or radiation. Erythropoietin is commonly used to stimulate red blood cell production for anemia treatment, but it takes about a week to manifest its clinical effect. The

subject invention describes the arginine vasopressin receptor 1B (AVPR1B) stimulatory molecules that can be used to stimulate hematopoietic stem cell proliferation. Preliminary results from animal studies suggest that the number of red blood cells and their precursors significantly increased on day 2 following AVP administration, an onset time much faster than erythropoietin. The AVPR1B stimulatory molecules can be used to jumpstart the system and erythropoietin can be used to sustain the effect. In addition, the AVPR1B inhibitory molecules can be used to suppress hematopoietic stem cell proliferation to treat polycythemia (overproduction of red blood cells).

Potential Commercial Applications

- Treatment of anemia caused by chronic diseases, chemotherapy, or radiation.
- Anemia patients who do not respond to erythropoietin.
- Polycythemia treatment.

Competitive Advantages: AVPR1B stimulatory molecules act faster than the commonly used erythropoietin for anemia treatment.

Development Stage

- Early-stage
- In vivo data available (animal)

Inventors: Eva Mezey and Miklos Krepuska (NIDCR); Balazs Mayer and Krisztian Nemeth (Semmelweis University Medical School)

Intellectual Property: HHS Reference No. E–619–2013/0—

- US Application No. 61/885,258 filed October 01, 2013 (E–619–2013/0–US–01)
- PCT Application No. PCT/US2014/058613 filed October 01, 2014 (E–619–2013/0–PCT–02)

Licensing Contact: Sally Hu, Ph.D., M.B.A.; 301–435–5605; *hus@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Dental and Craniofacial Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize treatment for anemia and polycythemia. For collaboration opportunities, please contact David Bradley, Ph.D. at *bradleyda@nidcr.nih.gov.*

Modified AAV5 Vectors for Enhanced Transduction and Reduced Antibody Neutralization

Description of Technology: Adeno-associated viruses (AAVs) are small nonpathogenic viruses and can integrate into the cellular genome. AAV vectors are among the most frequently used viral vectors for gene therapy because AAV vectors can infect both dividing and non-dividing cells, and can establish long-term transgene expression. Two major issues in gene therapy are the ability to efficiently transduce the target cells and to evade the immune response to vectors. The subject invention describes a mutated AAV serotype 5 by modifying sialic acid binding regions which mediate viral entry into host cells. Preliminary results from animal studies suggest that this modification can increase transduction by 3–4 folds in salivary glands and muscle, and can significantly decrease the potential of being neutralized by preexisting antibodies compared to the wild type. Thus, the modified AAV5 vectors seem to be optimal for gene therapy.

Potential Commercial Applications: Genetically engineered AAV5 vectors for gene therapy.

Competitive Advantages

- Enhanced transduction activity.
- Reduced the potential for being neutralized by preexisting antibodies.

Development Stage

- Early-stage
- In vivo data available (animal)

Inventors: John Chiorini and Sandra Afione-Wainer (NIDCR); Mavis Agbandje-Mckenna and Sujata Halder (University of Florida).

Publications

1. Afione S, et al. Identification and mutagenesis of the adeno-associated virus 5 sialic acid binding region. J Virol. 2015 Feb; 89(3): 1660–72. [PMID 25410855]
2. Chiorini J, et al. AAV4 Vector and the uses thereof. U.S. Patent 6,468,524, issued on October 22, 2002.
3. Chiorini J, et al. AAV5 Vector and the uses thereof. U.S. Patent 7,479,554, issued January 20, 2009, and U.S. Patent 6.984,517, issued on January 10, 2006.
4. Chiorini J, et al. AAV5 Vector for transducing brain cells and lung cells. U.S. Patent 6,855,314, issued on February 15, 2005.

Intellectual Property: HHS Reference No. E–097–2015/0—US Application No. 62/143,524 filed April 6, 2015.

Related Technologies

- E–175–2015: US 62/160,552.
- E–736–2013: PCT/US14/59825.
- E–142–2011 family: PCT/US12/34268, CA, EP and US.
- E–087–2011 family: PCT/US12/33556, EP and US.
- E–232–2011: US 14/428,929.
- E–194–2010: US 8,808,684.
- E–179–2005: US 8,283,151.
- E–227–2004: US 7,407,801.
- E–329–2003 family: US 8,137,960, US 8,685,722.
- E–105–2003: US 8,927,269.
- E–308–2001: US 7,419,817.
- E–071–2000: US 6,468,524.
- E–127–1998 family: US 6,984,517, AU, CA, EP, and JP.

Licensing Contact: Sally Hu, Ph.D., M.B.A.; 301–435–5606; *hus@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Dental and Craniofacial Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize modified AAV5 vector for gene therapy. For collaboration opportunities, please contact David Bradley, Ph.D. at *bradleyda@nidcr.nih.gov.*

A Novel Adeno-Associated Virus for Gene Therapy

Description of Technology: Adeno-associated viruses (AAVs) are small nonpathogenic viruses and can integrate into the cellular genome. AAV vectors are among the most frequently used viral vectors for gene therapy because AAV vectors can infect both dividing and non-dividing cells, and can establish long-term transgene expression. The subject invention describes a novel AAV termed ''44–9.'' AAV44–9 based vectors have high gene transfer activity in a number of cell types, including salivary gland cells, liver cells, and different types of neurons (*e.g.,* cells of the cortex, olfactory bulb, and brain stem, and Purkinje cells of the cerebellum). These vectors can deliver heterologous genes to particular target cells through site-specific administration. Preliminary results from animal studies suggest that AAV44–9 vectors can efficiently deliver genes of interest, and the protein products of the delivered genes can be detected in bloodstream and at the local tissues. Therefore, these vectors are suitable for gene therapy for cells/tissues that are not efficiently targeted by other vectors.

Potential Commercial Applications: AAV44–9 can be used as a delivery vector in gene therapy.

Competitive Advantages

- High gene transfer activity in a number of cell types including salivary gland cells, liver cells, and different types of neurons (*e.g.,* cells of the cortex, olfactory bulb, and brain stem, and Purkinje cells of the cerebellum).
- As a gene transfer vector for cells that are not efficiently targeted by other vector.

Development Stage

- In vitro data available
- In vivo data available (animal)

Inventors: John Chiorini and Giovanni Pasquale (NIDCR).

Publication: Schmidt M, *et al.* Identification and characterization of novel adeno-associated virus isolates in ATCC virus stocks. J Virol. 2006 May; 80 (10): 5082–5098. [PMID 16641301]

Intellectual Property: HHS Reference No. E–175–2015/0—US Application No. 62/160,552 filed May 12, 2015.

Related Technologies

- E–097–2015: US 62/143,524.
- E–736–2013: PCT/US14/59825.
- E–142–2011 family: PCT/US12/34268, CA, EP and US.
- E–087–2011 family: PCT/US12/33556, EP and US.
- E–232–2011: US 14/428,929.
- E–194–2010: US 8,808,684.
- E–179–2005: US 8,283,151.
- E–227–2004: US 7,407,801.
- E–329–2003 family: US 8,137,960, US 8,685,722.
- E–105–2003: US 8,927,269.
- E–308–2001: US 7,419,817.
- E–071–2000: US 6,468,524.
- E–127–1998 family: US 6,984,517, AU, CA, EP, and JP.

Licensing Contact: Sally Hu, Ph.D., M.B.A.; 301–435–5606; *hus@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Dental and Craniofacial Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize AAV44–9 vector for gene therapy. For collaboration opportunities, please contact David Bradley, Ph.D. at *bradleyda@nidcr.nih.gov*.

WNT1-Induced Secreted Protein-1 Knockout Mouse Model

Description of Technology: WNT1-induced secreted protein-1 (WISP1) is expressed at high levels in osteoblasts and their precursors. WIPS1 plays an important role in various aspects of bone formation. Scientists at the NIH generated *Wisp1*-deficient (*Wisp1*$^{-/-}$) mice. Deletion of *Wisp1* resulted in a decrease in bone mineral density, total bone volume, bone thickness, and biomechanical strength. *Wisp1* knockout mouse model can be used to study the molecular mechanisms of bone turnover and patho/physiology of tissues that express WISP1.

Potential Commercial Applications

- To study the molecular mechanisms of bone formation and osteodifferentiation.
- To study the patho/physiology of tissues that express WISP1, including cartilage during osteoarthritis, healing skin, and other soft tissues including lung, pancreas, and heart.

Development Stage: In vivo data available (animal).

Inventors: Marian F. Young, Mitsuaki Ono, Azusa Maeda (all of NIDCR).

Publication: Maeda A, et al. WNT1-induced secreted protein-1 (WISP1), a novel regulator of bone turnover and Wnt signaling. J Bio Chem. 2015 May 29;290(22):14004–18. [PMID 25864198]

Intellectual Property: HHS Reference No. E–234–2015/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Sally Hu, Ph.D., M.B.A.; 301–435–5606; *hus@mail.nih.gov*

Collaborative Research Opportunity: The National Institute of Dental and Craniofacial Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize WNT1-Induced Secreted Protein-1 Knockout Mouse Model. For collaboration opportunities, please contact David Bradley, Ph.D. at *bradleyda@nidcr.nih.gov*.

Dated: July 30, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–19082 Filed 8–3–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke: Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Review of U24 Applications for Parkinson's Disease Repositories.

Date: August 11, 2015.

Time: 9:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Joel A. Saydoff, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3205, MSC 9529, Bethesda, MD 20892–9529, 301–435–9223, *joel.saydoff@nih.gov*.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Review of U01 Applications for Parkinson's Disease Biomarker Program.

Date: August 12, 2015.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Joel A. Saydoff, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3205, MSC 9529, Bethesda, MD 20892–9529, 301–435–9223.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: July 29, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–19032 Filed 8–3–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Radiation Therapeutic.

Date: August 11, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Careen K. Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–3504, *tothct@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 29, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–19025 Filed 8–3–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences: Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council.

Date: September 9–10, 2015.

Open: September 9, 2015, 8:30 a.m. to 5:15 p.m.

Agenda: Discussion of program policies and issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: September 10, 2015, 8:30 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Contact Person: Gwen W. Collman, Ph.D., Interim Director, Division of Extramural Research & Training, National Institutes of Health, Nat. Inst. of Environmental Health Sciences, 615 Davis Dr., KEY615/3112, Research Triangle Park, NC 27709 (919) 541–4980, *collman@niehs.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.niehs.nih.gov/about/boards/naehsc/* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: July 29, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–19023 Filed 8–3–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases: Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Date: September 8, 2015.

Open: 8:30 a.m. to 12:15 p.m.

Agenda: Discussion of Program Policies.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, C Wing, Conference Room 6, Bethesda, MD 20892.

Closed: 1:15 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, C Wing, Conference Room 6, Bethesda, MD 20892.

Contact Person: Laura K. Moen, Ph.D., Director, Division of Extramural Research Activities, NIAMS/NIH, 6700 Democracy Boulevard, Suite 800, Bethesda, MD 20892, 301–451–6515 *moenl@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.niams.nih.gov* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis,

Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: July 29, 2014.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–19031 Filed 8–3–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (R13/U13).

Date: August 25–28, 2015.

Time: 9:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health 5601 Fisher Lane, Rockville, MD 20892, (Virtual Meeting).

Contact Person: Travis J. Taylor, Ph.D., Scientific Review Program, Division of Extramural Activities, Room 3G62B 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5082, *Travis.Taylor@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 28, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–19027 Filed 8–3–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Biobehavioral Predictors of Midlife Transitions.

Date: September 24, 2015.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Carmen P. Moten, MPH, Ph.D., Scientific Review Officer, National Institute On Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7703, *cmoten@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: July 28, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–19028 Filed 8–3–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2015–0017]

National Flood Insurance Program (NFIP); Assistance to Private Sector Property Insurers, Availability of FY 2016 Arrangement

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Each year, the Federal Emergency Management Agency (FEMA) is required by the Write-Your-Own (WYO) Program Financial Assistance/Subsidy Arrangement (Arrangement) to notify private insurance companies (Companies) and to make available to the Companies the terms for subscription or re-subscription to the Arrangement. In keeping with that requirement, this notice provides the terms to the Companies to subscribe or re-subscribe to the Arrangement.

FOR FURTHER INFORMATION CONTACT: Lloyd A. Hake, Division Director, Risk Insurance, Federal Insurance and Mitigation Administration, 1800 South Bell Street, Room 529, Arlington, VA 20598–3020, 202–646–3428 (phone), 202–646–7970 (facsimile), or *Lloyd.hake@fema.dhs.gov* (email).

SUPPLEMENTARY INFORMATION: Under the Write-Your-Own (WYO) Program Financial Assistance/Subsidy Arrangement (Arrangement), 79 (as of April 28, 2015) private sector property insurers sell flood insurance policies and adjust flood insurance claims under their own names based on an Arrangement with the Federal Insurance and Mitigation Administration (FIMA) published at 44 CFR part 62, Appendix A.

The WYO insurers retain an expense allowance and remit the remaining premium to the Federal Government. The WYO insurers pay flood losses and pay loss adjustment expenses based on a fee schedule through the regulated access of federal funds. In addition, under certain circumstances, reimbursement for litigation costs, including court costs, attorney fees, judgments, and settlements, are paid by FEMA based on documentation submitted by the WYO insurers.

The complete Arrangement is published in 44 CFR part 62, Appendix A. Each year, FEMA is required to publish in the **Federal Register** and make available to the Companies the terms for subscription or re-subscription to the Arrangement. 44 CFR part 62, Appendix A, Article V.B.

Signatory Companies should remain aware that all requirements of the Arrangement, including, but not limited to, financial accounting in issues involving all transactions, must be met. As set forth in Article II.A.1. of Appendix A to Part 62—Federal Emergency Management Agency, Federal Insurance Administration, Financial Assistance/Subsidy Arrangement, the Company is responsible for meeting all fiduciary responsibilities for control and disbursement of funds in connection with policy administration. This includes ensuring that all accounting for

policy administration is correct. If errors are made in policy administration, the Company shall be responsible for reimbursing any incorrect allocations, assessments, or other moneys compensated to that company by the Federal Government.

The Company is responsible for ensuring that all activities meet the requirements of this Arrangement and of the NFIP Financial Control Plan, 44 CFR part 62, Appendix B. The NFIP WYO Standards Committee may take remedial action in the event any such conduct is not corrected.

FEMA encourages all private insurance companies wishing to participate in the WYO Program for FY 2016 to contact the NFIP at *Kevin.Brown4@fema.dhs.gov* by September 4, 2015. Prior participation in the WYO Program does not guarantee that FEMA will approve continued participation. FEMA will evaluate requests to participate in light of publicly-available information, industry performance data, and other criteria listed in 44 CFR 62.24 and the Arrangement, 44 CFR part 62, Appendix A. Private insurance companies are encouraged to supplement this information with customer satisfaction surveys, industry awards or recognition, or other objective performance data. In addition, private insurance companies should work with their vendors and subcontractor involved in servicing and delivering their insurance lines to ensure FEMA receives the information necessary to effectively evaluate the criteria set forth in its regulations.

FEMA will send a copy of the offer for the FY 2016 Arrangement, together with related materials and submission instructions, to all private insurance companies successfully evaluated by the NFIP. If FEMA, after conducting its evaluation, chooses not to renew a Company's participation, FEMA, at its option, may require the continued performance of all or selected elements of the FY 2015 Arrangement for a period required for orderly transfer or cessation of the business and settlement of accounts, not to exceed 18 months, 44 CFR part 62, Appendix A, Article V.C. All evaluations, whether successful or unsuccessful, will inform both an overall assessment of the WYO Program and any potential changes FEMA may consider regarding the Arrangement in future fiscal years.

Any private insurance company with questions may contact FEMA in writing: DHS/FEMA, Federal Insurance and Mitigation Administration, Attn: Lloyd A. Hake, Division Director, Risk Insurance, Federal Insurance and Mitigation Administration, 1800 South Bell Street, Room 529, Arlington, VA 20598–3020, 202–646–3428 (phone), 202–646–7970 (facsimile), or *Lloyd.hake@fema.dhs.gov* (email).

Dated: July 24, 2015.

Roy Wright,

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

[FR Doc. 2015–19097 Filed 8–3–15; 8:45 am]

BILLING CODE 9110–11–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0078]

Agency Information Collection Activities: Application to File Declaration of Intention, Form N–300; Revision of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection. 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 October 5, 2015.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0078 in the subject box, the agency name and Docket ID USCIS–2008–0007. To avoid duplicate submissions, please use only one of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at *http://www.regulations.gov* under e-Docket ID number USCIS–2008–0007;

(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.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Laura Dawkins, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2008–0007 in the search box. 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.*

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:* Application to File Declaration of Intention.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form N–300; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form N–300 will be used by permanent residents to file a declaration of intention to become a citizen of the United States. This collection is also used to satisfy documentary requirements for those seeking to work in certain occupations or professions, or to obtain various licenses.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection N–300 is 45 and the estimated hour burden per response is .75 hours (45 minutes).

(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 34 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $168.75.

Dated: July 29, 2015.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2015–19020 Filed 8–3–15; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0096]

Agency Information Collection Activities: Genealogy Index Search Request and Genealogy Records Request. Forms G–1041 and G–1041A; Revision of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services (USCIS), Department of Homeland Security (DHS).

ACTION: 60-Day notice.

SUMMARY: DHS, USCIS invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved 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 October 5, 2015.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0096 in the subject box, the agency name and Docket ID USCIS–2006–0013. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at *www.regulations.gov* under e-Docket ID number USCIS–2006–0013;

(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.

FOR FURTHER INFORMATION CONTACT: 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* and enter USCIS–2006–0013 in the search box. If you need information on how to comment, or would like a copy of the form and instructions, you may contact us at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Laura Dawkins, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number 202–272–8377. Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833).

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*.

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:* Genealogy Index Search Request and Genealogy Records Request.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form G–1041 and G–1041A; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals and households. USCIS will use these forms to facilitate an accurate and timely response to genealogy index search and records requests.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection Form G–1041–4,186 responses (electronically submitted) at .50 hours (30 minutes) per response and 364 responses (submitted by mail) at .50 hours (30 minutes); Form G–1041A–1,824 responses (electronically submitted) at .5 hours (30 minutes) per response and 486 responses (submitted by mail) at .5 hours (30 minutes).

(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 3,430 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $3,187.50.

Dated: July 29, 2015.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2015–19021 Filed 8–3–15; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVW03500.L51050000.EA0000.LVRCF1504080 241A; MO#4500080991]

Notice of Temporary Closure and Temporary Restrictions of Specific Uses on Public Lands for the Burning Man Event, Pershing County, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Notice is hereby given that under the authority of the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) Winnemucca District, Black Rock Field Office, will implement a temporary closure and temporary restrictions to protect public safety and resources on public lands within and adjacent to the Burning Man event on the Black Rock Desert playa.

DATES: The temporary closure and temporary restrictions will be in effect from August 10, 2015 to September 21, 2015.

FOR FURTHER INFORMATION CONTACT: Gene Seidlitz, BLM District Manager, Winnemucca District, 5100 E. Winnemucca Blvd., Winnemucca, NV 89445–2921, telephone: 775–623–1500, email: *gseidlit@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 hours.

SUPPLEMENTARY INFORMATION: The temporary closure and temporary restrictions affect public lands within and adjacent to the Burning Man event permitted on the Black Rock Desert playa within the Black Rock Desert-High Rock Canyon Emigrant Trails National Conservation Area in Pershing County, Nevada. The legal description of the affected public lands in the temporary public closure area is:

Mount Diablo Meridian

T. 33 N., R. 24 E., unsurveyed,
- Sec. 1, that portion lying northwesterly of East Playa Road;
- Sec. 2, that portion lying northwesterly of East Playa Road;
- Sec. 3;
- Sec. 4, that portion lying southeasterly of Washoe County Road 34;
- Sec. 5;
- Sec. 8, NE¼;
- Sec. 9, N½;
- Sec. 10, N½;
- Sec. 11, that portion of the N½ lying northwesterly of East Playa Road.

T. 33½ N., R. 24 E., unsurveyed,
- Secs. 25, 26, and 27;
- Sec. 28, that portion lying easterly of Washoe County Road 34;
- Sec. 33, that portion lying easterly of Washoe County Road 34;
- Secs. 34, 35, and 36.

T. 34 N., R. 24 E., partly unsurveyed,
- Sec. 23, S½;
- Sec. 24, S½;
- Secs. 25 and 26;
- Sec. 27, E½NE¼, E½SW¼, SE¼;
- Sec. 33, NE¼NE¼, S½NE¼, that portion of the SW¼ lying northeasterly of Washoe County Road 34, SE¼;
- Secs. 34, 35, and 36.

T. 33 N., R. 25 E.,
- Sec. 4, that portion lying northwesterly of East Playa Road.

T. 34 N., R. 25 E., unsurveyed,
- Sec. 16, S½;
- Sec. 21;
- Sec. 22, W½NW¼, SW¼;
- Sec. 27, W½;
- Sec. 28;
- Sec. 33, that portion lying northwesterly of East Playa Road;
- Sec. 34, that portion of the W½ lying northwesterly of East Playa Road.

The temporary closure area comprises 14,153 acres, more or less, in Pershing County, Nevada.

The public closure is necessary for the period of time from August 10, 2015, through September 21, 2015, because of the Burning Man event activities in the area, starting with fencing the site perimeter, final setup, the actual event (August 30 through September 7), initial phases of cleanup, and concluding with final site cleanup.

The public closure area comprises about 13 percent of the Black Rock Desert playa. Public access to other areas of the playa will remain open and the other 87 percent of the playa outside the temporary closure area will remain open to dispersed casual use.

The event area is contained within the temporary closure area. The event area is defined as the portion of the temporary closure area (1) entirely contained within the event perimeter fence, including 50 feet from the outside of the event perimeter fence; and (2) within 25 feet from the outside edge of the event access road; and includes the entirety of the aircraft parking area outside the event perimeter fence.

The temporary closure and temporary restrictions are necessary to provide a safe environment for the participants of the Burning Man event and to members of the public visiting the Black Rock Desert, and to protect public land resources by addressing law enforcement and public safety concerns associated with the event. The event is expected to attract approximately 70,000 paid participants to a remote rural area, more than 90 miles from urban infrastructure and support, including public safety, transportation, and communication services. During the event, Black Rock City, the temporary city associated with the event, becomes the tenth-largest population area in Nevada. This event is authorized on public land under Special Recreation Permit #NVW03500–15–01.

While a majority of Burning Man event participants do not violate event

rules or BLM rules and regulations, a few participants at previous events have caused law enforcement and public safety incidents similar to those observed in urban areas of similar-size populations. Incidents in prior years include: Aircraft crashes; motor vehicle accidents with injuries both within and outside the event perimeter; fights; sexual assault; assault on law enforcement officers; reckless or threatening behavior; crimes against property; crowd control issues; possession and unlawful use of alcoholic beverages; endangerment of themselves or others; possession, use, and distribution of controlled substances; litter and unlawful dumping of waste.

The Burning Man event takes place within Pershing County, a rural county with a small population and a small Sheriff's Department. The temporary closure and temporary restrictions are necessary to enable BLM law enforcement personnel to provide for public safety and to protect the public lands, as well as to support and assist state and local agencies with enforcement of existing laws.

Implementation of the temporary restrictions will increase interaction with and education of users by BLM law enforcement and educational staff which will indirectly increase appreciation and protection of the public resources.

A temporary closure and temporary restrictions order, under the authority of 43 CFR 8364.1, is appropriate for a single event. A temporary closure and temporary restrictions order is specifically tailored to the timeframe that is necessary to provide a safe environment for the public and for participants at the Burning Man event, and to protect public land resources while avoiding imposing restrictions that may not be necessary in the area during the remainder of the year.

The BLM will post information signs and maps about the temporary closure and temporary restrictions at main entry points around the playa, at the BLM Winnemucca District Office, at the Nevada State Office, at the Black Rock Visitor Center and on the BLM's Web site: *www.blm.gov/nv/st/en/fo/wfo.html.*

Under the authority of Section 303(a) of FLPMA, 43 CFR 8360.0–7, and 43 CFR 8364.1, the BLM will enforce a temporary public closure and the following temporary restrictions will apply within and adjacent to the Burning Man event on the Black Rock Desert playa from August 10, 2015 through September 21, 2015:

Temporary Restrictions

(a) Aircraft Landing:

The public closure area is closed to aircraft landing, taking off, and taxiing. Aircraft is defined in Title 18, U.S.C., section 31(a)(1) and includes lighter-than-air craft and ultra-light craft. The following exceptions apply:

(1) All aircraft operations, including ultra-light and helicopter landings and takeoffs will occur at the designated 88NV Black Rock City Airport landing strips and areas defined by airport management. All takeoffs and landings will occur only during the hours of operation of the airport as described in the Burning Man Operating Plan. All pilots that use the Black Rock City Airport must agree to and abide by the published airport rules and regulations;

(2) Only helicopters providing emergency medical services may land at the designated Emergency Medical Services helicopter pad or at other locations when required for medical incidents. The BLM authorized officer or his/her delegated representative may approve other helicopter landings and takeoffs when deemed necessary for the benefit of the law enforcement operation; and

(3) Landings or takeoffs of lighter-than-air craft previously approved by the BLM authorized officer.

(b) Alcohol:

(1) Possession of an open container of an alcoholic beverage by the driver or operator of any motorized vehicle, whether or not the vehicle is in motion, is prohibited.

(2) Possession of alcohol by minors:

(i) The following are prohibited:

(A) Consumption or possession of any alcoholic beverage by a person under 21 years of age on public lands; and

(B) Selling, offering to sell, or otherwise furnishing or supplying any alcoholic beverage to a person under 21 years of age on public lands.

(3) Operation of a motor vehicle while under the influence of alcohol, narcotics, or dangerous drugs:

(i) Title 43 CFR 8341.1(f)(3) prohibits the operation of an off-road motor vehicle on public land while under the influence of alcohol, narcotics, or dangerous drugs.

(ii) In addition to the prohibition found at 43 CFR8341.1(f)(3), it is prohibited for any person to operate or be in actual physical control of a motor vehicle while:

(A) The operator is under the combined influence of alcohol, a drug, or drugs to a degree that renders the operator incapable of safe operation of that vehicle; or

(B) The alcohol concentration in the operator's blood or breath is 0.08 grams or more of alcohol per 100 milliliters of blood or 0.08 grams or more of alcohol per 210 liters of breath.

(C) It is unlawful for any person to drive or be in actual physical control of a vehicle on a highway or on premises to which the public has access with an amount of a prohibited substance in his or her urine or blood that is equal to or greater than the following nanograms per milliliter (ng/ml):

(*1*) Amphetamine: urine, 500 ng/ml; blood, 100 ng/ml;

(*2*) Cocaine: urine, 150 ng/ml; blood, 50 ng/ml;

(*3*) Cocaine metabolite: urine,150 ng/ml; blood, 50 ng/ml;

(*4*) Heroin: urine, 2,000 ng/ml; blood, 50 ng/ml;

(*5*) Heroin metabolite:

(*i*) Morphine: urine, 2,000 ng/ml; blood, 50 ng/ml;

(*ii*) 6-monoacetyl morphine: urine, 10 ng/ml; blood, 10 ng/ml;

(*6*) Lysergic acid diethylamide: urine, 25 ng/ml; blood,10 ng/ml;

(*7*) Marijuana: urine,10 ng/ml; blood, 2 ng/ml;

(*8*) Marijuana metabolite: urine, 15 ng/ml; blood, 5 ng/ml;

(*9*) Methamphetamine: urine, 500 ng/ml; blood,100 ng/ml;

(*10*) Phencyclidine: urine, 25 ng/ml; blood,10 ng/ml;

(iii) Tests:

(A) At the request or direction of any law enforcement officer authorized by the Department of the Interior to enforce this closure and restriction order, who has probable cause to believe that an operator of a motor vehicle has violated a provision of paragraph (i) or (ii) of this section, the operator shall submit to one or more tests of the blood, breath, saliva, or urine for the purpose of determining blood alcohol and drug content.

(B) Refusal by an operator to submit to a test is prohibited and proof of refusal may be admissible in any related judicial proceeding.

(C) Any test or tests for the presence of alcohol and drugs shall be determined by and administered at the direction of an authorized law enforcement officer.

(D) Any test shall be conducted by using accepted scientific methods and equipment of proven accuracy and reliability operated by personnel certified in its use.

(iv) Presumptive levels:

(A) The results of chemical or other quantitative tests are intended to supplement the elements of probable cause used as the basis for the arrest of an operator charged with a violation of paragraph (i) of this section. If the alcohol concentration in the operator's blood or breath at the time of testing is

less than alcohol concentrations specified in paragraph (ii)(B) of this section, this fact does not give rise to any presumption that the operator is or is not under the influence of alcohol.

(B) The provisions of paragraph (iv)(A) of this section are not intended to limit the introduction of any other competent evidence bearing upon the question of whether the operator, at the time of the alleged violation, was under the influence of alcohol, a drug or multiple drugs, or any combination thereof.

(4) Definitions:

(i) Open container: Any bottle, can, or other container which contains an alcoholic beverage, if that container does not have a closed top or lid for which the seal has not been broken. If the container has been opened one or more times, and the lid or top has been replaced, that container is an open container.

(ii) Possession of an open container includes any open container that is physically possessed by the driver or operator, or is adjacent to and reachable by that driver or operator. This includes, but is not limited, to containers in a cup holder or rack adjacent to the driver or operator, containers on a vehicle floor next to the driver or operator, and containers on a seat or console area next to a driver or operator.

(c) Drug Paraphernalia:

(1) The possession of drug paraphernalia is prohibited.

(2) Definition: Drug paraphernalia means all equipment, products and materials of any kind which are used, intended for use, or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, inhaling or otherwise introducing into the human body a controlled substance in violation of any state or Federal law, or regulation issued pursuant to law.

(d) Disorderly Conduct:

(1) Disorderly conduct is prohibited.

(2) Definition: Disorderly conduct means that an individual, with the intent of recklessly causing public alarm, nuisance, jeopardy, or violence; or recklessly creating a risk thereof:

(i) Engages in fighting or violent behavior;

(ii) Uses language, an utterance or gesture, or engages in a display or act that is physically threatening or menacing, or done in a manner that is likely to inflict injury or incite an immediate breach of the peace.

(iii) Obstructs, resists, or attempts to elude a law enforcement officer, or fails to follow their orders or directions.

(e) Eviction of Persons:

(1) The public closure area is closed to any person who:

(i) Has been evicted from the event by the permit holder, Black Rock City LLC, (BRC LLC) whether or not the eviction was requested by the BLM;

(ii) Has been evicted from the event by the BLM;

(iii) Has been ordered by a law enforcement officer to leave the area of the permitted event.

(2) Any person evicted from the event forfeits all privileges to be present within the perimeter fence or anywhere else within the public closure area even if they possess a ticket to attend the event.

(f) Fires:

The ignition of fires on the surface of the Black Rock playa without a burn blanket or burn pan is prohibited.

(g) Fireworks:

The use, sale or possession of personal fireworks is prohibited except for uses of fireworks approved by BRC LLC and used as part of a Burning Man sanctioned art burn event.

(h) Motor Vehicles:

(1) Must comply with the following requirements:

(i) The operator of a motor vehicle must possess a valid driver's license.

(ii) Motor vehicles and trailers must possess evidence of valid registration, except for mutant vehicles, or other vehicles registered with the BRC LLC organizers and operated within the scope of that registration.

(iii) Motor vehicles and trailers must possess evidence of valid insurance, except for mutant vehicles, or other vehicles registered with the BRC LLC organizers and operated within the scope of that registration.

(iv) Motor vehicles and trailers must not block a street used for vehicular travel or a pedestrian pathway.

(v) Motor vehicles must not exceed the posted speed limit.

(vi) No person shall occupy a trailer while the motor vehicle is in transit upon a roadway, except for mutant vehicles, or other vehicles registered with the BRC LLC organizers and operated within the scope of that registration.

(vii) Motor vehicles, other than a motorcycle or golf cart, must be equipped with at least two working headlamps, at least two functioning tail lamps and at least two functioning brake lights, except for mutant vehicles, or other vehicles registered with the BRC LLC organizers and operated within the scope of that registration, so long as they are adequately lit according to Black Rock City, LLC Department of Mutant Vehicle requirements.

(viii) Trailers pulled by motor vehicles must be equipped with at least two functioning tail lamps and at least two functioning brake lights.

(ix) Motor vehicles and trailers must display an unobstructed rear license plate and must be equipped with a mounted lamp to illuminate the rear license plate, except for mutant vehicles, or other vehicles registered with the BRC LLC organizers and operated within the scope of that registration.

(2) The public closure area is closed to motor vehicle use, except as provided below. Motor vehicles may be operated within the public closure area under the circumstances listed below:

(i) Participant arrival and departure on designated routes;

(ii) BLM, medical, law enforcement, and firefighting vehicles are authorized at all times;

(iii) Vehicles, mutant vehicles, or art cars operated by BRC LLC staff or contractors and service providers on behalf of BRC LLC are authorized at all times. These vehicles must display evidence of event registration in such manner that it is visible to the rear of the vehicle while the vehicle is in motion;

(iv) Vehicles used by disabled drivers and displaying official state disabled driver license plates or placards; or mutant vehicles and art cars, or other vehicles registered with the BRC LLC must display evidence of registration at all times in such manner that it is visible to the rear of the vehicle while the vehicle is in motion;

(iv) Motorized skateboards, electric assist bicycles, or Go-Peds with or without handlebars;

(v) Participant drop-off of approved burnables and wood to the Burn Garden/Wood Reclamation Stations (located on open playa at 3:00, 6:00, 9:00 Promenades and the Man base) from 9:00 a.m. Sunday, September 6, 2015 through the end of day Tuesday, September 8, 2015, post event; and

(vi) Passage through, without stopping, the public closure area on the west or east playa roads.

(3) Definitions:

(i) A motor vehicle is any device designed for and capable of travel over land and which is self-propelled by a motor, but does not include any vehicle operated on rails or any motorized wheelchair.

(ii) Motorized wheelchair means a self-propelled wheeled device, designed solely for and used by a mobility-impaired person for locomotion.

(iii) A trailer is any instrument designed to be hauled by a motor vehicle.

(i) Public Camping:

The public closure area is closed to public camping with the following exception: Burning Man event ticket holders who are camped in designated event areas provided by BRC LLC, and ticket holders who are camped in the authorized pilot camp. BRC LLC authorized staff, contractors, and BLM authorized event management related camps are exempt from this closure.

(j) Public Use:

The public closure area is closed to use by members of the public unless that person: Is traveling through, without stopping, the public closure area on the west or east playa roads; possesses a valid ticket to attend the event; is an employee or authorized volunteer with the BLM, a law enforcement officer, emergency medical service provider, fire protection provider, or another public agency employee working at the event and that individual is assigned to the event; is a person working at or attending the event on behalf of BRC LLC; or is authorized by BRC LLC to be onsite prior to the commencement of the event for the primary purpose of constructing, creating, designing or installing art, displays, buildings, facilities or other items and structures in connection with the event; or is a commercial operation to provide services to the event organizers and/or participants authorized by BRC LLC through a contract or agreement and authorized by BLM through a Special Recreation Permit.

(k) Waste Water Discharge:

The dumping or discharge to the ground of gray water is prohibited. Gray water is water that has been used for cooking, washing, dishwashing, or bathing and contains soap, detergent, food scraps, or food residue.

(l) Human Waste:

Depositing of human waste on the ground is prohibited.

(m) Unmanned Aircraft Systems:

(1) The use of unmanned aircraft systems (UAS) is prohibited, unless the operator is registered through and complies with the Remote Control BRC program (RCBRC) and operates the UAS in accordance with Federal laws and regulations.

(2) Definition:

(i) Unmanned aircraft means an aircraft operated without the possibility of direct human intervention from within or on the aircraft.

(ii) An unmanned aircraft system is the unmanned aircraft (UA) and all of the associated support equipment, control station, data links, telemetry, communications and navigation equipment, etc., necessary to operate the unmanned aircraft.

(n) Lasers:

(1) The possession and or use of handheld lasers is prohibited.

(2) Definition:

(i) A laser means any hand held laser beam device or demonstration laser product that emits a single point of light amplified by the stimulated emission of radiation that is visible to the human eye.

(o) Weapons:

(1) The possession of any weapon is prohibited except weapons within motor vehicles passing, without stopping, through the public closure area on the west or east playa roads.

(2) The discharge of any weapon is prohibited.

(3) The prohibitions above shall not apply to county, state, tribal, and Federal law enforcement personnel who are working in their official capacity at the event. ''Art projects'' that include weapons and are sanctioned by BRC LLC will be permitted after obtaining authorization from the BLM authorized officer.

(4) Definitions:

(i) Weapon means a firearm, compressed gas or spring powered pistol or rifle, bow and arrow, cross bow, blowgun, spear gun, hand-thrown spear, sling shot, irritant gas device, electric stunning or immobilization device, explosive device, any implement designed to expel a projectile, switch-blade knife, any blade which is greater than 10 inches in length from the tip of the blade to the edge of the hilt or finger guard nearest the blade (*e.g.,* swords, dirks, daggers, machetes), or any other weapon the possession of which is prohibited by state law. Exception: This rule does not apply in a kitchen or cooking environment or where an event worker is wearing or utilizing a construction knife for their duties at the event.

(ii) Firearm means any pistol, revolver, rifle, shotgun, or other device which is designed to, or may be readily converted to expel a projectile by the ignition of a propellant.

(iii) Discharge means the expelling of a projectile from a weapon.

Any person who violates the above rules and restrictions may be tried before a United States Magistrate and fined no more than $100,000, imprisoned no more than 12 months, or both, in accordance with 18 U.S.C. 3571(b), 43 U.S.C. 1733(a), and 43 CFR 8360.0–7. Such violations may also be subject to the enhanced penalties provided by 18 U.S.C. 3571 and 3581. In accordance with 43 CFR 8365.1–7, State or local officials may also impose penalties for violations of Nevada law.

Authority: 43 CFR 8364.1.

Gene Seidlitz,

District Manager, Winnemucca District.

[FR Doc. 2015–19160 Filed 8–3–15; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–L14400000.BJ0000; 15XL1109AF; MO#4500081852]

Notice of Filing of Plats of Survey; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plats of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on September 3, 2015.

DATES: Protests of the survey must be filed before September 3, 2015 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: Andrew Varilek, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5166 or (406) 896–5003, *ajvarile@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 Field Manager, Lewistown Field Office, and was necessary to delineate Federal lands. The lands we surveyed are:

Principal Meridian, Montana

T. 12 N., R. 22 E.

The plat, in two sheets, representing the dependent resurvey of a portion of the east boundary and a portion of the subdivisional lines and the subdivision of sections 13, 14,

23, 24, and 25, Township 12 North, Range 22 East, Principal Meridian, Montana, was accepted July 21, 2015.

T. 11 N., R. 23 E.

The plat, in one sheet, representing the dependent resurvey of a portion of the north boundary and a portion of the subdivisional lines and the subdivision of section 6, Township 11 North, Range 23 East, Principal Meridian, Montana, was accepted July 21, 2015.

We will place a copy of the plats, in three 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 these plats, in three 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 these plats, in three 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,

Acting Chief, Branch of Cadastral Survey, Division of Energy, Minerals and Realty.

[FR Doc. 2015–19051 Filed 8–3–15; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWY910000.L16100000.XX0000]

Notice of Public Meeting; Wyoming Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Wyoming Resource Advisory Council (RAC) will meet as indicated below.

DATES: The meeting is scheduled for, Wednesday, Aug. 19, 2015, from 8 a.m. to 4 p.m.

ADDRESSES: The meeting will be conducted by teleconference, which the public may attend the call in person at the Wyoming State Office, 5353 Yellowstone Road, Cheyenne, Wyoming.

FOR FURTHER INFORMATION CONTACT: Christian Venhuizen, Wyoming Resource Advisory Council Coordinator, Wyoming State Office, 5353 Yellowstone Road, Cheyenne, WY 82009; telephone 307–775–6103; email *cvenhuizen@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 10-member RAC advises the Secretary of the Interior on a variety of management issues associated with public land management in Wyoming. Planned agenda topics include discussions on the Greater Sage-Grouse and follow-up to previous RAC meetings. On Wednesday, Aug. 19, the meeting will begin at 8 a.m., in the Wyoming State Office's first floor conference room and adjourn for lunch at noon. The meeting will resume with a public comment period at 1 p.m. in the conference room. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited. If there are no members of the public interested in speaking, the meeting will move promptly to the next agenda item. The public may also submit written comments to the RAC by emailing *cvenhuizen@blm.gov,* with the subject line ''RAC Public Comment'' or by submitting comments during the meeting, at the Wyoming State Office, to the RAC coordinator. Typed or written comments will be provided to RAC members as part of the meeting's minutes.

Dated: July 14, 2015.

Mary Jo Rugwell,

Acting State Director.

[FR Doc. 2015–17802 Filed 8–3–15; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–18852; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before July 11, 2015. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service,1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by August 19, 2015. 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: July 17, 2015.

Roger Reed,

Acting Chief, National Register of Historic Places/National Historic Landmarks Program.

ARKANSAS

Pulaski County

MacArthur Park Historic District (Boundary Increase and Additional Documentation), Roughly bounded by Ferry, McGowan, Cumberland & Scott, E. 15th St., E. Capitol Ave., Little Rock, 15000536

MISSOURI

St. Louis County

Claverach Park, Roughly bounded by Broadview, Claverach, Crestwood, Harcourt, Hillvale & Ridgemoor Drs., Clayton Rd., Wydown Blvd., Clayton, 15000537

NEW YORK

Monroe County

Park Avenue and State Street Historic District, 15–121 Park Ave., 15–118 State, 36–54 South, 6 & 12 High & 14 & 20 Spring Sts., Brockport, 15000538

Orleans County

Holley Village Historic District, 1 Village Sq., 3–35 Frisbe Terrace, Public Sq., 32–34 Albion, 1–13 S. Main, 1 Wright, 2 White, 1 & 4–18 Thomas Sts., Holley, 15000539

Richmond County

Sylvan Grove Cemetery, Victory Blvd. at Glen St., Staten Island, 15000540

NORTH CAROLINA

Dare County

LIGHT VESSEL 71 (shipwreck), Address Restricted, Buxton, 15000541

TENNESSEE

Knox County

Gay Street Commercial Historic District (Boundary Increase and Additional Documentation), 626 S. Gay St., Knoxville, 15000542

TEXAS

Travis County

All Saints' Chapel, 209 W. 27th St., Austin, 15000543

Simpson Memorial Methodist Church, (East Austin MRA) 1701 E. 12th St., Austin, 15000544

VIRGINIA

Accomack County

Tangier Island Historic District (Boundary Increase), S. of Tangier Island in Chesapeake Bay, Tangier, 15000545

Chesapeake Independent City

Cornland School, 2309 Benefit Rd., Chesapeake (Independent City), 15000546

Danville Independent City

Danville Historic District (Boundary Increase), Jefferson Ave., Chestnut Pl., Grove, Chambers, 100 blks. Ross & Holbrook Sts., Danville (Independent City), 15000547

Halifax County

Mountain Road Historic District (Boundary Increase), Mountain Rd., Academy St., Poplar Ln., Halifax, 15000548

Hopewell Independent City

Downtown Hopewell Historic District (Boundary Increase and Decrease), E. Broadway Ave., S. Main & E. Poythress Sts., Hopewell (Independent City), 15000549

Pittsylvania County

Chatham Southern Railway Depot, 340 Whitehead St., Chatham, 15000550

WISCONSIN

Green County

Chalet of the Golden Fleece, 618 2nd St., New Glarus, 15000551

Rock County

Courier Building, 513 Vernal Ave., Milton, 15000552

[FR Doc. 2015–19011 Filed 8–3–15; 8:45 am]

BILLING CODE 4312–51–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–925]

Certain Communications or Computing Devices and Components Thereof Commission Determination Not To Review an Initial Determination Terminating the Investigation in its Entirety Based Upon Settlement; Termination of Investigation; and Vacatur of Order No. 34; Correction

AGENCY: U.S. International Trade Commission.

ACTION: Correction of Notice. The Commission hereby corrects the summary section of the notice published in the **Federal Register** July 29, 2015 (80 FR 45232).

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (''ALJ'') initial determination (''ID'') (Order No. 41) terminating the above-captioned investigation in its entirety based upon settlement. The commission has also determined to vacate Order No. 34 as moot.

FOR FURTHER INFORMATION CONTACT: Panyin A. Hughes, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–3042. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on August 21, 2014, based on a Complaint filed by Enterprise Systems Technologies S.a.r.l. of Luxembourg (''Enterprise''). 79 FR 49537–38 (Aug. 21, 2014). The Complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain communications or computing devices and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 6,691,302 (''the '302 patent''); 5,870,610; 6,594,366; and 7,454,201. The notice of investigation named the following respondents: HTC Corporation of Taoyuan, Taiwan; HTC America, Inc. of Bellevue, Washington; LG Electronics Inc. of Seoul, Republic of Korea; LG Electronics USA, Inc. of Englewood Cliffs, New Jersey; LG Electronics MobileComm U.S.A., Inc. of San Diego, California; Samsung Electronics Co. Ltd. of Seoul, Republic of Korea; Samsung Electronics America, Inc. of Ridgefield Park, New Jersey; Samsung Telecommunications America, LLC of Richardson, Texas (collectively, ''Remaining Respondents''); Apple Inc. of Cupertino, California (''Apple''); and Cirrus Logic Inc. of Austin, Texas (''Cirrus''). The Office of Unfair Import Investigations was also named as a party to the investigation.

On September 9, 2014, the ALJ issued an initial determination, Order No. 6, granting intervenor status to Google Inc. of Mountain View, California (''Google''). On March 9, 2015, the ALJ issued an ID, Order No. 20, terminating the investigation as to Cirrus. On June 5, 2015, the ALJ issued an ID, Order No. 37, terminating the investigation as to Apple. The Commission determined not to review those IDs.

On May 21, 2015, the ALJ issued Order No. 34, an initial determination terminating the '302 patent from the investigation based upon a lack of standing. Enterprise filed a petition for review on May 28, 2015. The parties subsequently moved for a 60-day extension to file any further briefing on the issue. The Commission granted the motion on June 1, 2015, and extended the date for determining whether to review Order No. 34 to August 21, 2015. Thus, Order No. 34 remains outstanding.

On June 22, 2015, Enterprise, Remaining Respondents, and Google jointly moved to terminate the investigation in its entirety based upon settlement. On June 29, 2015, the Commission investigative attorney filed a response in support of the motion. No other responses to the motion were received.

The ALJ issued the subject ID on July 1, 2015, and a corrected version on July 17, 2015, granting the joint motion for termination. The ALJ found that the settlement agreement satisfies the requirements of Commission Rule 210.21(b). She further found, pursuant to Commission Rule 210.50(b)(2), that there is no indication that termination of the investigation would adversely impact the public interest. No one petitioned for review of the ID.

The Commission has determined not to review the ID as corrected. In light of the settlement, the Commission has determined to vacate Order No. 34 as moot.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in art 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: July 29, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–18984 Filed 8–3–15; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration: Johnson Matthey, Inc.

ACTION: Notice of registration.

SUMMARY: Johnson Matthey, Inc. applied to be registered as an importer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Johnson Matthey, Inc., registration as an importer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated April 14, 2015, and published in the **Federal Register** on April 22, 2015, 80 FR 22559, Johnson Matthey, Inc., Pharmaceutical Materials, 2003 Nolte Drive, West Deptford, New Jersey 08066–1742 applied to be registered as an importer of certain basic classes of controlled substances. No comments or objections were submitted for this notice. Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417, (January 25, 2007).

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Johnson Matthey, Inc. to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of the basic classes controlled substances:

Controlled substance	Schedule
Coca Leaves (9040)	II
Thebaine (9333)	II
Opium, raw (9600)	II
Noroxymorphone (9668)	II
Poppy Straw Concentrate (9670)	II
Fentanyl (9801)	II

The company plans to import thebaine derivatives and fentanyl as reference standards.

The company plans to import the remaining listed controlled substances as raw materials, to be used in the manufacture of bulk controlled substances, for distribution to its customers.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19107 Filed 8–3–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15–15]

Adeline Davies Essien, M.D.; Decision and Order

On March 25, 2015, Administrative Law Judge (ALJ) Christopher B. McNeil issued the attached Recommended Decision. Neither party filed exceptions to the Recommended Decision.

Having reviewed the record in its entirety, I adopt the ALJ's findings of fact, conclusions of law and recommended order.[1] Accordingly, I will order that Respondent's DEA Certificate of Registration be revoked and that any pending application to renew or modify her registration be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(3), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration BE6969541, issued to Adeline Davies Essien, M.D., be, and it hereby is, revoked. I further order that any pending application of Adeline Davies Essien, M.D., to renew or modify her registration, be, and it hereby is, denied. This Order is effective September 3, 2015.

[1] I take official notice of the fact that, according to the registration records of the Agency, Respondent retains an active registration as of this date. Pursuant to 21 CFR 1316.59(e), Respondent may controvert this finding by filing a properly supported motion, no later than 10 days from the date of this Order.

Dated: July 27, 2015.

Chuck Rosenberg,

Acting Administrator.

Frank W. Mann, Esq., for the Government.

Thomas P. O'Connell, Esq., for the Respondent.

ORDER GRANTING THE GOVERNMENT'S MOTION FOR SUMMARY DISPOSITION and FINDINGS OF FACT, CONCLUSIONS OF LAW, AND RECOMMENDED DECISION OF THE ADMINISTRATIVE LAW JUDGE

Administrative Law Judge Christopher B. McNeil. On January 21, 2015, the Deputy Assistant Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause as to why the DEA should not revoke DEA Certificate of Registration Number BE6969541 issued to Adeline Davies Essien, M.D., the Respondent in this matter. The Order seeks to revoke Respondent's registration pursuant to 21 U.S.C. 824(a)(4) and 823(f), and to deny any pending applications for renewal or modification of such registration, and deny any applications for any new DEA registrations pursuant to 21 U.S.C. 823(f). As grounds for denial, the Government alleges that Respondent is ''currently without authority to handle controlled substances in the State of Illinois, the state in which [Respondent is] registered with the DEA.''

On February 27, 2015, the DEA's Office of Administrative Law Judges received Respondent's written request for a hearing, which is dated February 26, 2015. Respondent stated that she objected to the Government's allegation regarding Respondent's authority to handle controlled substances. Respondent further stated that she ''does have authority to practice medicine and handle controlled substances.''

On March 3, 2015, this Office issued an Order for Briefing on Allegations Concerning Respondent's Lack of State Authority, Order for Prehearing Statements, and Order Setting the Matter for Hearing. In the Order, I mandated that the parties provide briefs regarding the allegation that Respondent lacks state authority to handle controlled substances no later than 2:00 p.m. on March 17, 2015. In my Order, I also provided that responses to any briefs be submitted by no later than 2:00 p.m. on March 24, 2015. On March 17, 2015, I timely received the Government's Response to Order and Motion for Summary Disposition. According to the Government's motion,

Respondent is without authority to prescribe, administer, or dispense controlled substances in the State of Illinois. In its Exhibit One attachment, the Government provided evidence that the State of Illinois, the jurisdiction where she is licensed to practice medicine and where Respondent is registered with the DEA, considers her license ''Not Renewed'' with an expiration date of July 31, 2014. Additionally, the Government in its Exhibit Two attachment provided a sworn declaration of Laura Forester, Chief of Medical Prosecutions for the Illinois Department of Financial and Professional Regulation, stating that Respondent is not currently authorized under Illinois law to handle controlled substances. Based on this status, the Government moved for a summary disposition of these proceedings as well as a stay of these proceedings pending resolution of its Motion for Summary Disposition. Finding good cause was shown, I granted an Order Staying Proceedings with the exception of the March 24, 2015 deadline for Respondent's response to the Government's Motion for Summary Disposition.

Respondent filed a timely response to the Government's Motion for Summary Disposition on March 24, 2015. In her response, Respondent states that her Illinois State medical license case is pending appeal and is therefore not a final disposition. Respondent further attached an affidavit affirming that she has a case pending before the Illinois Administrative Law Court that is pending appeal. She also attached ''Exhibit B'' containing a statement from Lillian Walanka, who is representing Respondent before the Illinois Administrative Law Court. Ms. Walanka again confirms that the case is pending final action by Illinois authorities. Ms. Walanka states that although Respondent filed a timely renewal application of her controlled substances license, her controlled substances license was not renewed pending a Notice of Intent to Refuse to Renew by authorities in Illinois.

The substantial issue raised by the Government rests on an undisputed fact. The Government asserts that Respondent's DEA Certificate of Registration must be revoked because Respondent does not have an active controlled substance registration issued by the state in which she practices. Under DEA precedent, a practitioner's DEA Certificate of Registration for controlled substances must be summarily revoked if the applicant is not authorized to handle controlled substances in the state in which she maintains her DEA registration.[2] Pursuant to 21 U.S.C. 823(f), only a ''practitioner'' may receive a DEA registration. Under 21 U.S.C. 802(21), a ''practitioner'' must be ''licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute [or] dispense . . . controlled substance[s.]'' Given this statutory language, the DEA Administrator does not have the authority under the Controlled Substances Act to maintain a practitioner's registration if that practitioner is not authorized to dispense controlled substances.[3]

Respondent correctly argues in her response that a final disposition has not been made regarding her controlled substance registration in Illinois's administrative proceedings. However, Respondent mischaracterizes the Government's Motion for Summary Disposition when alleging that the Government is arguing that a final disposition had occurred. The Government is only arguing that Respondent is currently without authority to handle controlled substances in Illinois. To emphasize this point, the Government cites to the case of *Roger A. Rodriguez, M.D.* to demonstrate that even a temporary suspension warrants revocation.[4] As DEA Administrator Michele M. Leonhart previously stated in *James L. Hooper, M.D.,* ''the controlling question is not whether a practitioner's license to practice medicine in the state is suspended or revoked; rather, it is whether the Respondent is currently authorized to handle controlled substances in the state.'' [5] In *Hooper,* Administrator Leonhart concluded that ''even where a practitioner's state license has been suspended for a period of certain duration, the practitioner no longer meets the statutory definition of a practitioner.'' [6] In this case, Respondent's state controlled substance registration has been suspended for an indefinite duration. As detailed above, only a ''practitioner'' may receive a DEA registration. Therefore, I will recommend the revocation of Respondent's DEA registration.

Order Granting the Government's Motion for Summary Disposition and Recommendation

I find there is no genuine dispute regarding whether Respondent is a ''practitioner'' as that term is defined by 21 U.S.C. 802(21), and that based on the record the Government has established that Respondent is not a practitioner and is not authorized to dispense controlled substances in the state in which she seeks to practice with a DEA Certificate of Registration. I find no other material facts at issue. Accordingly, I GRANT the Government's Motion for Summary Disposition.

Upon this finding, I ORDER that this case be forwarded to the Administrator for final disposition and I recommended that Respondent's DEA Certificate of Registration should be REVOKED and any pending application for the renewal or modification of the same should be DENIED.

Dated: March 25, 2015

Christopher B. McNeil,

Administrative Law Judge.

[FR Doc. 2015–19122 Filed 8–3–15; 8:45 am]

BILLING CODE 4410–09–P

[2] *See* 21 U.S.C. 801(21), 823(f), 824(a)(3); *see also House of Medicine,* 79 FR 4959, 4961 (DEA Jan. 30, 2014); *Deanwood Pharmacy,* 68 FR 41662–01 (DEA July 14, 2003); *Wayne D. Longmore, M.D.,* 77 FR 67669–02 (DEA Nov. 13, 2012); *Alan H. Olefsky, M.D.,* 72 FR 42127–01 (DEA Aug. 1, 2007); *Layfe Robert Anthony, M.D.,* 67 FR 15811 (DEA May 20, 2002); *George Thomas, PA–C,* 64 FR 15811–02 (DEA Apr. 1, 1999); *Shahid Musud Siddiqui, M.D.,* 61 FR 14818–02 (DEA April 4, 1996); *Michael D. Lawton, M.D.,* 59 FR 17792–01 (DEA Apr. 14, 1994); *Abraham A. Chaplan, M.D.,* 57 FR 55280–03 (DEA Nov. 24, 1992). *See also Bio Diagnosis Int'l,* 78 FR 39327–03, 39331 (DEA July 1, 2013) (distinguishing distributor applicants from other ''practitioners'' in the context of summary disposition analysis).

[3] *See Abraham A. Chaplan, M.D.,* 57 FR 55280–03, 55280 (DEA Nov. 24, 1992), and cases cited therein. In *Chaplan,* DEA Administrator Robert C. Bonner adopts the ALJ's opinion that ''the DEA lacks statutory power to register a practitioner unless the practitioner holds state authority to handle controlled substances.'' *Id.*

[4] *Roger A. Rodriguez, M.D.,* 70 FR 33206, 33,207 (DEA June 7, 2005).

[5] *James L. Hooper, M.D.; Decision and Order,* 76 FR 71371–01, 71371 (DEA Nov. 17, 2011).

[6] *Id.* at 71372.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Manufacturer of Controlled Substances Registration: Sigma Aldrich Research Biochemicals, Inc.

ACTION: Notice of registration.

SUMMARY: Sigma Aldrich Research Biochemicals, Inc. applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Sigma Aldrich Research Biochemicals, Inc. registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated April 14, 2015, and published in the **Federal Register** on April 22, 2015,

80 FR 22557, Sigma Aldrich Research Biochemicals, Inc., 1–3 Strathmore Road, Natick, Massachusetts 01760–2447 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Sigma Aldrich Research Biochemicals, Inc. to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed:

Controlled substance	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
Mephedrone (4-Methyl-N-methylcathinone) (1248)	I
Aminorex (1585)	I
Alpha-ethyltryptamine (7249)	I
Lysergic acid diethylamide (7315)	I
Tetrahydrocannabinols (7370)	I
4-Bromo-2,5-dimethoxyamphetamine (7391)	I
4-Bromo-2,5-dimethoxyphenethylamine (7392)	I
4-Methyl-2,5-dimethoxyamphetamine (7395)	I
2,5-Dimethoxyamphetamine (7396)	I
3,4-Methylenedioxyamphetamine (7400)	I
N-Hydroxy-3,4-methylenedioxyamphetamine (7402)	I
3,4-Methylenedioxy-N-ethylamphetamine (7404)	I
3,4-Methylenedioxymethamphetamine (7405)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I
5-Methoxy-N,N-diisopropyltryptamine (7439)	I
1-[1-(2-Thienyl)cyclohexyl]piperidine (7470)	I
N-Benzylpiperazine (7493)	I
MDPV (3,4-Methylenedioxypyrovalerone) (7535)	I
Methylone (3,4-Methylenedioxy-N-methylcathinone) (7540)	I
Heroin (9200)	I
Normorphine (9313)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Nabilone (7379)	II
1-Phenylcyclohexylamine (7460)	II
Phencyclidine (7471)	II
Cocaine (9041)	II
Codeine (9050)	II
Ecgonine (9180)	II
Levomethorphan (9210)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Metazocine (9240)	II
Methadone (9250)	II
Morphine (9300)	II
Thebaine (9333)	II
Levo-alphacetylmethadol (9648)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Carfentanil (9743)	II
Fentanyl (9801)	II

The company plans to manufacture reference standards.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19166 Filed 8–3–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 15–16]

Pedro E. Lopez, M.D.; Decision and Order

On March 20, 2015, Chief Administrative Law Judge (CALJ) John J. Mulrooney, II, issued the attached Recommended Decision. Neither party filed exceptions to the Recommended Decision.

Having reviewed the record in its entirety, I adopt the CALJ's findings of fact,[1] conclusions of law, and

[1] I take official notice of the fact that, according to the registration records of the Agency, Respondent retains an active registration as of this date. Pursuant to 21 CFR 1316.59(e), Respondent may controvert this finding by filing a properly supported motion, no later than 10 days from the date of this Order.

recommended order. Accordingly, I will order that Respondent's DEA Certificate of Registration be revoked and that any pending applications to renew or modify his registration be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(3), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration BL2132049, issued to Pedro E. Lopez, M.D., be, and it hereby is, revoked. I further order that any pending application of Pedro E. Lopez, M.D., to renew or modify his registration, be, and it hereby is, denied. This Order is effective September 3, 2015.

Dated: July 27, 2015.

Chuck Rosenberg,

Acting Administrator.

Brian Bayly, Esq., for the Government.
Alan Rhine, Esq., for the Respondent.

ORDER GRANTING THE GOVERNMENT'S MOTION FOR SUMMARY DISPOSITION AND RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Chief Administrative Law Judge John J. Mulrooney, II. The Deputy Assistant Administrator, Drug Enforcement Administration (DEA or Government), issued an Order to Show Cause (OSC), dated February 6, 2015, proposing to revoke the DEA Certificate of Registration (COR), Number BL2132049, of Pedro E. Lopez, M.D. (Respondent), pursuant to 21 U.S.C. 824(a)(3) and 21 U.S.C. 823(f), and deny any pending applications for renewal or modification of the COR, pursuant to 21 U.S.C. 823(f).

In the OSC, the Government alleges that the Respondent is, *inter alia,* without ''authority to handle controlled substances in the State of Illinois'' as grounds for revocation of the Respondent's DEA registration. On March 6, 2015, the Respondent, by counsel, filed a Request for Hearing in the above-captioned matter. The Request for Hearing stated that a hearing is appropriate because ''the Respondent has instituted proceedings to restore his authority to handle controlled substances in Illinois.'' Req. for Hrg. at 1.

Consistent with my direction, the parties have briefed the issues. On March 11, 2015, the Government filed a Motion for Summary Disposition and Evidence in Support of its Motion for Summary Disposition (Motion for Summary Disposition), seeking that this tribunal issue a Recommended Decision granting the Government's Motion on the ground that the Respondent is currently without state authority to handle controlled substances. Mot. for Summary Disp. at 1. According to the Government's Motion, the State of Illinois, Department of Financial and Professional Regulation (IDFPR) suspended the Respondent's license to practice medicine, effective March 12, 2014, and that suspension order remains in effect. *Id.* Attached to the Government's Motion is the IDFPR Order dated March 12, 2014 suspending the Respondent's state Physician and Surgeon License No. 036.074815 on the grounds that the Respondent failed to comply with the provisions an Agreement of Care, Counseling and Treatment that he had entered into with IDFPR.[2] *Id.,* Attachment 1 at 1–2. Under the IDPFR Order, the Respondent's state license was indefinitely suspended for a minimum period of six months. *Id.,* Attachment 1 at 2.

On March 20, 2015, the Respondent, through counsel, filed a reply styled ''Response to the Government's Motion for Summary Disposition and Evidence in Support of its Motion for Summary Disposition'' (Respondent's Reply). In his Reply, the Respondent alleges that he is in the process of seeking reinstatement of his medical license from the state of Illinois. Resp't Reply at 2. In opposing the Government's requested relief, the Respondent avers that inasmuch as he is currently not prescribing controlled substances, granting a hearing, or at least deferring adjudication until his state privileges are restored presents no cognizable danger to the public. *Id.* at 2–3.

In order to revoke a registrant's DEA registration, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 CFR 1301.44(e) (2015). Once DEA has made its *prima facie* case for revocation of the registrant's DEA COR, the burden of production then shifts to the Respondent to show that, given the totality of the facts and circumstances in the record, revoking the registrant's registration would not be appropriate. *Morall* v. *DEA,* 412 F.3d 165, 174 (D.C. Cir. 2005); *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *U.S. Dept. of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72311 (1980).

The Controlled Substances Act (CSA) requires that, in order to maintain a DEA registration, a practitioner must be authorized to handle controlled substances in ''the jurisdiction in which he practices.'' *See* 21 U.S.C. 802(21) (2012) (''[t]he term 'practitioner' means a physician . . . licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice''); *see also* 21 U.S.C. 823(f) (2012) (''The Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.''). DEA has long held that possession of authority under state law to dispense controlled substances is an essential condition for obtaining and maintaining a DEA registration. *Serenity Café,* 77 FR 35027, 35028 (2012); *David W. Wang,* 72 FR 54297, 54298 (2007); *Sheran Arden Yeates,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104 (1993); *Bobby Watts, M.D.,* 53 FR 11919 (1988). Because ''possessing authority under state law to handle controlled substances is an essential condition for holding a DEA registration,'' this Agency has consistently held that ''the CSA requires the revocation of a registration issued to a practitioner who lacks [such authority].'' *Roy Chi Lung,* 74 FR 20346, 20347 (2009); *see also Scott Sandarg, D.M.D.,* 74 FR 17528, 174529 (2009); *John B. Freitas, D.O.,* 74 FR 17524, 17525 (2009); *Roger A. Rodriguez, M.D.,* 70 FR 33206, 33207 (2005); *Stephen J. Graham, M.D.,* 69 FR 11661 (2004); *Abraham A. Chaplan, M.D.,* 57 FR 55280 (1992); *see also Harrell E. Robinson,* 74 FR 61370, 61375 (2009).[3] ''[R]evocation is warranted even where a practitioner's state authority has been summarily suspended and the State has yet to provide the practitioner

Notwithstanding that the language of section 824(a) authorizes either the suspension or revocation of a registration upon the making of one of the five findings enumerated therein, the Agency has consistently interpreted the CSA as mandating revocation where a practitioner's state authority has been suspended or revoked. As the Fourth Circuit has held, ''[b]ecause § 823(f) and § 802(21) make clear that a practitioner's registration is dependent upon the practitioner having state authority to dispense controlled substances, the [Administrator's] decision to construe § 824(a)(3) as mandating revocation upon suspension of a state license is not an unreasonable interpretation of the CSA.'' *Hooper* v. *Holder,* 2012 WL 2020079, *2 (4th Cir. 2012) (unpublished).

[2] No objection to consideration of the Government's exhibit, or factual challenge to the matters asserted therein was asserted by the Respondent.

[3] *But see* 21 U.S.C. 824(a)(3) (2012) (''A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance *may* be suspended or revoked by the Attorney General upon a finding that the registrant . . . has had his State license or registration suspended, revoked, or denied by competent State authority . . . .'') (emphasis added).

with a hearing to challenge the State's action at which he may ultimately prevail.'' *Kamal Tiwari, M.D.,* 76 FR 71604, 71606, (2011); *see also Bourne Pharmacy, Inc.,* 72 FR 18273, 18274 (2007); *Anne Lazar Thorn,* 62 FR 12847 (1997). Additionally, Agency precedent has established that the existence of other proceedings in which the Respondent is involved is not a basis upon which to justify a stay of DEA administrative enforcement proceedings. *Grider Drug #1 & Grider Drug #2,* 77 FR 44069, 44104 n.97 (2012).

Congress does not intend for administrative agencies to perform meaningless tasks. *See Philip E. Kirk, M.D.,* 48 FR 32887 (1983), *aff'd sub nom. Kirk* v. *Mullen,* 749 F.2d 297 (6th Cir. 1984); *see also Puerto Rico Aqueduct & Sewer Auth.* v. *EPA,* 35 F.3d 600, 605 (1st Cir. 1994); *NLRB* v. *Int'l Assoc. of Bridge, Structural & Ornamental Ironworkers, AFL–CIO,* 549 F.2d 634 (9th Cir. 1977); *United States* v. *Consol. Mines & Smelting Co.,* 455 F.2d 432, 453 (9th Cir. 1971). Thus, it is well-settled that, where no genuine question of fact is involved, or when the material facts are agreed upon, a plenary, adversarial administrative proceeding is not required. *See Jesus R. Juarez, M.D.,* 62 FR 14945 (1997); *Dominick A. Ricci, M.D.,* 58 FR 51104 (1993). Here, the supplied IDFPR Order establishes, and the Respondent does not contest, that the Respondent is currently without authorization to handle controlled substances in Illinois, the jurisdiction where the Respondent holds the DEA COR that is the subject of this litigation.

Summary disposition of an administrative case is warranted where, as here, ''there is no factual dispute of substance.'' *See Veg-Mix, Inc.,* 832 F.2d 601, 607 (D.C. Cir. 1987) (''an agency may ordinarily dispense with a hearing when no genuine dispute exists'').[4] At this juncture, no genuine dispute exists over the fact that the Respondent lacks state authority to handle controlled substances in the state of Illinois. Because the Respondent lacks such state authority, both the plain language of applicable federal statutory provisions and Agency interpretive precedent dictate that the Respondent is not entitled to maintain his DEA registration. Simply put, there is no contested factual matter adducible at a hearing that would provide DEA with the authority to allow the Respondent to continue to hold his COR.

Accordingly, I hereby

GRANT the Government's Motion for Summary Disposition; and further

DENY the Respondent's Request for Stay; and further

RECOMMEND that the Respondent's DEA registration be REVOKED forthwith and any pending applications for renewal be **DENIED**.

Dated: March 20, 2015.

JOHN J. MULROONEY, II,
Chief Administrative Law Judge.

[FR Doc. 2015–19119 Filed 8–3–15; 8:45 am]

BILLING CODE 4410–09–P

[4] Even assuming, *arguendo,* the possibility that the Respondent's state controlled substances privileges could be reinstated, summary disposition would still be warranted because ''revocation is also appropriate when a state license has been suspended, but with the possibility of future reinstatement,'' *Rodriguez,* 70 FR at 33207 (citations omitted), and even where there is a judicial challenge to the state medical board action actively pending in the state courts. *Michael G. Dolin, M.D.,* 65 FR 5661, 5662 (2000).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 12–49]

AIM Pharmacy & Surgical S. Corp. Order

On May 8, 2015, the Administrator of the Drug Enforcement Administration, noting that the expiration date of Respondent's registration was June 30, 2014, ordered the parties to address whether the case is now moot. The Administrator's Order was served on Respondent's counsel at his address of record.

The Government filed a timely response and served a copy of its response on Respondent's counsel at his address of record. Govt. Response to Administrator's May 8, 2015 Order, at 1. Respondent has not filed a response.[1]

In its Response, the Government advises that Respondent neither submitted a renewal application prior to the expiration of its registration nor an application for a new registration. *Id.* The Government therefore acknowledges that this case is now moot. *Id.; see Ronald J. Riegel,* 63 FR 67132, 67133 (1998). Accordingly, I dismiss the Order to Show Cause.

It is so ordered.

Date: July 27, 2015.

Chuck Rosenberg,
Acting Administrator.

[FR Doc. 2015–19116 Filed 8–3–15; 8:45 am]

BILLING CODE 4410–09–P

[1] After both the Administrator's Order and the Government's Response were returned to the Agency as undelivered following efforts to serve both of Respondent's counsels, the Government determined through the New York State Unified Court System's database that each attorney had a different address than that listed in the record. Notice of Recent Order and Government's Response II, at 1–2. The Government represents that on June 30, 2015, it served both the Administrator's Order and its Response on each of Respondent's attorneys by mailing them to the addresses of Respondent's attorneys as listed in the New York Unified Court System's database. *Id.* at 2.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Manufacturer of Controlled Substances Registration: National Center for Natural Products Research (NIDA MPROJECT), Inc.

ACTION: Notice of registration.

SUMMARY: National Center for Natural Products Research (NIDA MPROJECT), Inc. applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants National Center for Natural Products Research (NIDA MPROJECT), Inc. registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated April 14, 2015, and published in the **Federal Register** on April 22, 2015, 80 FR 22559, National Center for Natural Products Research (NIDA MPROJECT), Inc., University of Mississippi, 135 Coy Waller Complex, University, Mississippi 38677–1848 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of National Center for Natural Products Research (NIDA MPROJECT), Inc. to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the basic classes of controlled substances:

Controlled substance	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I

The company plans to cultivate marihuana in support of the National Institute on Drug Abuse for research approved by the Department of Health and Human Services.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19172 Filed 8–3–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration: Sigma-Aldrich International GMBH, Sigma Aldrich Co., LLC

ACTION: Notice of registration.

SUMMARY: Sigma-Aldrich International GMBH, Sigma Aldrich Co., LLC applied to be registered as an importer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Sigma-Aldrich International GMBH, Sigma Aldrich Co., LLC registration as an importer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated April 14, 2015, and published in the **Federal Register** on April 22, 2015, 80 FR 22552, Sigma-Aldrich International GMBH, Sigma Aldrich Co., LLC, 3500 Dekalb Street, St. Louis, Missouri 63118 applied to be registered as an importer of certain basic classes of controlled substances. No comments or objections were submitted for this notice. Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417, (January 25, 2007).

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Sigma-Aldrich International GMBH, Sigma Aldrich Co., LLC to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of the basic classes controlled substances:

Controlled substance	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
Mephedrone (4-Methyl-N-methylcathinone (1248)	I
N-Ethylamphetamine (1475)	I
Aminorex (1585)	I
Gamma Hydroxybutyric Acid (2010)	I
Methaqualone (2565)	I
Alpha-ethyltryptamine (7249)	I
Ibogaine (7260)	I
Lysergic acid diethylamide (7315)	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Mescaline (7381)	I
4-Bromo-2,5-dimethoxyamphetamine (7391)	I
4-Bromo-2,5-dimethoxyphenethylamine (7392)	I
4-Methyl-2,5-dimethoxyamphetamine (7395)	I
2,5-Dimethoxyamphetamine (7396)	I
3,4-Methylenedioxyamphetamine (7400)	I
N-Hydroxy-3,4-methylenedioxyamphetamine (7402)	I
3,4-Methylenedioxy-N-ethylamphetamine (7404)	I
3,4-Methylenedioxymethamphetamine (7405)	I
4-Methoxyamphetamine (7411)	I
Bufotenine (7433)	I
Diethyltryptamine (7434)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
1-[1-(2-Thienyl)cyclohexyl]piperidine (7470)	I
N-Benzylpiperazine (7493)	I
MDPV (3,4-Methylenedioxypyrovalerone) (7535)	I
Heroin (9200)	I
Normorphine (9313)	I
Etonitazene (9624)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II

Controlled substance	Schedule
Glutethimide (2550)	II
Nabilone (7379)	II
Phencyclidine (7471)	II
Cocaine (9041)	II
Codeine (9050)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Ethylmorphine (9190)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Morphine (9300)	II
Thebaine (9333)	II
Opium, powdered (9639)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances for sale to research facilities for drug testing and analysis.

In reference to drug codes 7360 and 7370, the company plans to import a synthetic cannabidiol and a synthetic tetrahydrocannabinol. No other activity for these drug codes are authorized for this registration.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19159 Filed 8–3–15; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration: Hospira

ACTION: Notice of registration.

SUMMARY: Hospira applied to be registered as an importer of certain basic class of controlled substances. The Drug Enforcement Administration (DEA) grants Hospira registration as an importer of this controlled substance.

SUPPLEMENTARY INFORMATION: By notice dated March 20, 2015, and published in the **Federal Register** on March 27, 2015, 80 FR 16426, Hospira, 1776 North Centennial Drive, McPherson, Kansas 67460–1247 applied to be registered as an importer of a certain basic class of controlled substance. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Hospira to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of remifentanil (9739) a basic class of controlled substance listed in schedule II.

The company plans to import remifentanil for use in dosage form manufacturing.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19106 Filed 8–3–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Manufacturer of Controlled Substances Registration: Cayman Chemicals Company

ACTION: Notice of registration.

SUMMARY: Cayman Chemicals Company applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Cayman Chemicals Company registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated April 14, 2015, and published in the **Federal Register** on April 22, 2015, 80 FR 22557, Cayman Chemicals Company, 1180 East Ellsworth Road, Ann Arbor, Michigan 48108 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Cayman Chemicals Company to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed:

Controlled substance	Schedule
3-Fluoro-N-methylcathinone (3-FMC) (1233)	I
Cathinone (1235)	I
Methcathinone (1237)	I
4-Fluoro-N-methylcathinone (4-FMC) (1238)	I
Pentedrone (α-methylaminovalerophenone (1246)	I
Mephedrone (4-Methyl-N-methylcathinone (1248)	I
4-Methyl-N-ethylcathinone (4-MEC) (1249)	I
Naphyrone (1258)	I
N-Ethylamphetamine (1475)	I
N,N-Dimethylamphetamine (1480)	I
Aminorex (1585)	I
4-Methylaminorex (cis isomer) (1590)	I
Gamma Hydroxybutyric Acid (2010)	I
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl) indole) (6250)	I
SR-18 (Also known as RCS-8) (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl) indole) (7008)	I
5-Flouro-UR-144 and XLR11 [1-(5-Fluoro-pentyl) 1H-indol-3-yl] (2,2,3,3-tetramethylcyclopropyl) methanone (7011)	I
AB-FUBINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide) (7012)	I
JWH-019 (1-Hexyl-3-(1-naphthoyl) indole) (7019)	I
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide) (7035)	I
APINACA and AKB48 N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide (7048)	I
JWH-081 (1-Pentyl-3-(1-(4-methoxynaphthoyl) indole) (7081)	I
SR-19 (Also known as RCS-4) (1-Pentyl-3-[(4-methoxy)-benzoyl] indole) (7104)	I
JWH-018 (also known as AM678) (1-Pentyl-3-(1-naphthoyl) indole) (7118)	I
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl) indole) (7122)	I
UR-144 (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (7144)	I
JWH-073 (1-Butyl-3-(1-naphthoyl)indole (7173)	I
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl) indole) (7200)	I
AM-2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl) indole) (7201)	I
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl) indole) (7203)	I
PB-22 (Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate) (7222)	I
5F-PB-22 (Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate) (7225)	I
Alpha-ethyltryptamine (7249)	I
CP-47,497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol) (7297)	I
CP-47,497 C8 Homologue (5-(1,1-Dimethyloctyl)-2-[(1R,3S) 3-hydroxycyclohexyl-phenol) (7298)	I
Lysergic acid diethylamide (7315)	I
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7) (7348)	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Mescaline (7381)	I
2-(4-Elthylthio-2,5-dimethoxyphenyl) ethanamine (2C-T-2) (7385)	I
3,4,5-Trimethoxyamphetamine (7390)	I
4-Bromo-2,5-dimethoxyamphetamine (7391)	I
4-Bromo-2,5-dimethoxyphenethylamine (7392)	I
4-Methyl-2,5-dimethoxyamphetamine (7395)	I
2,5-Dimethoxyamphetamine (7396)	I
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl) indole) (7398)	I
2,5-Dimethoxy-4-ethylamphetamine (7399)	I
3,4-Methylenedioxyamphetamine (7400)	I
5-Methoxy-3,4-methylenedioxyamphetamine (7401)	I
N-Hydroxy-3,4-methylenedioxyamphetamine (7402)	I
3,4-Methylenedioxy-N-ethylamphetamine (7404)	I
3,4-Methylenedioxymethamphetamine (7405)	I
4-Methoxyamphetamine (7411)	I
5-Methoxy-N-N-dimethyltryptamine (7431)	I
Alpha-methyltryptamine (7432)	I
Bufotenine (7433)	I
Diethyltryptamine (7434)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
5-Methoxy-N,N-diisopropyltryptamine (7439)	I
N-Benzylpiperazine (7493)	I
4-Methyl-alphapyrrolidinopropiophenone (4-MePPP) (7498)	I
2-(2,5-Dimethoxy-4-methylphenyl) ethanamine (2C-D) (7508)	I
2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine(2C-E) (7509)	I
2-(2,5-Dimethoxyphenyl) ethanamine (2C-H) (7517)	I
2-(4-Iodo-2,5-dimethoxyphenyl) ethanamine (2C-I) (7518)	I
2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine (2C-C) (7519)	I
2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine (2C-N) (7521)	I
2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine (2C-P) (7524)	I
2-(4-Isopropylthio)-2,5-dimethoxyphenyl) ethanamine (2C-T-4) (7532)	I
MDPV (3,4-Methylenedioxypyrovalerone) (7535)	I
Methylone (3,4-Methylenedioxy-N-methylcathinone) (7540)	I
Butylone (7541)	I

Controlled substance	Schedule
Pentylone (7542)	I
alpha-pyrrolidinopentiophenone (α-PVP) (7545)	I
alpha-pyrrolidinobutiophenone (α-PBP) (7546)	I
AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole) (7694)	I
Desomorphine (9055)	I
Oxycodone (9143)	II
Dihydromorphine (9145)	I
Heroin (9200)	I
Morphine-N-oxide (9307)	I
Normorphine (9313)	I
Tilidine (9750)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Lisdexamfetamine (1205)	II
Pentobarbital (2270)	II
Phencyclidine (7471)	II
Phenylacetone (8501)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Levomethorphan (9210)	II
Meperidine (9230)	II
Meperidine intermediate-B (9233)	II
Methadone (9250)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273)	II
Morphine (9300)	II
Thebaine (9333)	II
Oxymorphone (9652)	II
Sufentanil (9740)	II

The company plans to manufacture reference standards for distribution to their research and forensics customers.

In reference to drug codes 7360 Marihuana, and 7370 (THC), the company plans to bulk manufacture these drugs as synthetic. No other activities for these drug codes are authorized for this registration.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19163 Filed 8–3–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Research Triangle Institute

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before September 3, 2015. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before September 3, 2015.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODXL, 8701 Morrissette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152. Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (January 25, 2007).

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (''Deputy Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on March 12, 2015, Research Triangle Institute, Kenneth S. Rehder, Hermann Building East Institute Drive, P.O. Box 12194, Research Triangle Park, North Carolina 27709–2194 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Schedule
AB-PINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1-1H-indazole-3-carboxamide) (7023)	I
AB-CHMINACA (N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (7031)	I
AM-2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl)indole) (7201)	I
AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole) (7694)	I
JWH-018 (also known as AM678) (1-Pentyl-3-(1-naphthoyl) indole) (7118)	I
JWH-073 (1-Butyl-3-(1-naphthoyl)indole) (7173)	I

Controlled substance	Schedule
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole) (7200)	I
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl) indole) (6250)	I
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole) (7019)	I
JWH-081 (1-Pentyl-3-(1-(4-methoxynaphthoyl) indole) (7081)	I
JWH-122 (-Pentyl-3-(4-methyl-1-naphthoyl) indole) (7122)	I
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl) indole) (7203)	I
JWH-398 (1-Pentyl-3-(4-chloro-1-naphththoyl) indole) (7398)	I
THJ-2201 [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalene-1-yl)methanone (7024)	I
1-(1-Phenylcyclohexyl)pyrrolidine (7458)	I
1-[1-(2-Thienyl)cyclohexyl]piperidine (7470)	I
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine (7473)	I
1-Methyl-4-phenyl-4-propionoxypiperidine (9661)	I
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine (9663)	I
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7) (7348)	I
2,5-Dimethoxy-4-ethylamphetamine (7399)	I
2,5-Dimethoxyamphetamine (7396)	I
2-(2,5-Dimethoxy-4-methylphenyl) ethanamine (2C-D) (7508)	I
2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine (2C-E) (7509)	I
2-(2,5-Dimethoxyphenyl) ethanamine (2C-H) (7517)	I
2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine (2C-N) (7521)	I
2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine (2C-P) (7524)	I
2-(4-isopropylthio)-2,5-dimethoxyphenyl) ethanamine (2C-T-4) (7532)	I
2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe) (7536)	I
2,5-Dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7) (7348)	I
2-(4-Ethylthio-2,5-dimethoxyphenyl) ethanamine (2C-T-2) (7385)	I
2-(4-Lodo-2,5-dimethoxyphenyl) ethanamine (2C-I) (7518)	I
2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine (2C-C) (7519)	I
3,4,5-Trimethoxyamphetamine (7390)	I
3,4-Methylenedioxyamphetamine (7400)	I
3,4-Methylenedioxy-N-ethylamphetamine (7404)	I
3,4-Methylenedioxymethamphetamine (7405)	I
3-Methylfentanyl (9813)	I
3-Methylthiofentanyl (9833)	I
4-Bromo-2,5-dimethoxyamphetamine (7391)	I
4-Bromo-2,5-dimethoxyphenethylamine (7392)	I
4-Methyl-2,5-dimethoxyamphetamine (7395)	I
4-Methylaminorex (cis isomer) (1590)	I
4-Methoxyamphetamine (7411)	I
5-Methoxy-3,4-methylenedioxyamphetamine (7401)	I
5-Methoxy-N,N-dimethyltryptamine (7431)	I
5-Methoxy-N,N-diisopropyltryptamine (7439)	I
Acetorphine (9319)	I
Acetyl-alpha-methylfentanyl (9815)	I
Acetyldihydrocodeine (9051)	I
Acetylmethadol (9601)	I
Allylprodine (9602)	I
Alpha-ethyltryptamine (7249)	I
Alpha-methylfentanyl (9814)	I
Alpha-methylthiofentanyl (9832)	I
Alpha-methyltryptamine (7432)	I
Alphacetylmethadol except levo-alphacetylmethadol (9603)	I
Alphameprodine (9604)	I
Alphamethadol (9605)	I
Aminorex (1585)	I
Benzethidine (9606)	I
Benzylmorphine (9052)	I
Beta-hydroxy-3-methylfentanyl (9831)	I
Beta-hydroxyfentanyl (9830)	I
Betacetylmethadol (9607)	I
Betameprodine (9608)	I
Betamethadol (9609)	I
Betaprodine (9611)	I
Bufotenine (7433)	I
CP-47,497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl-phenol) (7297)	I
CP-47,497 C8 Homologue (5-(1,1-Dimethyloctyl)-2-[(1R,3S)3-hydroxycyclohexyl-phenol) (7298)	I
Cathinone (1235)	I
Clonitazene (9612)	I
Codeine methylbromide (9070)	I
Codeine-N-oxide (9053)	I
Cyprenorphine (9054)	I
Desomorphine (9055)	I
Dextromoramide (9613)	I
Diampromide (9615)	I
Diethylthiambutene (9616)	I

Controlled substance	Schedule
Diethyltryptamine (7434)	I
Difenoxin (9168)	I
Dihydromorphine (9145)	I
Dimenoxadol (9617)	I
Dimepheptanol (9618)	I
Dimethylthiambutene (9619)	I
Dimethyltryptamine (7435)	I
Dioxaphetyl butyrate (9621)	I
Dipipanone (9622)	I
Drotebanol (9335)	I
Ethylmethylthiambutene (9623)	I
Etonitazene (9624)	I
Etorphine (except HCl) (9056)	I
Etoxeridine (9625)	I
Fenethylline (1503)	I
Furethidine (9626)	I
Gamma Hydroxybutyric Acid (2010)	I
Heroin (9200)	I
Hydromorphinol (9301)	I
Hydroxypethidine (9627)	I
Ibogaine (7260)	I
Ketobemidone (9628)	I
Levomoramide (9629)	I
Levophenacylmorphan (9631)	I
Lysergic acid diethylamide (7315)	I
MDPV (3,4-Methylenedioxypyrovalerone) (7535)	I
Marihuana (7360)	I
Mecloqualone (2572)	I
Mephedrone (1248)	I
Mescaline (7381)	I
Methaqualone (2565)	I
Methcathinone (1237)	I
Methyldesorphine (9302)	I
Methyldihydromorphine (9304)	I
Methylone (3,4-Methylenedioxy-N-methylcathinone) (7540)	I
Morpheridine (9632)	I
Morphine methylbromide (9305)	I
Morphine methylsulfonate (9306)	I
Morphine-N-Oxide (9307)	I
Myrophine (9308)	I
N,N-Dimethylamphetamine (1480)	I
N-Benzylpiperazine (7493)	I
N-Ethyl-3-piperidyl benzilate (7482)	I
N-Ethylamphetamine (1475) N-Ethyl-1-phenylcyclohexylamine (7455)	I
N-Hydroxy-3,4-methylenedioxyamphetamine (7402)	I
Nicocodeine (9309)	I
Nicomorphine (9312)	I
N-Methyl-3-piperidyl benzilate (7484)	I
Noracymethadol (9633)	I
Norlevorphanol (9634)	I
Normethadone (9635)	I
Normorphine (9313)	I
Norpipanone (9636)	I
Para-Fluorofentanyl (9812)	I
Parahexyl (7374)	I
Peyote (7415)	I
Phenadoxone (9637)	I
Phenampromide (9638)	I
Phenomorphan (9647)	I
Phenoperidine (9641)	I
Pholcodine (9314)	I
Piritramide (9642)	I
Proheptazine (9643)	I
Properidine (9644)	I
Propiram (9649)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
Racemoramide (9645)	I
SR-18 (Also known as RCS-8) (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl) indole) (7008)	I
SR-19 (Also known as RCS-4) (1-Pentyl-3-[(4-methoxy)-benzoyl] indole (7104)	I
Tetrahydrocannabinols (7370)	I
Thebacon (9315)	I
Thiofentanyl (9835)	I
Tilidine (9750)	I

Controlled substance	Schedule
Trimeperidine (9646)	I
1-Phenylcyclohexylamine (7460)	II
1-Piperidinocyclohexanecarbonitrile (8603)	II
4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333)	II
Alfentanil (9737)	II
Alphaprodine (9010)	II
Amobarbital (2125)	II
Amphetamine (1100)	II
Anileridine (9020)	II
Bezitramide (9800)	II
Carfentanil (9743)	II
Coca Leaves (9040)	II
Cocaine (9041)	II
Codeine (9050)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273)	II
Dihydrocodeine (9120)	II
Dihydroetorphine (9334)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Ethylmorphine (9190)	II
Etorphine HCl (9059)	II
Fentanyl (9801)	II
Glutethimide (2550)	II
Hydrocodone (9193)	II
Hydromorphone (9150)	II
Isomethadone (9226)	II
Levo-alphacetylmethadol (9648)	II
Levomethorphan (9210)	II
Levorphanol (9220)	II
Lisdexamfetamine (1205)	II
Meperidine (9230)	II
Meperidine intermediate-A (9232)	II
Meperidine intermediate-B (9233)	II
Meperidine intermediate-C (9234)	II
Metazocine (9240)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Metopon (9260)	II
Moramide-intermediate (9802)	II
Morphine (9300)	II
Nabilone (7379)	II
Opium, raw (9600)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium powdered (9639)	II
Opium poppy/Poppy Straw (9650)	II
Oripavine (9330)	II
Poppy Straw Concentrate (9670)	II
Opium, granulated (9640)	II
Oxycodone (9143)	II
Oxymorphone (9652)	II
Pentobarbital (2270)	II
Phenazocine (9715)	II
Phencyclidine (7471)	II
Phenmetrazine (1631)	II
Phenylacetone (8501)	II
Piminodine (9730)	II
Racemethorphan (9732)	II
Racemorphan (9733)	II
Remifentanil (9739)	II
Secobarbital (2315)	II
Sufentanil (9740)	II
Tapentadol (9780)	II
Thebaine (9333)	II

The company plans to import small quantities of the listed controlled substances for the National Institute on Drug Abuse (NIDA) for research activities.

The company plans to import analytical reference standards for distribution to its customers for research

and analytical purposes. Placement of these drug codes onto the company's registration does not translate into automatic approval of subsequent permit applications to import controlled substances. Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under to 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19158 Filed 8–3–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Cedarburg Pharmaceuticals, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before October 5, 2015.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODXL, 8701 Morrissette Drive, Springfield, Virginia 22152. Request for hearings should be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (''Deputy Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on July 28, 2014, Cedarburg Pharmaceuticals, Inc., 870 Badger Circle, Grafton, Wisconsin 53024 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I

The company plans to manufacture the above-listed controlled substances in bulk for distribution to its customers. In reference to drug code 7360 marihuana, the company plans to bulk manufacture cannabidiol as a synthetic intermediate. This controlled substance will be further synthesized to bulk manufacture a synthetic tetrahydrocannabinol 7370. No other activity for this drug code is authorized for this registration.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19165 Filed 8–3–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Manufacturer of Controlled Substances Registration: Cody Laboratories, Inc.

ACTION: Notice of registration.

SUMMARY: Cody Laboratories, Inc. applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Cody Laboratories, Inc. registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated April 14, 2015, and published in the **Federal Register** on April 22, 2015, 80 FR 22560, Cody Laboratories, Inc., Steve Hartman-Vice President of Compliance, 601 Yellowstone Avenue, Cody, Wyoming 82414 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Cody Laboratories, Inc. to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed:

Controlled substance	Schedule
Dihydromorphine (9145)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333).	II
Phenylacetone (8501)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Ecgonine (9180)	II
Hydrocodone (9193)	II
Meperidine (9230)	II
Methadone (9250)	II
Morphine (9300)	II
Thebaine (9333)	II
Oxymorphone (9652)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19168 Filed 8–3–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Manufacturer of Controlled Substances Registration: Johnson Matthey, Inc.

ACTION: Notice of registration.

SUMMARY: Johnson Matthey, Inc. applied to be registered as a manufacturer of certain basic classes of controlled

substances. The Drug Enforcement Administration (DEA) grants Johnson Matthey, Inc. registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated February 11, 2015, and published in the **Federal Register** on February 19, 2015, 80 FR 8902, Johnson Matthey, Inc., Pharmaceuticals Materials, 900 River Road, Conshohocken, Pennsylvania 19428 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted to this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Johnson Matthey, Inc. to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed:

Controlled substance	Schedule
Gamma Hydroxybutyric Acid (2010).	I
Amphetamine (1100)	II
Methylphenidate (1724)	II
Codeine (9050)	II
Oxycodone (9143)	II
Diphenoxylate (9170)	II
Hydrocodone (9193)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone intermediate (9254)	II
Morphine (9300)	II
Thebaine (9333)	II

The company plans to manufacture the listed controlled substances in bulk for distribution and sale to its customers.

The thebaine (9333) will be used to manufacture other controlled substances for sale in bulk to its customers.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19100 Filed 8–3–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration: Actavis Laboratories FL, Inc.

ACTION: Notice of registration.

SUMMARY: Actavis Laboratories FL, Inc. applied to be registered as an importer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Actavis Laboratories FL, Inc., registration as an importer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated April 14, 2015, and published in the **Federal Register** on April 22, 2015, 80 FR 22554, Actavis Laboratories FL, Inc., 4955 Orange Drive, Davie, Florida 33314 applied to be registered as an importer of a certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Actavis Laboratories FL, Inc. to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of the following basic classes of controlled substances:

Controlled substance	Schedule
Amphetamine (1100)	II
Methylphenidate (1724)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Fentanyl (9801)	II

The company plans to import the above-listed controlled substances for clinical trials, research and analytical purposes.

The import of the above-listed basic classes of controlled substances would be granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished Food and Drug Administration approved or non-approved dosage form for commercial distribution in the United States.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19162 Filed 8–3–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration: Almac Clinical Services Inc. (ACSI)

ACTION: Notice of registration.

SUMMARY: Almac Clinical Services Inc. (ACSI) applied to be registered as an importer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Almac Clinical Services Inc. (ACSI) registration as an importer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated April 14, 2015, and published in the **Federal Register** on April 22, 2015, 80 FR 22556, Almac Clinical Services Inc. (ACSI), 25 Fretz Road, Souderton, Pennsylvania 18964 applied to be registered as an importer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Almac Clinical Services Inc. (ACSI) to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of the following basic classes of controlled substances:

Controlled substance	Schedule
Oxycodone (9143)	II
Hydromorphone (9150)	II
Tapentadol (9780)	II

Controlled substance	Schedule
Fentanyl (9801)	II

The company plans to import small quantities of the listed controlled substances in dosage form to conduct clinical trials.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19109 Filed 8–3–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration: Meridian Medical Technologies

ACTION: Notice of registration.

SUMMARY: Meridian Medical Technologies applied to be registered as an importer of a certain basic class of controlled substance. The Drug Enforcement Administration (DEA) grants Meridian Medical Technologies registration as an importer of this controlled substance.

SUPPLEMENTARY INFORMATION: By notice dated April 14, 2015, and published in the **Federal Register** on April 22, 2015, 80 FR 22553, Meridian Medical Technologies, 2555 Hermelin Drive, St. Louis, Missouri 63144 applied to be registered as an importer of a certain basic class of controlled substance. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Meridian Medical Technologies to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of morphine (9300), a basic class controlled substance listed in schedule II.

The company manufactures a product containing morphine in the United States. The company exports this product to customers around the world. The company has been asked to ensure that its product, which is sold to European customers, meets the standards established by the European Pharmacopeia, administered by the Directorate for the Quality of Medicines (EDQM). In order to ensure that its product will meet European specifications, the company seeks to import morphine supplied by EDQM for use as reference standards.

This is the sole purpose for which the company will be authorized by the DEA to import morphine.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19164 Filed 8–3–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Manufacturer of Controlled Substances Registration: Pharmacore, Inc.

ACTION: Notice of registration.

SUMMARY: Pharmacore, Inc. applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Pharmacore, Inc. registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated April 14, 2015, and published in the **Federal Register** on April 22, 2015, 80 FR 22554, Pharmacore, Inc., 4180 Mendenhall Oaks Parkway, High Point, North Carolina 27265 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Pharmacore, Inc. to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the basic classes of controlled substances:

Controlled substance	Schedule
Oxymorphone (9652)	II
Noroxymorphone (9668)	II

The company plans to manufacture the listed controlled substance as an active pharmaceutical ingredient (API) for clinical trials.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19099 Filed 8–3–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Manufacturer of Controlled Substances Registration: Cambrex Charles City

ACTION: Notice of registration.

SUMMARY: Cambrex Charles City applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Cambrex Charles City registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated April 14, 2015, and published in the **Federal Register** on April 22, 2015, 80 FR 22555, Cambrex Charles City, 1205 11th Street, Charles City, Iowa 50616 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Cambrex Charles City to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and

local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed:

Controlled substance	Schedule
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333).	II
Phenylacetone (8501)	II
Cocaine (9041)	II
Codeine (9050)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Opium, raw (9600)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Opium, granulated (9640)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Poppy Straw Concentrate (9670)	II
Alfentanil (9737)	II
Remifentanil (9739)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers, for dosage form development, for clinical trials, and for use in stability qualification studies.

Dated: July 29, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015–19111 Filed 8–3–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employment and Training Administration

Comment Request for Proposed Information Collection for Employment and Training Administration Financial Report Form #9130 (OMB Control No. 1205–0461), Extension With Changes

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance 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 requirements on respondents can be properly assessed. Currently, the Employment and Training Administration is soliciting comments concerning the collection of data for quarterly financial reporting on federally funded programs, on Form ETA–9130 (currently due to expire December 31, 2015).

A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Submit written comments to the office listed in the addresses section below on or before October 5, 2015.

ADDRESSES: Send written comments to Maggie Ewell, Division of Policy, Review, and Resolution, Office of Grants Management, Room N–4716, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Telephone number: 202–693–3160 (this is not a toll-free number). Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD). Fax: 202–693–2705. Email: *Ewell.Maggie@dol.gov.* To obtain a copy of the proposed information collection request (ICR), please contact the person listed above.

SUPPLEMENTARY INFORMATION:

I. Background

ETA awards approximately $8 billion in formula and discretionary grants each year to an average of 1,000 recipients. Financial reports for each of these grants must be submitted quarterly on the financial report form ETA–9130. Recipients include but are not limited to: State Employment Security Agencies which are comprised of three components: Wagner Peyser Employment Service, Unemployment Insurance program, and Trade Program Grant Agreements; as well as Workforce Innovation and Opportunity Act (WIOA) Youth, Adult, and Dislocated Worker programs; National Dislocated Worker Grants; National Farmworker Jobs Program (NFJP); Indian and Native American programs; the Senior Community Service Employment Program; Workforce Innovation and Opportunity Act discretionary grants; and H–1B Job Training Grants.

Financial reporting requirements for Federal programs prescribed by the Office of Management and Budget (OMB) have changed with the implementation of the Uniform Guidance, which went into effect on December 26, 2014, replacing numerous previously applicable Circulars. These changes affect both the ETA–9130 reporting form and its instructions. However, they do not affect the collection burden, but instead only update certain key terms and definitions.

Additionally, with the passage of WIOA, there are numerous new statutory requirements that impact financial reporting, including but not limited to new and/or revised limitations and baselines that require the addition of new and modification of existing reporting line items on ETA–9130 Financial Reports, as outlined in this TEGL. Other reporting line items have been added and removed in an effort to streamline Federal financial reporting and make form ETA–9130 more closely resemble the SF–425 (OMB 0348–0061), which is the standard financial reporting form for Federal grant recipients.

ETA has utilized the data collected to assess the effectiveness of ETA programs and to monitor and analyze the financial activity of its grantees. Grantees are provided with pre-designed software to reflect the requirements of ETA Form 9130 so that the required data will be reported electronically. ETA strives to reduce reporting time for our recipients. Several sections of the 9130 have pre-filled line items or automatically calculated line items, which is convenient and time saving for our recipients.

This data collection format permits ETA to evaluate program effectiveness and to monitor and analyze financial activity, while complying with OMB efforts to streamline Federal financial reporting.

II. Review Focus

The Department is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used;

• enhance the quality, utility, and clarity of the information to be collected; and

• minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

III. Current Actions

Type of Review: Revised collection.

Title: US DOL Employment and Training Administration Financial Reporting Form, ETA 9130.

OMB Number: 1205–0461.

Affected Public: State, Local, and Tribal Governments.

Estimated Total Annual Respondents: 1,000.

Estimated Total Annual Responses: 20,000.

Estimated Total Annual Burden Hours: 15,000.

Total Estimated Annual Other Costs Burden: $0.

We will summarize and/or include in the request for OMB approval of the ICR, the comments received in response to this comment request; they will also become a matter of public record.

Portia Wu,

Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2015–18986 Filed 8–3–15; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Diesel-Powered Equipment in Underground Coal Mines

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Mine Safety and Health Administration (MSHA) sponsored information collection request (ICR) titled, ''Diesel-Powered Equipment in Underground Coal Mines,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before September 3, 2015.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201410-1219-002* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–MSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Diesel-Powered Equipment in Underground Coal Mines information collection requirements codified in regulations 30 CFR part 75. The MSHA requires a mine operator to provide important safety and health protection to an underground coal miner who works on and around diesel-powered equipment. Engines powering diesel equipment are potential contributors to fires and explosion hazards in the confined environment of an underground coal mine where combustible coal dust and explosive methane gas are present. In addition, diesel equipment operating in an underground coal mine can pose serious health risks to miners from exposure to diesel exhaust emissions, including diesel particulates, oxides of nitrogen, and carbon monoxide. Diesel exhaust is a lung carcinogen in animals.

This information collection pertains to diesel equipment maintenance and use; tests and maintenance of fire suppression systems on both the equipment and at fueling stations; and exhaust gas sampling. Records are required to document essential testing and maintenance of diesel-powered equipment are conducted regularly by a qualified person; any corrective action is taken; and a person performing covered maintenance, repairs, examinations, or tests is trained and qualified to perform such tasks.

The subject information collection requirements are found in regulations 30 CFR 75.1901(a), Diesel fuel requirements; 75.1904(b)(4)(i), Underground diesel fuel tanks and safety cans; 75.1906(d), Transport of diesel fuel; 75.1911(j), Fire suppression systems for diesel-powered equipment and fuel transportation units; 75.1912(i), Fire suppression systems for permanent underground diesel fuel storage facilities; 75.1914(f)(2), (g), (h)(1), and (h)(2), Maintenance of diesel-powered equipment; sections 75.1915(b)(5), (c)(1), and (c)(2), Training and qualification of persons working on diesel-powered equipment. Federal Mine Safety and Health Act of 1977 sections 801(a) and 803(h) authorize this information collection. *See* 30 U.S.C. 811(a), 813(h).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0119.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on August 31, 2015. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information

about this ICR, see the related notice published in the **Federal Register** on May 11, 2015 (80 FR 26952).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1219–0119. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–MSHA.

Title of Collection: Diesel-Powered Equipment in Underground Coal Mines.

OMB Control Number: 1219–0119.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 151.

Total Estimated Number of Responses: 177,659.

Total Estimated Annual Time Burden: 14,422 hours.

Total Estimated Annual Other Costs Burden: $322,624.

Dated: July 29, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–19038 Filed 8–3–15; 8:45 am]

BILLING CODE 4510–43–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0001]

Sunshine Act Meeting Notice

DATES: August 3, 10, 17, 24, 31, September 7, 2015.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed

Week of August 3, 2015

Thursday, August 6, 2015

9:25 a.m. Affirmation Session (Public Meeting) (Tentative) Crow Butte Resource, Inc. (License Renewal for the In Situ Leach Facility, Crawford, Nebraska), Petitions for review of LBP–15–2 and LBP–15–11 (Tentative)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

9:30 a.m. Strategic Programmatic Overview of the Operating Reactors Business Line (Public Meeting) (Contact: Nathan Sanfilippo: 301–415–8744)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

1 p.m. Discussion of Management and Personnel Issues (Closed—Ex. 2 & 6)

Week of August 10, 2015—Tentative

Thursday, August 13, 2015

9 a.m. Briefing on Greater-Than-Class-C Low-Level Radioactive Waste (Public Meeting) (Contact: Gregory Suber: 301–415–8087)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of August 17, 2015—Tentative

There are no meetings scheduled for the week of August 17, 2015.

Week of August 24, 2015—Tentative

There are no meetings scheduled for the week of August 24, 2015.

Week of August 31, 2015—Tentative

There are no meetings scheduled for the week of August 31, 2015.

Week of September 7, 2015—Tentative

Tuesday, September 8, 2015

9:30 a.m. Briefing on Project AIM 2020 (Public Meeting) (Contact: Karen Fitch: 301–415–7358)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Thursday, September 10, 2015

9:30 a.m. Briefing on NRC International Activities (Closed—Ex. 1 & 9)

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The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Glenn Ellmers at 301–415–0442 or via email at *Glenn.Ellmers@nrc.gov.*

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.* braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0727, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: July 30, 2015.

Glenn Ellmers,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2015–19176 Filed 7–31–15; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0165]

Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; opportunity to comment, request a hearing, and petition for leave to intervene; order.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received and is considering approval of two amendment requests. The amendment requests are for Shearon Harris Nuclear Power Plant,

Unit No. 1; and H.B Robison Steam Electric Plant, Unit No. 2. The NRC proposes to determine that each amendment request involves no significant hazards consideration. In addition, each amendment request contains sensitive unclassified non-safeguards information (SUNSI).

DATES: Comments must be filed by September 3, 2015. A request for a hearing must be filed by October 5, 2015. Any potential party as defined in § 2.4 of Title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to SUNSI is necessary to respond to this notice must request document access by August 14, 2015.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0165. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Shirley Rohrer, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–5411, email: *Shirley.Rohrer@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0165 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0165.

• *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 (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2015–0165, facility name, unit number(s), application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Background

Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the NRC is publishing this notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This notice includes notices of amendments containing SUNSI.

III. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish a notice of issuance in the **Federal Register**. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing

and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html*. System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html*. Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html*.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance

available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)-(iii).

For further details with respect to this amendment action, see the application for amendment which is available for public inspection at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. Publicly available documents created or received at the NRC are accessible electronically through ADAMS in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR's Reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*

Duke Energy Progress Inc., Docket No. 50–400, Shearon Harris Nuclear Power Plant, Unit No. 1, New Hill, North Carolina

Duke Energy Progress Inc., Docket No. 50–261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of amendment request: March 5, 2015. A publicly-available version is in ADAMS under Accession No. ML15075A221.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). This amendment requests the NRC's review and approval of a revised reactor core design methodology report, DPC–NE–2005–P, ''Thermal-Hydraulic Statistical Core Design Methodology,'' and adoption of the revised methodology into the Technical Specifications for each facility. The revised methodology report will add a site-specific appendix for each facility.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change extends use of DPC–NE–2005–P–A, ''Thermal-Hydraulic Statistical Core Design Methodology'' to Shearon Harris Nuclear Power Plant (SHNPP) and H. B. Robinson Steam Electric Plant (HBRSEP). The NRC has previously reviewed and approved use of this methodology, stating it is direct and general enough to be widely applicable to any Pressurized Water Reactor (PWR) core. The methodology will be applied to SHNPP and HBRSEP after approval by the NRC. The proposed methodology does not affect the performance of any equipment used to mitigate the consequences of an analyzed accident. There is no impact on the source term or pathways assumed in accidents previously assumed. No analysis assumptions are violated and there are no adverse effects on the factors that contribute to offsite or onsite dose as the result of an accident. No accident probabilities or consequences will be impacted by this LAR [license amendment request].

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change extends use of DPC–NE–2005–P–A, ''Thermal-Hydraulic Statistical Core Design Methodology'' to Shearon Harris Nuclear Power Plant (SHNPP) and H. B. Robinson Steam Electric Plant (HBRSEP). It does not change any system functions or maintenance activities. The change does not involve physical alteration of the plant, that is, no new or different type of equipment will be installed. The change does not alter assumptions made in the safety analyses but ensures that the core will operate within safe limits. This change does not create new failure modes or mechanisms which are not identifiable during testing, and no new accident precursors are generated.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change extends use of DPC–NE–2005–P–A, ''Thermal-Hydraulic Statistical Core Design Methodology'' to Shearon Harris Nuclear Power Plant (SHNPP) and H. B. Robinson Steam Electric Plant (HBRSEP). The NRC has previously reviewed and approved use of this methodology, stating it is direct and general enough to be widely applicable to any PWR core. The methodology will be applied to SHNPP and HBRSEP after approval by the NRC. Consistent with the existing methodology, the use of the proposed methodology will continue to ensure that all applicable design and safety limits are satisfied such that the fission product barriers will continue to perform their design functions.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lara S. Nichols, Deputy General Counsel, Duke Energy Corporation, 550 South Tyron Street, Mail Code DEC45A, Charlotte, North Carolina 28202.

NRC Branch Chief: Shana R. Helton.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Duke Energy Progress Inc., Docket No. 50–400,Shearon Harris Nuclear Power Plant, Unit No. 1, New Hill, North Carolina

Duke Energy Progress Inc., Docket No. 50–261,H.B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request such access. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *OGCmailcenter@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly-available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order[2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after the requestor is granted access to that information. However, if more than 25 days remain between the date the petitioner is granted access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline. This provision does not extend the time for filing a request for a hearing and petition to intervene, which must comply with the requirements of 10 CFR 2.309.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and need for access, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requester may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

with jurisdiction pursuant to 10 CFR 2.318(a); or (c) officer if that officer has been designated to rule on information access issues.

H. Review of Grants of Access. A party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed with the Chief Administrative Judge within 5 days of the notification by the NRC staff of its grant of access.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. Attachment 1 to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated at Rockville, Maryland, this 23rd day of July, 2015.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

ATTACHMENT 1—General Target Schedule for Processing and Resolving Requests for Access to Sensitive Unclassified Non-Safeguards Information in This Proceeding

Day	Event/Activity
0	Publication of Federal Register notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

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[3] Requesters should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0181]

Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Biweekly notice.

SUMMARY: Pursuant to Section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from July 9, 2015, to July 22, 2015. The last biweekly notice was published on July 21, 2015.

DATES: Comments must be filed by September 30, 2015. A request for a hearing must be filed by October 5, 2015.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0181. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Lynn Ronewicz, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–1927 email: *Lynn.Ronewicz@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0181 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0181.
- *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 (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2015–0181, facility name, unit number(s), application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov,* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in section 50.92 of Title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave to Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also identify the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nr.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then

submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8:00 a.m. and 8:00 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii).

For further details with respect to these license amendment applications, see the application for amendment which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

Duke Energy Carolinas, LLC, Docket Nos. 50–413 and 50–414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina; Docket Nos. 50–369 and 50–370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina

Date of amendment request: June 23, 2015. A publicly-available version is in ADAMS under Accession No. ML15190A381.

Description of amendment request: The amendments would delete text from the Technical Specifications that was included to facilitate a phased implementation of new nuclear instrumentation systems.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Criterion 1:

Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

This LAR [license amendment request] proposes administrative non-technical changes only. These proposed changes do not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, or configurations of the facility. The proposed changes do not alter or prevent the ability of structures, systems[,] and components (SSCs) to perform their intended function to mitigate the consequences of an initiating event witin the assumed acceptance limits.

Given the above discussion, it is concluded the proposed amendment does not significantly increase the probability or consequences of an accident previously evaluated.

Criterion 2:

Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The LAR proposes administrative non-technical changes only. The proposed changes will not alter the design requirements of any [SSC] or its function during accident conditions. No new or different accidents result from the changes proposed. The changes do not involve a physical alteration of the plant or any changes in methods governing normal plant operation. The changes do not alter assumptions made in the safety analysis.

Given the above discussion, it is concluded the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Criterion 3:

Does the proposed amendment involve a significant reduction in the margin of safety?

Response: No.

This LAR proposes administrative non-technical changes only. The proposed changes do not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The safety analysis acceptance criteria are not affected by these changes. The proposed changes will not result in plant operation in a configuration outside the design basis. The proposed changes do not adversely affect systems that respond to safely shutdown the plant and to maintain the plant in a safe shutdown condition.

Given the above discussion, it is concluded [that] the proposed amendment does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lara S. Nichols, Associate General Counsel, Duke Energy Corporation, 526 South Church Street—EC07H, Charlotte, NC 28202.

NRC Branch Chief: Robert J. Pascarelli.

Duke Energy Progress, Inc., Docket No. 50–261, H.B. Robinson Steam Electric Plant Unit No. 2, Darlington County, South Carolina

Date of amendment request: May 13, 2015. A publicly-available version is in ADAMS under Accession No. ML15133A452.

Description of amendment request: The amendment would revise the emergency plan by changing the emergency action levels from a scheme based upon Revision 4 of Nuclear Energy Institute (NEI) 99–01, ''Methodology for Development of Emergency Action Levels,'' to one based upon Revision 6 of NEI 99–01, ''Development of Emergency Action Levels for Non-Passive Reactors.'' The NRC formally endorsed NEI 99–01, Revision 6, in a letter dated March 28, 2013 (ADAMS Accession No. ML12346A463).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

These changes affect the HBRSEP2 [H. B. Robinson Steam Electric Plant Unit No. 2] Emergency Plan and do not alter any of the requirements of the Operating License or the Technical Specifications. The proposed changes do not modify any plant equipment and do not impact any failure modes that could lead to an accident. Additionally, the proposed changes do not impact the consequence of any analyzed accident since the changes do not affect any equipment related to accident mitigation.

Based on this discussion, the proposed amendment does not increase the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

These changes affect the HBRSEP2 Emergency Plan and do not alter any of the requirements of the Operating License or the Technical Specifications. They do not modify any plant equipment and there is no impact on the capability of the existing equipment to perform their intended functions. No system setpoints are being modified and no changes are being made to the method in which plant operations are conducted. No new failure modes are introduced by the proposed changes. The proposed amendment does not introduce an accident initiator or malfunctions that would cause a new or different kind of accident.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

These changes affect the HBRSEP2 Emergency Plan and do not alter any of the requirements of the Operating License or the Technical Specifications. The proposed changes do not affect any of the assumptions used in the accident analysis, nor do they affect any operability requirements for equipment important to plant safety.

Therefore, the proposed changes will not result in a significant reduction in the margin of safety as defined in the bases for technical specifications covered in this license amendment request.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Lara S. Nichols, Deputy General Counsel, Duke Energy Corporation, 550 South Tyron Street, Mail Code DEC45A, Charlotte, NC 28202.

NRC Branch Chief: Shana R. Helton.

Entergy Nuclear Operations, Inc., Docket Nos. 50–003, 50–247, and 50–286, Indian Point Nuclear Generating, Unit Nos. 1, 2, and 3, Westchester County, New York

Date of amendment request: June 16, 2015. A publicly available version is in ADAMS under Accession No. ML15173A070.

Description of amendment request: The amendments would change the Indian Point Nuclear Generating, Unit Nos. 1, 2, and 3 Cyber Security Plan (CSP) Milestone 8 full implementation date from June 30, 2016, to December 31, 2017.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change to the CSP Implementation Schedule is administrative in nature. This change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change does not require any plant modifications which affect the performance capability of the structures, systems, and components relied upon to mitigate the consequences of postulated accidents and has no impact on the probability or consequences of an accident previously evaluated.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change to the CSP Implementation Schedule is administrative in nature. This proposed change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change does not require any plant modifications which affect the performance capability of the structures, systems, and components relied upon to mitigate the consequences of postulated accidents and does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

Plant safety margins are established through limiting conditions for operation, limiting safety system settings, and safety limits specified in the technical specifications. The proposed change to the CSP Implementation Schedule is administrative in nature. In addition, the milestone date delay for full implementation of the CSP has no substantive impact because other measures have been taken which provide adequate protection during this period of time. Because there is no change to established safety margins as a result of this change, the proposed change does not involve a significant reduction in a margin of safety.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ms. Jeanne Cho, Assistant General Counsel, Entergy Nuclear Operations, Inc., 440 Hamilton Avenue, White Plains, NY 10601.

Acting NRC Branch Chief: Michael I. Dudek.

Entergy Nuclear Operations, Inc., Docket No. 50–333, James A. FitzPatrick Nuclear Power Plant, Oswego County, New York

Date of amendment request: June 22, 2015. A publicly available version is in ADAMS under Accession No. ML15173A380.

Description of amendment request: The amendment would change the James A. FitzPatrick Nuclear Power Plant Cyber Security Plan (CSP) Milestone 8 full implementation date from June 30, 2016, to December 15, 2017.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change to the CSP Implementation Schedule is administrative in nature. This change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change does not require any plant modifications which affect the performance capability of the structures, systems, and components relied upon to mitigate the consequences of postulated accidents and has no impact on the probability or consequences of an accident previously evaluated.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change to the CSP Implementation Schedule is administrative in nature. This proposed change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change does not require any plant modifications which affect the performance capability of the structures, systems, and components relied upon to mitigate the consequences of postulated accidents and does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

Plant safety margins are established through limiting conditions for operation, limiting safety system settings, and safety limits specified in the technical specifications. The proposed change to the CSP Implementation Schedule is administrative in nature. In addition, the milestone date delay for full implementation of the CSP has no substantive impact because other measures have been taken which provide adequate protection during this period of time. Because there is no change to established safety margins as a result of this change, the proposed change does not involve a significant reduction in a margin of safety.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ms. Jeanne Cho, Assistant General Counsel, Entergy Nuclear Operations, Inc., 440 Hamilton Avenue, White Plains, NY 10601.

Acting NRC Branch Chief: Michael I. Dudek.

Entergy Nuclear Operations, Inc., Docket No. 50–255, Palisades Nuclear Plant (PNP), Van Buren County, Michigan

Date of amendment request: June 11, 2015. A publicly-available version is in ADAMS under Accession No. ML15162A736.

Description of amendment request: The amendment would change the PNP Cyber Security Plan (CSP) Milestone 8 full implementation date from the previously approved date of June 30, 2016, to December 15, 2017.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change to the CSP implementation schedule is administrative in nature. This change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change does not require any plant modifications which affect the performance capability of the structures, systems, and components relied upon to mitigate the consequences of postulated accidents, and has no impact on the probability or consequences of an accident previously evaluated.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change to the CSP implementation schedule is administrative in nature. This proposed change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change does not require any plant modifications which affect the performance capability of the structures, systems, and components relied upon to mitigate the consequences of postulated accidents and does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

Plant safety margins are established through limiting conditions for operation,

limiting safety system settings, and safety limits specified in the technical specifications. The proposed change to the CSP implementation schedule is administrative in nature. In addition, the milestone date delay for full implementation of the CSP has no substantive impact because other measures have been taken which provide adequate protection during this period of time. Because there is no change to established safety margins as a result of this change, the proposed change does not involve a significant reduction in a margin of safety.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Ms. Jeanne Cho, Senior Counsel, Entergy Services, Inc., 440 Hamilton Ave., White Plains, NY 10601.

NRC Branch Chief: David L. Pelton.

NextEra Energy Seabrook LLC, et al., Docket No. 50–443, Seabrook Station, Unit No. 1, Rockingham County, New Hampshire

Date of amendment request: July 13, 2015. A publicly-available version is in ADAMS under Accession No. ML15198A027.

Description of amendment request: The amendment would change the Technical Specifications (TSs). The proposed change would add a note to TS Surveillance Requirement (SR) 4.4.1.3.4, which requires verification that residual heat removal loop operations susceptible to gas accumulation are sufficiently filled with water in accordance with the Surveillance Frequency Control Program.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, along with NRC edits in square brackets, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

SR 4.4.1.3.4 verifies RHR [residual heat removal] loop locations susceptible to gas accumulation are sufficiently filled with water in accordance with the Surveillance Frequency Control Program. The proposed change adds a note to allow SR 4.4.1.3.4 to be performed 12 hours after entering the Mode of Applicability. Gas accumulation in the subject system is not an initiator of any accident previously evaluated. As a result, the probability of any accident previously evaluated is not significantly increased. The proposed note does not change SR 4.4.1.3.4 which ensures that the subject system continues to be capable of performing its assumed safety function and is not rendered inoperable due to gas accumulation.

Thus, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any previously evaluated?

Response: No.

The proposed change does not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. In addition, the proposed change does not impose any new or different requirements that could initiate an accident. The proposed change does not alter assumptions made in the safety analysis and is consistent with the safety analysis assumptions.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in the margin of safety?

Response: No.

The proposed change does not adversely affect any current plant safety margins or the reliability of the equipment assumed in the safety analysis. Therefore, there are no changes being made to any safety analysis assumptions, safety limits, or limiting safety system settings that would adversely affect plant safety as a result of the proposed change.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: William Blair, Managing Attorney—Nuclear, Florida Power & Light Company, P.O. Box 14000, Juno Beach, FL 33408–0420.

NRC Branch Chief: Douglas A. Broaddus.

PSEG Nuclear LLC, Docket Nos. 50–272 and 50–311, Salem Nuclear Generating Station, Unit Nos. 1 and 2, Salem County, New Jersey

Date of amendment request: April 3, 2015, as supplemented by letter dated June 2, 2015. Publicly-available versions are in ADAMS under Accession Nos. ML15093A291 and ML15153A193, respectively.

Description of amendment request: The amendments would revise Technical Specification (TS) 3/4.3.1, ''Reactor Trip System Instrumentation,'' to support planned plant modifications to replace the existing source range (SR) and intermediate range (IR) nuclear instrumentation with a Thermo Scientific Neutron Flux Monitoring Systems. Specifically, the changes would modify the SR and IR neutron flux reactor trip Allowable Values and the permissive P–6 reset value, and would add two new footnotes to the Channel Functional Test and Channel Calibration in TS 3/4.3.1, Table 4.3–1.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Do the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The Nuclear Instrumentation System (NIS) provides indication and plant protection through the reactor trip function; it is not an accident initiator or precursor. The reactor trip is part of the plant's accident mitigation response. Thus, the probability of an accident previously evaluated is not significantly increased.

The performance of the replacement SR and IR detectors and associated equipment will equal or exceed that of the existing Westinghouse instrumentation. The proposed changes are based on accepted industry standards and will preserve assumptions in the applicable accident analyses. The proposed changes do not affect the integrity of the fission product barriers utilized for the mitigation of radiological dose consequences as a result of an accident. The proposed changes do not alter any assumptions previously made in the radiological consequences evaluations, nor do they affect mitigation of the radiological consequences of an accident previously evaluated.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Do the proposed changes create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The manner in which the Reactor Trip System (RTS) provides plant protection is not changed. The replacement SR and IR detectors and associated equipment do not affect accident initiation sequences or response scenarios as modeled in the safety analyses. The SR and IR detectors and associated equipment are not accident initiators or precursors. The only physical changes to the plant involve the replacement detectors and associated equipment. The replacement SR and IR detectors and

associated equipment have been designed to applicable regulatory and industry standards.

No changes to the overall manner in which the plant is operated are being proposed. Existing accident scenarios remain unchanged and new or different accident scenarios are not created. The types of accident defined in the Updated Final Safety Analysis Report (UFSAR) continue to represent the credible spectrum of events analyzed to determine safe plant operation.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. Do the proposed changes involve a significant reduction in a margin of safety?

Response: No.

Margin of safety is related to the confidence in the ability of the fission product barriers to perform their intended functions. These barriers include the fuel cladding, the reactor coolant system pressure boundary, and the containment. Neither the modification to replace the SR and IR detectors and associated equipment, nor the proposed Technical Specification changes will impact these barriers. Accident mitigating equipment will not be adversely impacted as a result of the modification. The safety systems credited in the safety analyses continue to remain available to perform their required mitigation functions. The proposed changes do not affect any safety analysis conclusions because the SR and IR neutron flux reactor trips are not explicitly credited in any accident analyses. Their functional capability enhances the overall reliability of the Reactor Protection System.

Therefore, the proposed changes do not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jeffrie J. Keenan, PSEG Nuclear LLC—N21, P.O. Box 236, Hancocks Bridge, NJ 08038.

NRC Branch Chief: Douglas A. Broaddus.

III. Previously Published Notices of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices either because time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the **Federal Register** on the day and page cited. This notice does not extend the notice period of the original notice.

Exelon Generation Company, LLC and PSEG Nuclear LLC, Docket No. 50–278, Peach Bottom Atomic Power Station (PBAPS), Unit 3, York and Lancaster Counties, Pennsylvania

Date of amendment request: May 29, 2015. A publicly-available version is in ADAMS under Accession No. ML15149A473.

Description of amendment request: The amendment would change a license condition pertaining to the PBAPS, Unit 3, replacement steam dryer (RSD). Currently, the license condition requires that a revised analysis for the RSD be submitted to the NRC, as a report, at least 90 days prior to the start of the Unit 3 extended power uprate (EPU) outage. The proposed amendment would reduce the period before the outage by which the analysis is to be submitted from 90 days to 30 days. The licensee indicated that the EPU outage is scheduled to start on September 14, 2015.

*Date of publication of individual notice in **Federal Register***: June 10, 2015 (80 FR 32991).

Expiration date of individual notice: July 10, 2015 (public comments); August 10, 2015 (hearing requests).

Tennessee Valley Authority, Docket No. 50–390, Watts Bar Nuclear Plant (WBN), Unit 1, Rhea County, Tennessee

Date of amendment request: June 17, 2015. A publicly-available version is in ADAMS under Accession No. ML15170A474.

Description of amendment request: The amendment would modify the technical specifications to define support systems needed in the first 48 hours after a unit shutdown when steam generators are not available for heat removal. The proposed change is required to support dual unit operation of WBN (a licensing decision for WBN, Unit 2, is currently expected to be made in the fall of 2015). The proposed amendment also requests changes consistent with Technical Specification Task Force-273–A, Revision 2, ''SFDP [Safety Function Determination Program] Clarifications,'' to provide clarification related to the requirements of the SFDP.

*Date of publication of individual notice in **Federal Register***: July 17, 2015 (80 FR 42554).

Expiration date of individual notice: August 16, 2015 (public comments); September 15, 2015 (hearing requests).

IV. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Final Determination of No Significant Hazards Consideration and Opportunity for a Hearing. (Exigent Public Announcement or Emergency Circumstances)

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

DTE Electric Company, Docket No. 50–341, Fermi 2, Monroe County, Michigan

Date of amendment request: September 16, 2014, as supplemented by letter dated April 17, 2015.

Brief description of amendment: The amendment revised the Technical Specifications (TSs) by relocating

specific surveillance frequencies to a licensee-controlled program. The changes are based on NRC-approved TS Task Force (TSTF) Change Traveler TSTF–425, Revision 3, ''Relocate Surveillance Frequencies to Licensee Control—RITSTF [Risk-Informed TSTF] Initiative 5b.''

Date of issuance: July 14, 2015.

Effective date: As of the date of issuance and shall be implemented within 120 days of issuance.

Amendment No.: 201. A publicly-available version is in ADAMS under Accession No. ML15155B416; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Facility Operating License No. NPF–43: Amendment revised the Facility Operating License and TSs.

*Date of initial notice in **Federal Register***: November 12, 2014 (79 FR 67199). The supplemental letter dated April 17, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 14, 2015.

No significant hazards consideration comments received: None.

Exelon Generation Company, LLC and PSEG Nuclear LLC, Docket Nos. 50–277 and 50–278, Peach Bottom Atomic Power Station, Units 2 and 3, York and Lancaster Counties, Pennsylvania

Date of amendment request: July 25, 2014, as supplemented by letters dated January 13, 2015, and May 26, 2015.

Brief description of amendments: The amendments changed the definition in the Technical Specifications (TSs) for RECENTLY IRRADIATED FUEL. Specifically, the amendments revised requirements pertaining to secondary containment hatches in order to facilitate activities performed during refueling outages.

Date of issuance: July 17, 2015.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment Nos.: 298 and 301. A publicly-available version is in ADAMS under Accession No. ML15162A139; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–44 and DPR–56: The amendments revised the Facility Operating Licenses and the TSs.

*Date of initial notice in **Federal Register***: September 30, 2014 (79 FR 58816). The supplemental letters dated January 13, 2015, and May 26, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 17, 2015.

No significant hazards consideration comments received: No.

Exelon Generation Company, LLC, Docket Nos. 50–317 and 50–318, Calvert Cliffs Nuclear Power Plant (CCNPP), Unit Nos. 1 and 2, Calvert County, Maryland

Date of amendment request: September 18, 2014, as supplemented by letters dated February 17, 2015, and April 2, 2015.

Brief description of amendments: The amendments revised Technical Specification (TS) 5.5.16, ''Containment Leakage Rate Testing Program,'' by replacing the reference to Regulatory Guide 1.163 (September 1995) with a reference to Topical Report (TR) Nuclear Energy Institute (NEI) 94–01, Revision 3–A, and Section 4.1, ''Limitations and Conditions for NEI TR 94–01, Revision 2,'' of the NRC Safety Evaluation in NEI 94–01, Revision 2–A, dated October 2008. This reference is the implementation document to develop 10 CFR part 50, appendix J, Option B, performance-based primary containment leakage testing program for CCNPP, Unit Nos. 1 and 2. The changes allow an increase in the Type A test interval from the current 10 years to a maximum of 15 years, and allow an increase in the Type C test interval from the current 60 months to 75 months. The change also deletes the one-time exceptions granted to the Type A test interval and exceptions from the post-modification Type A test when the steam generators at CCNPP are replaced.

Date of issuance: July 16, 2015.

Effective date: As of the date of issuance and shall be implemented within 75 days of issuance.

Amendment Nos.: 310 and 288. A publicly-available version is in ADAMS under Accession No. ML15154A661; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–53 and DPR–69: Amendments revised the Renewed Facility Operating Licenses and TSs.

*Date of initial notice in **Federal Register***: November 25, 2014 (79 FR 70214). The supplemental letters dated February 17, 2015, and April 2, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 16, 2015.

No significant hazards consideration comments received: No.

FirstEnergy Nuclear Operating Company, et al., Docket Nos. 50–334 and 50–412, Beaver Valley Power Station, Unit Nos. 1 and 2 (BVPS–1 and 2), Beaver County, Pennsylvania

Date of amendment request: September 4, 2014, as supplemented by letter dated December 1, 2014.

Brief description of amendments: The amendments revised the BVPS Emergency Planning Zone boundary to align it with the boundary that is currently in use by the emergency management agencies of the three counties that implement public protective actions around BVPS.

Date of issuance: July 9, 2015.

Effective date: As of the date of issuance and shall be implemented within 90 days of issuance.

Amendment Nos.: 294 and 181. A publicly-available version is in ADAMS under Accession No. ML15131A006; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. DPR–66 and NPF–73: Amendments revised the Facility Operating License.

*Date of initial notice in **Federal Register***: October 28, 2014 (79 FR 64224). The supplemental letter dated December 1, 2014, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 9, 2015.

No significant hazards consideration comments received: No.

Florida Power and Light Company, et al., Docket Nos. 50–335 and 50–389, St. Lucie Plant, Unit Nos. 1 and 2, St. Lucie County, Florida

Date of amendment request: July 14, 2014, as supplemented by letter dated June 30, 2015.

Brief description of amendments: The amendments revised the Technical Specifications (TSs) by modifying or adding surveillance requirements to verify that system locations susceptible to gas accumulation are sufficiently filled with water and to provide allowances that permit performance of the verification. The changes address NRC Generic Letter 2008–01, ''Managing Gas Accumulation in Emergency Core Cooling, Decay Heat Removal, and Containment Spray Systems'' (ADAMS Accession No. ML072910759), as described in Revision 2 of Technical Specification Task Force-523, ''Generic Letter 2008–01, Managing Gas Accumulation'' (ADAMS Accession No. ML13053A075).

Date of issuance: July 20, 2015.

Effective date: As of the date of issuance and shall be implemented within 120 days of issuance.

Amendment Nos.: 224 and 174. The amendments are in ADAMS under Accession No. ML15182A160; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–67 and NPF–16: Amendments revised the TSs.

*Date of initial notice in **Federal Register***: October 28, 2014 (79 FR 64225). The licensee's supplement dated June 30, 2015, did not expand the scope of the request and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 20, 2015.

No significant hazards consideration comments received: No.

Florida Power & Light Company, Docket Nos. 50–250 and 50–251, Turkey Point Nuclear Generating, Unit Nos. 3 and 4, Miami-Dade County, Florida

Date of amendment request: April 9 2014, as supplemented by letters dated August 29, 2014, and February 20, April 3, and July 7, 2015.

Brief description of amendments: The amendments revised the Technical Specifications (TSs) by relocating specific surveillance frequency requirements to a licensee-controlled program with implementation of Nuclear Energy Institute (NEI) 04–10, ''Risk Informed Technical Specification Initiative 5b, Risk Informed Method for Control of Surveillance Frequencies'' (ADAMS Accession No. ML071360456). The NEI 04–10 methodology provides reasonable acceptance guidelines and methods for evaluating the risk increase of proposed changes to surveillance frequencies, consistent with Regulatory Guide 1.177, ''An Approach for Plant-Specific Risk-Informed Decisionmaking: Technical Specifications'' (ADAMS Accession No. ML003740176). The changes are consistent with NRC-approved Technical Specification Task Force (TSTF) Standard Technical Specifications Change TSTF–425, ''Relocate Surveillance Frequencies to Licensee Control—RITSTF [Risk Informed Technical Specifications Task Force] Initiative 5b,'' Revision 3 (ADAMS Accession No. ML090850642). The **Federal Register** notice published on July 6, 2009 (74 FR 31996), announced the availability of TSTF–425, Revision 3. The amendments also include editorial changes to the TSs, administrative deviations from TSTF–425, and other changes resulting from differences between the licensee's TSs and the TSs on which TSTF–425 was based.

Date of issuance: July 16, 2015.

Effective date: As of the date of issuance and shall be implemented within 90 days of issuance.

Amendment Nos.: 263 and 258. The amendments are in ADAMS under Accession No. ML15166A320; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–31 and DPR–41: Amendments revised the Facility Operating License and TSs.

*Date of initial notice in **Federal Register***: The NRC staff initially made a proposed determination that the amendment request dated April 9, 2014, involved no significant hazards consideration (NSHC) (July 22, 2014, 79 FR 44551). By letters dated August 29, 2014, and February 20, 2015, the licensee provided clarifying information that did not expand the scope of the application and did not change the NRC staff's original proposed NSHC determination, as published in the **Federal Register** on July 22, 2014 (79 FR 44551). Subsequently, by letter dated April 3, 2015, the licensee supplemented its amendment request with a proposed change that expanded the scope of the request. Therefore, the NRC published a second proposed NSHC determination in the **Federal Register** on May 12, 2015 (80 FR 27199), which superseded the notice dated July 22, 2014 (79 FR 44551). The licensee's supplement dated July 7, 2015, did not expand the scope of the request and did not change the staff's proposed NSHC determination that was published in the **Federal Register** on May 12, 2015 (80 FR 27199).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 16, 2015.

No significant hazards consideration comments received: No.

Nebraska Public Power District, Docket No. 50–298, Cooper Nuclear Station, Nemaha County, Nebraska

Date of amendment request: July 17, 2014, as supplemented by letter dated February 19, 2015.

Brief description of amendment: The amendment moved the Linear Heat Generation Rate (LHGR) and Single Loop Operation LHGR limits from the Technical Requirements Manual to the Technical Specifications (TSs). Accordingly, the amendment added TS 3.2.3, ''Linear Heat Generation Rate (LHGR),'' and modified TS 1.1, ''Definitions''; TS 3.4.1, ''Recirculation Loops Operating''; TS 3.7.7, ''The Main Turbine Bypass System''; and TS 5.6.5, ''Core Operating Limits Report (COLR).''

Date of issuance: July 14, 2015.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment No.: 251. A publicly-available version is in ADAMS under Accession No. ML15168A171; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–46: Amendment revised the Facility Operating License and TSs.

*Date of initial notice in **Federal Register***: September 30, 2014 (79 FR 58820). The supplemental letter dated February 19, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 14, 2015.

No significant hazards consideration comments received: No.

NextEra Energy, Point Beach, LLC, Docket Nos. 50–266 and 50–301, Point Beach Nuclear Plant, Units 1 and 2, Town of Two Creeks, Manitowoc County, Wisconsin

Date of amendment request: July 18, 2014, as supplemented by letter dated November 7, 2015.

Brief description of amendment: The amendment changed the Cyber Security Plan for Point Beach Nuclear Plants, Units 1 and 2, by revising the completion date of Milestone 8 of the Cyber Security Plan Implementation schedule.

Date of issuance: July 14, 2015.

Effective date: These amendments will be effective as of their date of issuance.

Amendment Nos.: 252 and 256. A publicly-available version is in ADAMS under Accession No. ML15155A539; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–24 and DPR–27: Amendments revised the Facility Operating License and Technical Specifications.

*Date of initial notice in **Federal Register***: January 6, 2015 (80 FR 536). The supplemental letter dated November 7, 2014, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 14, 2015.

No significant hazards consideration comments received: No.

NextEra Energy Seabrook, LLC., Docket No. 50–443, Seabrook Station, Unit No. 1, Rockingham County, New Hampshire

Date of amendment request: July 24, 2014, as supplemented by two letters dated December 11, 2014, and a letter dated June 30, 2015.

Brief description of amendment: The amendment revised Seabrook Station Technical Specification (TS) 3.3.3.1, ''Radiation Monitoring for Plant Operations,'' to eliminate duplicate requirements, resolve an inconsistency, and correct a deficiency.

Date of issuance: July 17, 2015.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment No.: 149. A publicly-available version is in ADAMS under Accession No. ML15096A131; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Facility Operating License No. NPF–86: Amendment revised the Facility Operating License and Technical Specifications.

*Date of initial notice in **Federal Register***: September 30, 2014 (79 FR 58821). The supplemental letters dated December 11, 2014, and June 29, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated July 17, 2015.

No significant hazards consideration comments received: No.

Southern California Edison Company, et al., Docket Nos. 50–361 and 50–362, San Onofre Nuclear Generating Station (SONGS), Units 2 and 3, San Diego County, California

Date of amendment request: March 21, 2014, as supplemented by letters dated October 1, 2014; and February 23, February 25, and March 18, 2015.

Brief description of amendment: The amendments revised the SONGS, Units 2 and 3, Facility Operating Licenses and associated Technical Specifications (TSs) to conform to the permanent shutdown and defueled status of these facilities.

Date of issuance: July 17, 2015.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment Nos.: 230 and 223. A publicly-available version is in ADAMS under Accession No. ML15139A390; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. NPF–10 and NPF–15: The amendments revised the Facility Operating Licenses and TSs.

*Date of initial notice in **Federal Register***: September 16, 2014 (79 FR 55513). The supplemental letters dated October 1, 2014; and February 23, February 25, 2015, and March 18, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated July 17, 2015.

No significant hazards consideration comments received: No.

V. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Final Determination of No Significant Hazards Consideration and Opportunity for a Hearing. (Exigent Public Announcement or Emergency Circumstances)

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Because of exigent or emergency circumstances associated with the date the amendment was needed, there was not time for the Commission to publish, for public comment before issuance, its usual notice of consideration of issuance of amendment, proposed no significant hazards consideration determination, and opportunity for a hearing.

For exigent circumstances, the Commission has either issued a **Federal Register** notice providing opportunity for public comment or has used local media to provide notice to the public in the area surrounding a licensee's facility of the licensee's application and of the Commission's proposed determination of no significant hazards consideration. The Commission has provided a reasonable opportunity for the public to comment, using its best efforts to make available to the public means of communication for the public to respond quickly, and in the case of telephone comments, the comments have been recorded or transcribed as appropriate and the licensee has been informed of the public comments.

In circumstances where failure to act in a timely way would have resulted, for example, in derating or shutdown of a nuclear power plant or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, the Commission may not have had an opportunity to provide for public comment on its no significant hazards consideration determination. In such case, the license amendment has been issued without opportunity for

comment. If there has been some time for public comment but less than 30 days, the Commission may provide an opportunity for public comment. If comments have been requested, it is so stated. In either event, the State has been consulted by telephone whenever possible.

Under its regulations, the Commission may issue and make an amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that no significant hazards consideration is involved.

The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that the amendment involves no significant hazards consideration. The basis for this determination is contained in the documents related to this action. Accordingly, the amendments have been issued and made effective as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the application for amendment, (2) the amendment to Facility Operating License or Combined License, as applicable, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment, as indicated. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

A. Opportunity To Request a Hearing and Petition for Leave to Intervene

The Commission is also offering an opportunity for a hearing with respect to the issuance of the amendment. Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852, and electronically on the Internet at the NRC's Web site, *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If there are problems in accessing the document, contact the PDR's Reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also identify the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing. Since the Commission has made a final determination that the amendment involves no significant hazards consideration, if a hearing is requested, it will not stay the effectiveness of the amendment. Any hearing held would take place while the amendment is in effect.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nr.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the

hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8:00 a.m. and 8:00 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii).

For further details with respect to these license amendment applications, see the application for amendment which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

Indiana Michigan Power Company, Docket No. 50–315, Donald C. Cook Nuclear Plant, Unit 1, Berrien County, Michigan

Date of amendment request: June 29, 2015, as supplemented by letter dated July 2, 2015.

Brief description of amendment: The amendment revised Technical Specification (TS) 3.3.2, ''Engineered Safety Feature Actuation System (ESFAS) Instrumentation,'' by adding a new condition for one or more inoperable required channels for main feedwater pump trips, changing Table 3.3.2–1 to add a footnote to the Applicable Mode Column for Mode 2 and to reflect the new Condition, and renumbering existing Conditions.

Date of issuance: July 10, 2015.

Effective date: As of the date of issuance and shall be implemented within 30 days of issuance.

Amendment No.: 328. A publicly-available version is in ADAMS under Accession No. ML15187A002; documents related to the amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–58: Amendment revised the Renewed Facility Operating License and TSs.

Public comments requested as to proposed no significant hazards consideration (NSHC): Yes. Public

notice of the proposed amendment was published in *The Herald-Palladium,* located in the City of St. Joseph, Berrien County, Michigan, on July 3 and July 4, 2015. The notice provided an opportunity to submit comments on the Commission's proposed NSHC determination. No comments were received.

The Commission's related evaluation of the amendment, finding of exigent circumstances, State consultation, public comments, and final NSHC determination are contained in a Safety Evaluation dated July 10, 2015.

Attorney for licensee: Robert B. Haemer, Senior Nuclear Counsel, One Cook Place, Bridgman, MI 49106.

NRC Branch Chief: David L. Pelton.

Dated at Rockville, Maryland, this 27th day of July, 2015.

For the Nuclear Regulatory Commission.

George A. Wilson, Jr.,

Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2015–18896 Filed 8–3–15; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2015–116; Order No. 2625]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an additional Global Expedited Package Services 3 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 6, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
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III. Ordering Paragraphs

I. Introduction

On July 29, 2015, the Postal Service filed notice that it has entered into an additional Global Expedited Package Services 3 (GEPS 3) negotiated service agreement (Agreement).[1]

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket No. CP2015–116 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than August 6, 2015. The public portions of the filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Lyudmila Y. Bzhilyanskaya to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2015–116 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, Lyudmila Y. Bzhilyanskaya is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than August 6, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–19085 Filed 8–3–15; 8:45 am]

BILLING CODE 7710–FW–P

[1] Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, July 29, 2015 (Notice).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75548; File No. SR–CBOE–2015–070]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Amending Its Simple Auction Liaison (''SAL'') Rule

July 29, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 24, 2015, Chicago Board Options Exchange, Incorporated (''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend its SAL rule to make it explicit that 6.13A(d) applies to Hybrid 3.0 classes.

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.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend language to clarify that certain

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

provisions of its SAL rule apply to select option classes. The operation of the Exchange's SAL rule is codified in Rule 6.13A. The purpose of this proposed change is to clarify that the provisions found in 6.13A(d) apply to Hybrid 3.0 classes. The original filing [3] which introduced SAL for the Hybrid 3.0 classes stated that the provisions of Rule 6.13A will apply, however, the Exchange is proposing to amend Rule 6.13A to add clarity and avoid confusion by making this more explicit. The Exchange believes that the proposed changes will bring added clarity to its Trading Permit Holders (''TPHs'') regarding the SAL rule and which classes it applies to.

Currently, Rule 6.13A(d) states that an auction will terminate early under certain circumstances related to the Hybrid System.[4] As an administrative clean-up change, the Exchange is proposing to add language to 6.13A.04 to specifically state that the same circumstances that may cause an auction to terminate early under 6.13A(d) also apply to Hybrid 3.0 classes. The Exchange believes that adding this language will bring greater clarity to the Exchange Rules.

The Exchange believes the proposed change will allow the Exchange to clarify that Rule 6.13A(d) applies to Hybrid 3.0 classes as well. The proposed change will allow the Exchange to remove the ambiguity of its rule text regarding SAL in order to lessen confusion about which provisions apply to Hybrid 3.0 classes. In addition, the Exchange believes the lack of explicit reference to 6.13A(d) applying to Hybrid 3.0 classes is somewhat ambiguous and has the potential to cause confusion. Thus, the Exchange believes by further clarifying the language, it will be clearer which SAL provisions apply to Hybrid 3.0 classes.

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.[5] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [6] 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.

In particular, the proposed rule change is consistent with these provisions as it will more accurately reflect the intentions of the Exchange for 6.13A(d) to apply to Hybrid 3.0 classes. The purpose of the proposed change is to add clarity to the rule text, however, the current practices of the Exchange will remain the same. The Exchange believes the proposed rule change will help avoid confusion, thereby removing impediments to and perfecting the mechanism of a free and open market and national market system.

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. The Exchange does not believe that the proposed rule change imposes any burden on intramarket competition because it applies to all TPHs. SAL will continue to function in the same manner as it currently functions. Furthermore, the Exchange does not believe that the proposed rule change imposes any burden on intermarket competition because it specifies that paragraph (d): (1) Will apply to all classes activated in Hybrid 3.0; (2) applies equally to all intermarket users and; (3) otherwise just makes technical changes to improve readability.

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:

A. Significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. 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 [7] and Rule 19b–4(f)(6) [8] 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–2015–070 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–2015–070. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of

[3] *See* Securities Exchange Release No. 56951 (December 12, 2007), 72 FR 71977 (December 19, 2007) (SR–CBOE–2007–074).

[4] *See* Exchange Rule 6.13A(d).

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6).

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–2015–070 and should be submitted on or before August 25, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–19016 Filed 8–3–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75540; File No. SR–NYSEArca–2015–50]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of the Cambria Sovereign High Yield Bond ETF and the Cambria Value and Momentum ETF Under NYSE Arca Equities Rule 8.600

July 28, 2015.

I. Introduction

On June 19, 2015, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') 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 shares (''Shares'') of the Cambria Sovereign High Yield Bond ETF and the Cambria Value and Momentum ETF (each a ''Fund,'' and collectively ''Funds'') under NYSE Arca Equities Rule 8.600. The proposed rule change was published for comment in the **Federal Register** on July 2, 2015.[3] On July 1, 2015, the Exchange filed Amendment No. 1 to the proposed rule change.[4] The Commission received no comments on the proposed rule change. The Commission is publishing this notice to solicit comments on Amendment No. 1 from interested persons, and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. The Exchange's Description of the Proposed Rule Change[5]

The Exchange proposes to list and trade the Shares under NYSE Arca Equities Rule 8.600, which governs the listing and trading of Managed Fund Shares. The Shares will be offered by the Cambria ETF Trust (''Trust''), a Delaware statutory trust which is registered with the Commission as an open-end management investment company.[6] Cambria Investment Management, L.P. (''Cambria'' or the ''Adviser'') will serve as the investment adviser of the Funds. SEI Investments Distribution Co. will be the principal underwriter and distributor of the Funds' Shares. SEI Investments Global Funds Services (''SEI GFS'') will serve as the accountant and administrator of the Funds. Brown Brothers Harriman & Co. will serve as the custodian and transfer agent of the Funds' assets.

Cambria Sovereign High Yield Bond ETF

The Exchange states that, under normal market conditions,[7] at least 80% of the value of the Fund's net assets (plus borrowings for investment purposes) will be invested in sovereign and quasi-sovereign high yield bonds (commonly known as ''junk bonds''). For the purposes of this policy, sovereign and quasi-sovereign high yield bonds include exchange-traded funds (''ETFs'')[8] and exchange-traded notes (''ETNs'')[9] that invest in or have exposure to such bonds. The Fund will invest in emerging and developed countries, including countries located in the G–20 and other countries. Sovereign bonds include debt securities issued by a national government, instrumentality or political sub-division. Quasi-sovereign bonds include debt securities issued by a supra-national government or a state-owned enterprise or agency. The sovereign and quasi-sovereign bonds that the Fund will invest in may be denominated in local and foreign currencies. The Fund may invest in securities of any duration or maturity. The Exchange states that the Fund may invest up to 20% of its net assets in money market instruments or other high quality debt securities, cash or cash equivalents, or ETFs and ETNs that invest in, or provide exposure to, such instruments or securities.

Cambria Value and Momentum ETF

The Exchange states that, under normal market conditions, at least 80% of the value of the Fund's net assets will be invested in U.S. exchange-listed equity securities that are undervalued according to various valuation metrics.

In attempting to avoid overvalued and downtrending markets, the Fund may use U.S. exchange-traded stock index futures or options thereon, or take short positions in ETFs to attempt to hedge the long equity portfolio during times when Cambria believes that the U.S. equity market is overvalued from a valuation standpoint, or Cambria's models identify unfavorable trends and momentum in the U.S. equity market. The Fund may hedge up to 100% of the value of the Fund's long portfolio using these strategies. During certain periods, including to collateralize the Fund's investments in futures contracts, the Fund may invest up to 20% of the value

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[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 75311 (June 26, 2015), 80 FR 38253 (''Notice'').

[4] In Amendment No. 1, the Exchange deletes references to investments that the Funds will not be utilizing and clarifies that U.S. exchange-listed and traded ADRs are included as ''Other Investments'' only with respect to the Cambria Sovereign High Yield Bond ETF. Amendment No. 1 is available at: *http://www.sec.gov/comments/sr-nysearca-2015-50/nysearca201550.shtml.*

[5] The Commission notes that additional information regarding the Trust, the Fund, its investments, and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, calculation of net asset value (''NAV''), distributions, and taxes, among other things, can be found in the Notice and the Registration Statement, as applicable. *See* Notice, *supra* note 3, and Registration Statement, *infra* note 6.

[6] The Exchange states that the Trust will be registered under the 1940 Act. According to the Exchange, on August 27, 2014, the Trust filed an amendment to the Trust's registration statement on Form N–1A under the Securities Act of 1933 (the ''1933 Act'') (15 U.S.C. 77a), and under the 1940 Act relating to the Funds (File Nos. 333–180879 and 811–22704) (the ''Registration Statement''). The Exchange states that the Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act. *See* Investment Company Act Release No. 30340 (File No. 812–13959) (January 4, 2013).

[7] The term ''under normal market conditions'' includes, but is not limited to, the absence of extreme volatility or trading halts in the equity 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.

[8] For purposes of this filing, the term ''ETFs'' includes Investment Company Units (as described in NYSE Arca Equities Rule 5.2(j)(3)); Portfolio Depositary Receipts (as described in NYSE Arca Equities Rule 8.100); and Managed Fund Shares (as described in NYSE Arca Equities Rule 8.600). All ETFs will be listed and traded in the U.S. on a national securities exchange. While the Funds may invest in inverse ETFs, the Funds will not invest in leveraged (*e.g.,* 2X, –2X, 3X or –3X) ETFs.

[9] For purposes of this filing, the term ''ETNs'' includes Index-Linked Securities (as described in NYSE Arca Equities Rule 5.2(j)(6)). All ETNs will be listed and traded in the U.S. on a national securities exchange. The Funds will not invest in leveraged (*e.g.,* 2X, –2X, 3X or –3X) ETNs.

of its net assets in U.S. dollar and non-U.S. dollar denominated money market instruments or other high quality debt securities, or ETFs that invest in these instruments. The Fund may invest in securities of companies in any industry, and will limit the maximum allocation to any particular sector.

Other Investments

According to the Exchange, while each Fund, under normal market conditions, will invest at least 80% of the value of its net assets (plus borrowings for investment purposes) in the securities and other assets described above, each Fund may invest its remaining assets in the securities and financial instruments described below.

A Fund may invest a portion of its assets in cash or cash items pending other investments or to maintain liquid assets required in connection with some of a Fund's investments. A Fund may invest in corporate debt securities. A Fund may invest in commercial paper, master notes and other short-term corporate instruments that are denominated in U.S. dollars. A Fund may invest in the following types of debt securities in addition to those described above as principal investments: Securities issued or guaranteed by the U.S. Government, its agencies, instrumentalities, and political subdivisions; securities issued or guaranteed by foreign governments, their authorities, agencies, instrumentalities and political subdivisions; securities issued or guaranteed by supra-national agencies; corporate debt securities; time deposits; notes; inflation-indexed securities; and repurchase agreements; indexed bonds; and zero coupon securities.[10] The Cambria Sovereign High Yield Bond ETF may gain exposure to foreign securities by purchasing U.S. exchange-listed and traded American Depositary Receipts (''ADRs'') and each of the Funds may gain exposure to foreign securities by purchasing exchange-traded European Depositary Receipts (''EDRs'') and Global Depositary Receipts (''GDRs'', together with ADRs and EDRs, ''Depositary Receipts'').[11] The Cambria Sovereign High Yield Bond ETF may enter into forward foreign currency contracts.

III. Discussion and Commission's Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of Section 6 of the Act [12] and the rules and regulations thereunder applicable to a national securities exchange.[13] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[14] 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 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 Funds and the Shares must comply with the requirements of NYSE Arca Equities Rule 8.600 for the Shares 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,[15] which sets forth Congress's 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. According to the Exchange, quotation and last-sale information for the Shares and equity portfolio holdings of the Funds that are U.S. exchange listed, including common stocks, preferred stocks, ETFs, ETNs, Depositary Receipts, and real estate investment trusts (''REITs''), will be available via the Consolidated Tape Association high-speed line. In addition, the Intraday Indicative Value (''IIV''), which is the Portfolio Indicative Value as defined in NYSE Arca Equities Rule 8.600(c)(3), will be widely disseminated at least every 15 seconds during the Core Trading Session by one or more major market data vendors.[16] On each business day, before commencement of trading in Shares in the Core Trading Session (as defined in NYSE Arca Equities Rule 7.34(a)(2)), each Fund will disclose on its Web site the Disclosed Portfolio (as defined in NYSE Arca Equities Rule 8.600(c)(2)) that will form the basis for such Fund's calculation of NAV at the end of the business day.[17] The NAV of each Fund will be calculated each business day by SEI GFS as of the close of regular trading on the NYSE, generally 4:00 p.m., Eastern Time on each day that the NYSE is open. A basket composition file, which will include the security names and share quantities required to be delivered in exchange for each Fund's shares, together with estimates and actual cash components, will be publicly disseminated daily prior to the opening of the New York Stock Exchange via the National Securities Clearing Corporation. 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. The Web site for the Funds will include a form of the prospectus for the Funds and additional data relating to NAV and other applicable 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 Commission notes that 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

[10] The debt and other fixed income securities in which a Fund may invest include fixed and floating rate securities of any maturity.

[11] *See* Amendment No. 1, *supra* note 4. The Exchange states that not more than 10% of the net assets of a Fund in the aggregate invested in exchange-traded equity securities shall consist of equity securities whose principal market is not a member of the Intermarket Surveillance Group (''ISG'') or party to a comprehensive surveillance sharing agreement (''CSSA'') with the Exchange. *See* Notice, *supra* note 3, 80 FR at 38255.

[12] 15 U.S.C. 78f.

[13] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 15 U.S.C. 78f(b)(5).

[15] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[16] According to the Exchange, the IIV does not necessarily reflect the precise composition of the current portfolio of securities held by a Fund at a particular point in time. The IIV should not be viewed as a ''real-time'' update of the NAV of a Fund because the approximate value may not be calculated in the same manner as the NAV. The quotations for certain investments may not be updated during U.S. trading hours if such holdings do not trade in the U.S., except such quotations may be updated to reflect currency fluctuations.

[17] On a daily basis, the Funds will disclose on their Web site the following information for each Fund regarding their portfolio holdings, 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, such as the type of swap); the identity of the security, commodity, index or other asset or instrument underlying the holding, if any; for options, the option strike price; quantity held (as measured by, for example, par value, notional value or number of shares, contracts or units); 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 a Fund's portfolio. The Web site information will be publicly available at no charge.

will be made available to all market participants at the same time.[18] In addition, trading in the Shares will be subject to NYSE Arca Equities Rule 8.600(d)(2)(D), which sets forth circumstances under which Shares of a Fund may be halted. The Exchange may halt trading in the Shares if trading is not occurring in the securities and/or the financial instruments constituting the Disclosed Portfolio of a Fund, or if other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.[19] Further, the Commission notes that the Reporting Authority that provides the Disclosed Portfolio of each Fund 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.[20] The Commission notes that the Financial Industry Regulatory Authority (''FINRA''), on behalf of the Exchange,[21] will communicate as needed regarding trading in the Shares and any underlying common stocks, preferred stocks, Depositary Receipts, REITs, ETFs, ETNs, futures and options on futures with other markets and other entities that are members of the Intermarket Surveillance Group. FINRA, on behalf of the Exchange, may obtain trading information regarding trading in the Shares, ETFs, ETNs, futures and options on futures from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares, common stocks, preferred stocks, Depositary Receipts, REITs, ETFs, ETNs, futures and options on futures from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange states that it has a general policy prohibiting the distribution of material, non-public information by its employees. The Exchange also states that the Adviser is not registered as a broker-dealer or affiliated with a broker-dealer. In the event (a) the Adviser or any sub-adviser becomes registered as a broker-dealer or newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, the Exchange states that the Adviser will implement a fire wall with respect to its relevant personnel or broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

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 additional representations, including:

(1) The Shares of each Fund will conform to the initial and continued listing criteria under NYSE Arca Equities Rule 8.600.

(2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(3) Trading in the Shares will be subject to the existing trading surveillances, administered by FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws and these 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 federal securities laws applicable to trading on the Exchange.

(4) Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (a) the procedures for purchases and redemptions of Shares in Creation Unit aggregations (and that Shares are not individually redeemable); (b) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its Equity Trading Permit Holders to learn the essential facts relating to every customer prior to trading the Shares; (c) the risks involved in trading the Shares during the Opening and Late Trading Sessions when an updated Portfolio Indicative Value will not be calculated or publicly disseminated; (d) how information regarding the Portfolio Indicative Value and the Disclosed Portfolio is disseminated; (e) the requirement that Equity Trading Permit Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading information.

(5) For initial and/or continued listing, the Funds will be in compliance with Rule 10A–3 under the Act,[22] as provided by NYSE Arca Equities Rule 5.3.

(6) A minimum of 100,000 Shares of each Fund will be outstanding at the commencement of trading on the Exchange.

(7) Not more than 10% of the net assets of a Fund in the aggregate invested in exchange-traded equity securities shall consist of equity securities whose principal market is not a member of the ISG or party to a CSSA with the Exchange.

This approval order is based on all of the Exchange's representations.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act[23] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Solicitation of Comments on Amendment No. 1

Interested persons are invited to submit written data, views, and arguments concerning whether Amendment No. 1 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-2015–50 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–NYSEArca-2015–50. 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

[18] *See* NYSE Arca Equities Rule 8.600(d)(1)(B).

[19] *See* NYSE Arca Equities Rule 8.600(d)(2)(C) (providing additional considerations for the suspension of trading in or removal from listing of Managed Fund Shares on the Exchange). 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 each Fund. Trading in Shares of a Fund will be halted if the circuit breaker parameters in NYSE Arca Equities Rule 7.12 have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

[20] *See* NYSE Arca Equities Rule 8.600(d)(2)(B)(ii).

[21] The Exchange states that, while FINRA surveils trading on the Exchange pursuant to a regulatory services agreement, the Exchange is responsible for FINRA's performance under this regulatory services agreement.

[22] 17 CFR 240.10A–3.

[23] 15 U.S.C. 78f(b)(5).

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–NYSEArca-2015–50 and should be submitted on or before *August 25, 2015.*

V. Accelerated Approval of Proposed Rule Change as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the thirtieth day after the date of publication of notice in the **Federal Register.** Amendment No. 1 supplements the proposed rule change by deleting references to investments that the Funds will not be utilizing and clarifies that U.S. Exchange-listed and traded ADRs are included as ''Other Investments'' only with respect to the Cambria Sovereign High Yield Bond ETF. The Commission believes that this additional information provides clarity about the Funds' permitted investments. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[24] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[25] that the proposed rule change (SR–NYSEArca-2015–50), as modified by Amendment No. 1, be, and it hereby is, approved on an accelerated basis.

[24] 15 U.S.C. 78s(b)(2).

[25] 15 U.S.C. 78s(b)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–18883 Filed 8–3–15; 8:45 am]

BILLING CODE 8011–01–P

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Rule 17f–2(a), SEC File No. 270–34, OMB Control No. 3235–0034.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17f–2(a) (17 CFR 240.17f–2(a)), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit the existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval. Rule 17f–2(a) (Fingerprinting Requirements for Securities Professionals) requires that securities professionals be fingerprinted. This requirement serves to identify security-risk personnel, to allow an employer to make fully informed employment decisions, and to deter possible wrongdoers from seeking employment in the securities industry. Partners, directors, officers, and employees of exchanges, brokers, dealers, transfer agents, and clearing agencies are included.

The Commission staff estimates that approximately 4,500 respondents will submit an aggregate total 300,700 new fingerprint cards each year or approximately 67 fingerprint cards per year per registrant. The staff estimates that the average number of hours necessary to complete a fingerprint card is one-half hour. Thus, the total estimated annual burden is 150,350 hours for all respondents (300,700 times one-half hour). The average internal labor cost of compliance per hour is approximately $283. Therefore, the total estimated annual internal labor cost of compliance for all respondents is $42,549,050 (150,350 times $283).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number. Please direct your written comments to: Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 28, 2015.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–19012 Filed 8–3–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Rule 17Ad–4(b) & (c); SEC File No. 270–264, OMB Control No. 235–0341.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in the following rule: Rule 17Ad–4(b) & (c) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). The Commission plans to submit this existing collection of information to the

Office of Management and Budget (''OMB'') for extension and approval.

Rule 17Ad–4(b) & (c) (17 CFR 240.17Ad–4) is used to document when transfer agents are exempt, or no longer exempt, from the minimum performance standards and certain recordkeeping provisions of the Commission's transfer agent rules. Pursuant to Rule 17Ad–4(b), if the Commission or the Office of the Comptroller of the Currency (''OCC'') is the appropriate regulatory authority (''ARA'') for an exempt transfer agent, that transfer agent is required to prepare and maintain in its possession a notice certifying that it is exempt from certain performance standards and recordkeeping and record retention provisions of the Commission's transfer agent rules. This notice need not be filed with the Commission or OCC. If the Board of Governors of the Federal Reserve System (''Fed'') or the Federal Deposit Insurance Corporation (''FDIC'') is the transfer agent's ARA, that transfer agent must prepare a notice and file it with the Fed or FDIC.

Rule 17Ad–4(c) sets forth the conditions under which a registered transfer agent loses its exempt status. Once the conditions for exemption no longer exist, the transfer agent, to keep the appropriate regulatory authority (''ARA'') apprised of its current status, must prepare, and file if the ARA for the transfer agent is the Board of Governors of the Federal Reserve System (''BGFRS'') or the Federal Deposit Insurance Corporation (''FDIC''), a notice of loss of exempt status under paragraph (c). The transfer agent then cannot claim exempt status under Rule 17Ad–4(b) again until it remains subject to the minimum performance standards for non-exempt transfer agents for six consecutive months.

ARAs use the information contained in the notices required by Rules 17Ad–4(b) and 17Ad–4(c) to determine whether a registered transfer agent qualifies for the exemption, to determine when a registered transfer agent no longer qualifies for the exemption, and to determine the extent to which that transfer agent is subject to regulation.

The Commission estimates that approximately 10 registered transfer agents each year prepare or file notices in compliance with Rules 17Ad–4(b) and 17Ad–4(c). The Commission estimates that each such registered transfer agent spends approximately 1.5 hours to prepare or file such notices for an aggregate total annual burden of 15 hours (1.5 hours times 10 transfer agents).

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents; 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 in writing within 60 days of this publication.

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget control number.

Please direct your written comments to: Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 28, 2015.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–19013 Filed 8–3–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75550; File No. SR–EDGA–2015–28]

Self-Regulatory Organizations; EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Rule 11.11, Routing to Away Trading Centers

July 29, 2015.

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 July 21, 2015, EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6)(iii) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend Rule 11.11, Routing to Away Trading Centers, to: (i) Delete references to the ROOC routing option; and (ii) update routing options IOCM and ICMT to reflect a recent proposed rule change by EDGX Exchange, Inc. (''EDGX'') in which EDGX replaced the MidPoint Match Order with the MidPoint Peg Order.[5]

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 11.11, Routing to Away Trading Centers, to: (i) Delete references to the ROOC routing option; and (ii) update routing options IOCM and ICMT to reflect a recent proposed rule change by EDGX in which EDGX replaced the MidPoint Match Order with the MidPoint Peg Order.[6]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6)(iii).

[5] *See* Securities Exchange Act Release No. 75479 (July 17, 2015) (SR–EDGX–2015–33).

[6] *See supra* note 5.

ROOC Routing Option

Under Rule 11.11(g)(8), an order utilizing the ROOC routing option is designated by the User [7] to participate in the opening, re-opening (following a halt, suspension, or pause), or closing process of a primary listing market (BATS, NYSE, Nasdaq, NYSE MKT, or NYSE Arca) if received before the opening/re-opening/closing time of such market. If shares remain unexecuted after attempting to execute in the opening, re-opening, or closing process, they are either posted to the EDGA Book,[8] executed, or routed to destinations on the System [9] routing table.[10]

Because few Users elect the ROOC routing option, the Exchange has determined that the current demand does not warrant the infrastructure and ongoing maintenance expenses required to support the product. Therefore, the Exchange proposes to delete the ROOC routing option under Rule 11.11(g)(8) as well as a reference to the ROOC routing option under Rule 11.11(g)(16). Users seeking to route orders to participate in the opening, re-opening, or closing process of a primary listing market may use alternative methods, such as connecting to those markets directly or through a third party service provider, or electing another routing option offered by the Exchange that enables a User to post an order to certain primary listing markets.[11]

IOCM and ICMT Routing Options

The Exchange also proposes to amend Rules 11.11(g)(11) and (12) to update routing options IOCM and ICMT to reflect a recent rule change by EDGX in which EDGX replaced the MidPoint Match Order with the MidPoint Peg Order.[12] Rule 11.11(g)(11) describes IOCM as a routing option under which an order checks the System for available shares and then is sent, as a MidPoint Match Order with a Time-in-Force of IOC,[13] to EDGX. Similarly, Rule 11.11(g)(12) describes ICMT as a routing option under which an order checks the System for available shares, then is sent to destinations on the System routing table and then is sent, as a MidPoint Match Order with a Time-in-Force of IOC, to EDGX. Under both IOCM and ICMT, if shares remain unexecuted after routing, they are posted to the EDGA Book, unless otherwise instructed by the User.

On July 8, 2015, EDGX filed a proposed rule change with the Commission for immediate effectiveness to, among other things, replace the MidPoint Match Order with the MidPoint Peg Order.[14] Therefore, the Exchange proposes to update the description of the IOCM and ICMT routing options to replace references to the MidPoint Match Order with the MidPoint Peg Order.

Implementation Date

The Exchange intends to implement the proposed changes to the descriptions of the IOCM and ICMT routing option immediately.[15] The Exchange will alert Users via a Trading Notice of the date upon which it will discontinue the ROOC routing option.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [16] in general, and furthers the objectives of Section 6(b)(5) of the Act [17] in particular, in that it is designed 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 Exchange does not believe that this proposal will permit unfair discrimination among customers, brokers, or dealers because the ROOC routing option will no longer be available and the updates to the IOCM and ICMT routing options would apply to all Users equally. The Exchange has few Users electing the ROOC routing option and has determined that the current demand does not warrant the infrastructure and ongoing maintenance expense required to support the product. Routing through the Exchange is voluntary and alternative routing options offered by the Exchange as well as other methods remain available to Users that wish to route orders to participate in the opening, re-opening, or closing process of the primary listing market.[18] In addition, the ROOC routing option is not a core product offering by the Exchange, nor is the Exchange required by the Act to offer such a product. The proposed updates to routing options IOCM and ICMT are in response to a recent rule change by EDGX in which EDGX replaced the MidPoint Match Order with the MidPoint Peg Order.[19] The proposal is intended to accurately describe how orders utilizing the IOCM or ICMT routing options are to be handled by the Exchange in light of the EDGX proposed rule change mentioned above. Therefore, the Exchange believes the proposed rule change would make its rules clearer and less confusing for investors; thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, and, in general, protecting investors and the public interest.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposal will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues but rather avoid investor confusion by eliminating the ROOC routing option that is to be discontinued by the Exchange as well as update the IOCM and ICMT routing options in response to a recent proposed rule change by EDGX.[20]

[7] The term ''User'' is defined as ''any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3.'' *See* Exchange Rule 1.5(ee).

[8] The term ''EDGA Book is defined as ''the System's electronic file of orders.'' Rule 1.5(d).

[9] The term ''System'' is defined as ''the electronic communications and trading facility designated by the Board through which securities orders of Users are consolidated for ranking, execution and, when applicable, routing away.'' Rule 1.5(cc).

[10] The term ''System routing table'' refers to the proprietary process for determining the specific trading venues to which the System routes orders and the order in which it routes them. Rule 11.11(g). Orders in BATS listed securities designated for participation in the re-opening process on BATS following a halt, suspension, or pause remain on the EDGA Book and be eligible for execution once the halt, suspension, or pause has been lifted. Rule 11.11(g)(8).

[11] *See e.g.,* Rule 11.11(g)(4) (describing the INET routing option under which an order checks the System for available shares and then is sent to Nasdaq. If shares remain unexecuted after routing, they are posted on the Nasdaq book, unless otherwise instructed by the User), Rule 11.11(g)(5) (describing the RDOT routing option under which an order checks the System for available shares and then is sent to destinations on the System routing table. If shares remain unexecuted after routing, they are sent to the NYSE and can be re-routed by the NYSE. Any remainder will be posted to the NYSE, unless otherwise instructed by the User), *and* Rule 11.11(g)(6) (describing the RDOX routing option under which an order checks the System for available shares, is then sent to the NYSE and can be re-routed by the NYSE. If shares remain unexecuted after routing, they are posted on the NYSE book, unless otherwise instructed by the User).

[12] *See supra* note 5.

[13] *See* Rule 11.6(q)(1).

[14] *See supra* note 5.

[15] Implementation of the proposed rule change immediately upon filing is contingent upon the Commission granting a waiver of the 30-day operative delay. 17 CFR 240.19b–4(f)(6)(iii).

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] *See supra* note 11 and accompanying text.

[19] *See supra* note 5.

[20] *Id.*

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the 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, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.[21]

A proposed rule change filed pursuant to Rule 19b–44(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–44(f)(6)(iii) permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. Waiver of the 30-day operative delay would allow the Exchange to modify its rules in a timely manner by: (i) Eliminating a rule that accounts for a service the Exchange intends to discontinue; and (ii) updating its rules to accurately describe how orders utilizing those routing options function in light of the recent proposed rule change by EDGX, thereby avoiding potential investor confusion during the operative delay period. Based on the foregoing, the Commission believes the waiver of the operative delay is consistent with the protection of investors and the public interest.[22] The Commission hereby grants the waiver and designates the proposal operative upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–EDGA–2015–28 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–EDGA–2015–28. 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 will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–EDGA–2015–28 and should be submitted on or before August 25, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–19015 Filed 8–3–15; 8:45 am]

BILLING CODE 8011–01–P

[21] In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[22] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31728; 812–14337]

AMG Pantheon Private Equity Fund, LLC, et al.; Notice of Application

July 29, 2015.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(c) and 18(i) of the Act and for an order pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end management investment companies to issue multiple classes of units of beneficial interest (''Units'') with varying sales loads and to impose asset-based distribution and/or service fees, and contingent deferred sales loads (''CDSCs'').

APPLICANTS: AMG Pantheon Private Equity Fund, LLC (the ''Feeder Fund''), AMG Pantheon Private Equity Master Fund, LLC (the ''Master Fund''), Pantheon Ventures (US) LP (the ''Adviser'') and AMG Distributors, Inc. (the ''Placement Agent'').

FILING DATES: The application was filed on July 25, 2014, and amended on December 30, 2014 and May 13, 2015.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on August 21, 2015, and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state

the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants, c/o Mark Duggan, AMG Funds LLC, 800 Connecticut Avenue, Norwalk, Connecticut 06854.

FOR FURTHER INFORMATION CONTACT: Barbara T. Heussler, Senior Counsel, at (202) 551–6990 or Mary Kay Frech, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Feeder Fund and the Master Fund, each organized as a Delaware limited liability company, are registered under the Act as closed-end, non-diversified management investment companies. The Feeder Fund intends to invest substantially all of its assets in the Master Fund in reliance on section 12(d)(1)(E) of the Act. The Master Fund expects to pursue its investment objective by investing primarily in private equity investments. To maintain liquidity, the Master Fund will invest in exchange-traded funds (''ETFs'') designed to track equity indexes and, to a lesser extent, in cash and short-term securities. In addition, the Master Fund may use derivative instruments, primarily equity options and swaps, for hedging purposes to help protect the value of its ETF investments.

2. The Adviser, a Delaware limited partnership, is registered as an investment adviser under the Investment Advisers Act of 1940 and serves as investment adviser to the Feeder Fund and the Master Fund. The Placement Agent, a broker-dealer registered under the Securities Exchange Act of 1934 (''1934 Act''), acts as the principal underwriter of the Feeder Fund. Affiliated Managers Group, Inc., a publicly-traded company, indirectly owns a majority of the interests of the Adviser and indirectly owns 100% of the shares of the Placement Agent. The Placement Agent is under common control with the Adviser and is an affiliated person, as defined in section 2(a)(3) of the Act, of the Adviser.

3. The Feeder Fund offers its Units [1] in private placement transactions on a continuous basis at net asset value per unit, as described in the Feeder Fund's confidential memorandum (''Confidential Memorandum'').[2] Units of the Feeder Fund are not offered or traded in a secondary market and are not listed on any securities exchange or quoted on any quotation medium. Applicants do not expect that any secondary market will develop for the Units.

4. The Feeder Fund currently offers a single class of Units (the ''Advisory Class Units'') at net asset value subject to an asset-based distribution and/or service fee (''Distribution and/or Service Fee'') pursuant to a distribution and service plan adopted in conformity with rule 12b–1 under the Act (a ''Distribution and Service Plan''). The Feeder Fund proposes to offer continuously two additional classes of Units, each having its own expense structure (''Transactional Class Units'' and ''Institutional Class Units''), in addition to any additional classes of Units that may be offered in the future. The Transactional Class Units would be offered at net asset value and may (but would not necessarily) be subject to a front-end sales load and an annual asset-based Distribution and/or Service Fee. The Institutional Class Units would be offered at net asset value, and it is anticipated that they would not be subject to a front-end sales load or an annual asset-based Distribution and/or Service Fee. All the classes would be subject to minimum purchase requirements.

5. In order to provide a limited degree of liquidity to unitholders, the Feeder Fund may from time to time offer to repurchase Units at their then current net asset value pursuant to written tenders by unitholders in accordance with rule 13e–4 under the 1934 Act.[3] Repurchases will be made at such times, in such amounts and on such terms as may be determined by the Feeder Fund's board of directors (''Board''), in its sole discretion.[4] The Adviser anticipates that it will recommend to the Board that the Feeder Fund repurchase Units from investors on a quarterly basis.

6. Applicants request that the order also apply to any other registered closed-end management investment company that conducts a continuous offering of its Units, existing now or in the future, for which the Adviser or the Placement Agent or any entity controlling, controlled by, or under common control with the Adviser or the Placement Agent acts as investment adviser or principal underwriter, and which provides periodic liquidity with respect to its Units through tender offers conducted in compliance with rule 13e–4 under the 1934 Act.[5]

7. Applicants represent that the asset-based Distribution and/or Service Fees will comply with the provisions of rule 2830(d) of the Conduct Rules of the National Association of Securities Dealers, Inc. (''NASD Conduct Rule 2830'') as if that rule applied to the Feeder Fund.[6] Applicants also represent that the Feeder Fund will disclose in its Confidential Memorandum or prospectus, the fees, expenses and other characteristics of each class of Units offered for sale by the Confidential Memorandum or prospectus, as is required for open-end, multiple class funds under Form N–1A. The Feeder Fund will disclose fund expenses borne by unitholders during the reporting period in shareholder reports and describe in its Confidential Memorandum or prospectus any arrangements that result in breakpoints

[1] ''Units'' includes any other equivalent designation of a proportionate ownership interest of the Feeder Fund (or any other registered closed-end management investment company relying on the requested order).

[2] The Units are currently only being sold and will only be sold to persons who are ''accredited investors,'' as defined in Regulation D under the Securities Act of 1933 (''Securities Act''). The Feeder Fund reserves the right to conduct a public offering of the Units under the Securities Act in the future.

[3] Likewise, the Master Fund's repurchase offers are conducted pursuant to rule 13e–4 under the 1934 Act.

[4] Units are subject to an early withdrawal fee at a rate of 2% of the aggregate net asset value of the unitholder's Units repurchased by the Feeder Fund (the ''Early Withdrawal Fee'') if the interval between the date of purchase of the Units and the valuation date with respect to the repurchase of those Units is less than one year. The Early Withdrawal Fee will equally apply to all classes of Units of the Feeder Fund, consistent with section 18 of the Act and rule 18f–3 under the Act. To the extent the Feeder Fund determines to waive, impose scheduled variations of, or eliminate the Early Withdrawal Fee, it will comply with the requirements of rule 22d–1 under the Act as if the Early Withdrawal Fee were a CDSC and as if the Feeder Fund were an open-end investment company and the Feeder Fund's waiver, scheduled variation or elimination of the Early Withdrawal Fee will apply uniformly to all unitholders of the Feeder Fund regardless of class.

[5] The Feeder Fund and any other investment company relying on the requested relief will do so in a manner consistent with the terms and conditions of the application. Applicants represent that any person presently intending to rely on the requested relief is listed as an applicant.

[6] Any references to NASD Conduct Rule 2830 include any successor or replacement rule to NASD Conduct Rule 2830 that may be adopted by the Financial Industry Regulatory Authority (''FINRA'').

in or elimination of sales loads.[7] The Feeder Fund and the Placement Agent will also comply with any requirements that may be adopted by the Commission or FINRA regarding disclosure at the point of sale and in transaction confirmations about the costs and conflicts of interest arising out of the distribution of open-end investment company shares, and regarding prospectus disclosure of sales loads and revenue sharing arrangements as if those requirements applied to the Feeder Fund and the Placement Agent.[8] In addition, applicants will comply with applicable enhanced fee disclosure requirements for funds of funds.[9]

8. The Feeder Fund will allocate all expenses incurred by it among the various classes of Units based on the respective net assets of the Feeder Fund attributable to each such class, except that the net asset value and expenses of each class will reflect the expenses associated with the Distribution and Service Plan of that class (if any), shareholder service fees attributable to a particular class, and any other incremental expenses of that class. Expenses of the Feeder Fund, allocated to a particular class of the Feeder Fund's Units, will be borne on a pro rata basis by each outstanding Unit of that class. Applicants state that the Feeder Fund will comply with the provisions of rule 18f–3 under the Act as if it were an open-end investment company.

9. The Feeder Fund may offer an exchange privilege or conversion feature on certain of its future classes of Units, and any such privilege or feature introduced in the future will comply with rule 11a–1, rule 11a–3, and rule18f–3 under the Act as if the Feeder Fund were an open-end investment company.

10. In the event the Feeder Fund imposes a CDSC, the applicants will comply with the provisions of rule 6c–10 under the Act, as if that rule applied to closed-end management investment companies. With respect to any waiver of, scheduled variation in, or elimination of the CDSC, the Feeder Fund will comply with rule 22d–1 under the Act and apply the CDSC uniformly to all unitholders of a given class.

Applicants' Legal Analysis

Multiple Classes of Shares

1. Section 18(c) of the Act provides, in relevant part, that a closed-end investment company may not issue or sell any senior security if, immediately thereafter, the company has outstanding more than one class of senior security. Applicants state that the creation of multiple classes of Units of the Feeder Fund may be prohibited by section 18(c).

2. Section 18(i) of the Act provides that each share of stock issued by a registered management investment company will be a voting stock and have equal voting rights with every other outstanding voting stock. Applicants state that permitting multiple classes of Units of the Feeder Fund may violate section 18(i) of the Act because each class would be entitled to exclusive voting rights with respect to matters solely related to that class.

3. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction or any class or classes of persons, securities or transactions from any provision of the Act, or from any rule under the Act, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an exemption under section 6(c) from sections 18(c) and 18(i) to permit the Feeder Fund to issue multiple classes of Units.[10]

4. Applicants submit that the proposed allocation of expenses and voting rights among multiple classes is equitable and will not discriminate against any group or class of unitholders. Applicants submit that the proposed arrangements would permit the Feeder Fund to facilitate the distribution of Units and provide investors with a broader choice of unitholder options. Applicants assert that the proposed closed-end investment company multiple class structure does not raise the concerns underlying section 18 of the Act to any greater degree than open-end investment companies' multiple class structures that are permitted by rule 18f–3 under the Act. Applicants state that the Feeder Fund will comply with the provisions of rule 18f–3 as if it were an open-end investment company.

CDSCs

5. Applicants believe that the requested relief meets the standards of section 6(c) of the Act. Rule 6c–10 under the Act permits open-end investment companies to impose CDSCs, subject to certain conditions. Applicants state that any CDSC imposed by the Feeder Fund will comply with rule 6c–10 under the Act as if the rule were applicable to closed-end investment companies. The Feeder Fund also will disclose CDSCs in accordance with the requirements of Form N–1A concerning CDSCs as if the Feeder Fund were an open-end investment company. Applicants further state that the Feeder Fund will apply the CDSC (and any waivers or scheduled variations of the CDSC) uniformly to all unitholders of a given class and consistently with the requirements of rule 22d–1 under the Act.

Asset-Based Distribution and/or Service Fees

6. Section 17(d) of the Act and rule 17d–1 under the Act prohibit an affiliated person of a registered investment company or an affiliated person of such person, acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates unless the Commission issues an order permitting the transaction. In reviewing applications submitted under section 17(d) and rule 17d–1, the Commission considers whether the participation of the investment company in a joint enterprise or joint arrangement is consistent with the provisions, policies and purposes of the Act, and the extent to which the participation is on a basis different from or less advantageous than that of other participants.

7. Rule 17d–3 under the Act provides an exemption from section 17(d) and rule 17d–1 to permit open-end investment companies to enter into distribution arrangements pursuant to rule 12b–1 under the Act. Applicants request an order under section 17(d) and rule 17d–1 under the Act to permit the Feeder Fund to impose asset-based Distribution and/or Service Fees. Applicants have agreed to comply with rules 12b–1 and 17d–3 as if those rules applied to closed-end investment companies.

[7] See Shareholder Reports and Quarterly Portfolio Disclosure of Registered Management Investment Companies, Investment Company Act Release No. 26372 (Feb. 27, 2004) (adopting release); and Disclosure of Breakpoint Discounts by Mutual Funds, Investment Company Act Release No. 26464 (June 7, 2004) (adopting release).

[8] See Confirmation Requirements and Point of Sale Disclosure Requirements for Transactions in Certain Mutual Funds and Other Securities, and Other Confirmation Requirement Amendments, and Amendments to the Registration Form for Mutual Funds, Investment Company Act Release No. 26341 (Jan. 29, 2004) (proposing release).

[9] Fund of Funds Investments, Investment Company Act Release Nos. 26198 (Oct. 1, 2003) (proposing release) and 27399 (Jun. 20, 2006) (adopting release). See also Rules 12d1–1, *et seq.* under the Act.

[10] The Master Fund will not issue multiple classes of its units and is an applicant because of the master-feeder structure.

Applicants' Condition

The Applicants agree that any order granting the requested relief will be subject to the following condition:

Applicants will comply with the provisions of rules 6c–10, 12b–1, 17d–3, 18f–3, 22d–1, and, where applicable, 11a–3 under the Act, as amended from time to time or replaced, as if those rules applied to closed-end management investment companies, and will comply with the NASD Conduct Rule 2830, as amended from time to time, as if that rule applied to all closed-end management investment companies.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–19018 Filed 8–3–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

ACTION: 60-Day notice of submission of information collection approval from the Office of Management and Budget and request for comments.

Upon Written Request Copies Available From: U.S. Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

New Generic ICR: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

SEC File No. 270–789, OMB Control No. 3235–XXXX.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, the Securities and Exchange Commission 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.).

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.

Below is the projected average estimates for the next three years:

Current Actions: New collection of information.

Type of Review: New Collection.

Expected Annual Number of activities: [10].

Respondents: [20,000].

Annual responses: [20,000].

Frequency of Response: Once per request.

Average minutes per response: [10].

Burden hours: [3500].

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

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.

Please direct your written comments to: Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 28, 2015.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–18885 Filed 8–3–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copy Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Form N–8A. SEC File No. 270–135, OMB Control No. 3235–0175.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

The Investment Company Act of 1940 (''Investment Company Act'') (15 U.S.C. 80a–1 *et seq.*) requires investment companies to register with the Commission before they conduct any business in interstate commerce. Section 8(a) of the Investment Company Act provides that an investment company shall be deemed to be registered upon receipt by the Commission of a notification of

registration in such form as the Commission prescribes. Form N–8A (17 CFR 274.10) is the form for notification of registration that the Commission has adopted under section 8(a). The purpose of such notification of registration provided on Form N–8A is to notify the Commission of the existence of investment companies required to be registered under the Investment Company Act and to enable the Commission to administer the provisions of the Investment Company Act with respect to those companies. After an investment company has filed its notification of registration under section 8(a), the company is then subject to the provisions of the Investment Company Act which govern certain aspects of its organization and activities, such as the composition of its board of directors and the issuance of senior securities. Form N–8A requires an investment company to provide its name, state of organization, form of organization, classification, the name and address of each investment adviser of the investment company, the current value of its total assets, and certain other information readily available to the investment company. If the investment company is filing a registration statement as required by Section 8(b) of the Investment Company Act concurrently with its notification of registration, Form N–8A requires only that the registrant file the cover page (giving its name, address, and agent for service of process) and sign the form in order to effect registration.

Based on recent filings of notifications of registration on Form N–8A, we estimate that about 92 investment companies file such notifications each year. An investment company must only file a notification of registration on Form N–8A once. The currently approved average hour burden per investment company of preparing and filing a notification of registration on Form N–8A is one hour. Based on the Commission staff's experience with the requirements of Form N–8A and with disclosure documents generally—and considering that investment companies that are filing notifications of registration on Form N–8A simultaneously with the registration statement under the Investment Company Act are only required by Form N–8A to file a signed cover page—we continue to believe that this estimate is appropriate. Therefore, we estimate that the total annual hour burden to prepare and file notifications of registration on Form N–8A is 92 hours. The currently approved cost burden of Form N–8A is $443 per filing. We are updating the estimated cost burden to $449 to account for the effects of inflation. Therefore, we estimate that the total annual cost burden to associated with preparing and filing notifications of registration on Form N–8A is about $41,308.

Estimates of average burden hours and costs are made solely for the purposes of the Paperwork Reduction Act, and are not derived from a comprehensive or even representative survey or study of the costs of Commission rules and forms. Compliance with the collection of information requirements of Form N–8A is mandatory. Responses to the collection of information will not be kept confidential. 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.

Written comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information 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 in writing within 60 days of this publication.

Please direct your written comments to Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, C/O Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 28, 2015.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–18887 Filed 8–3–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75547; File No. SR–BYX–2015–33]

Self-Regulatory Organizations; BATS Y-Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Rule 11.13, Order Execution and Routing

July 29, 2015.

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 July 21, 2015, BATS Y-Exchange, Inc. (the ''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6)(iii) thereunder,[4] which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend Rule 11.13, Order Execution and Routing, to: (i) Delete references to the ROOC routing option; and (ii) update routing options IOCM and ICMT to reflect a recent proposed rule change by EDGX Exchange, Inc. (''EDGX'') in which EDGX replaced the MidPoint Match Order with the MidPoint Peg Order.[5]

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6)(iii).

[5] *See* Securities Exchange Act Release No. 75479 (July 17, 2015) (SR–EDGX–2015–33).

proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 11.13, Order Execution and Routing, to: (i) Delete references to the ROOC routing option; and (ii) update routing options IOCM and ICMT to reflect a recent proposed rule change by EDGX in which EDGX replaced the MidPoint Match Order with the MidPoint Peg Order.[6]

ROOC Routing Option

Under Rule 11.13(b)(3)(N), an order utilizing the ROOC routing option is designated by the User[7] to participate in the opening, re-opening (following a halt, suspension, or pause), or closing process of a primary listing market (BATS BZX, NYSE, Nasdaq, NYSE MKT, or NYSE Arca) if received before the opening/re-opening/closing time of such market. If shares remain unexecuted after attempting to execute in the opening, re-opening, or closing process, they are either posted to the BATS Book,[8] executed, or routed to destinations on the System[9] routing table.[10]

Because few Users elect the ROOC routing option, the Exchange has determined that the current demand does not warrant the infrastructure and ongoing maintenance expenses required to support the product. Therefore, the Exchange proposes to delete the ROOC routing option under 11.13(b)(3)(N). Users seeking to route orders to participate in the opening, re-opening, or closing process of a primary listing market may use alternative methods, such as connecting to those markets directly or through a third party service provider, or electing another routing option offered by the Exchange that enables a User to post an order to certain primary listing markets.[11]

IOCM and ICMT Routing Options

The Exchange also proposes to amend Rules 11.13(b)(3)(O) and (P) to update routing options IOCM and ICMT to reflect a recent rule change by EDGX in which EDGX replaced the MidPoint Match Order with the MidPoint Peg Order.[12] Rule 11.13(b)(3)(O) describes IOCM as a routing option under which an order checks the System for available shares and then is sent, as a MidPoint Match Order with a Time-in-Force of IOC[13] to EDGX. Similarly, Rule 11.13(b)(3)(P) describes ICMT as a routing option under which an order checks the System for available shares, then is sent to destinations on the System routing table and then is sent, as a MidPoint Match Order with a Time-in-Force of IOC to EDGX. Under ICMT, if shares remain unexecuted after routing, they are posted to the BATS Book, unless otherwise instructed by the User.

On July 8, 2015, EDGX filed a proposed rule change with the Commission for immediate effectiveness to, among other things, replace the MidPoint Match Order with the MidPoint Peg Order.[14] Therefore, the Exchange proposes to update the description of the IOCM and ICMT routing options to replace references to the MidPoint Match Order with the MidPoint Peg Order.

Implementation Date

The Exchange intends to implement the proposed changes to the descriptions of the IOCM and ICMT routing option immediately.[15] The Exchange will alert Users via a Trading Notice of the date upon which it will discontinue the ROOC routing option.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[16] in general, and furthers the objectives of Section 6(b)(5) of the Act[17] in particular, in that it is designed 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 Exchange does not believe that this proposal will permit unfair discrimination among customers, brokers, or dealers because the ROOC routing option will no longer be available and the updates to the IOCM and ICMT routing options would apply to all Users equally. The Exchange has few Users electing the ROOC routing option and has determined that the current demand does not warrant the infrastructure and ongoing maintenance expense required to support the product. Routing through the Exchange is voluntary and alternative routing options offered by the Exchange as well as other methods remain available to Users that wish to route orders to participate in the opening, re-opening, or closing process of the primary listing market.[18] In addition, the ROOC routing option is not a core product offering by the Exchange, nor is the Exchange required by the Act to offer such a product. The proposed updates to routing options IOCM and ICMT are in response to a recent rule change by EDGX in which EDGX replaced the MidPoint Match Order with the MidPoint Peg Order.[19] The proposal is intended to accurately describe how orders utilizing the IOCM or ICMT routing options are to be handled by the Exchange in light of the EDGX proposed rule change mentioned above. Therefore, the Exchange believes the proposed rule change would make its rules clearer and less confusing for investors; thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, and, in

[6] *See supra* note 5.

[7] The term ''User'' is defined as ''any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3.'' *See* Exchange Rule 1.5(cc).

[8] The term ''BATS Book is defined as ''the System's electronic file of orders.'' Rule 1.5(e).

[9] The term ''System'' is defined as ''the electronic communications and trading facility designated by the Board through which securities orders of Users are consolidated for ranking, execution and, when applicable, routing away.'' Rule 1.5(aa).

[10] The term ''System routing table'' refers to the proprietary process for determining the specific trading venues to which the System routes orders and the order in which it routes them. Rule 11.13(b)(3). The ROOC routing option does not route to the reopening process for BATS BZX. Rule 11.13(b)(3)(N).

[11] *See e.g.,* Rule 11.13(b)(3)(J) (describing the INET routing option under which an order checks the System for available shares and then is sent to Nasdaq. If shares remain unexecuted after routing, they are posted on the Nasdaq book, unless otherwise instructed by the User), Rule 11.13(b)(3)(K) (describing the RDOT routing option under which an order checks the System for available shares and then is sent to destinations on the System routing table. If shares remain unexecuted after routing, they are sent to the NYSE and can be re-routed by the NYSE. Any remainder will be posted to the NYSE, unless otherwise instructed by the User), *and* 11.13(b)(3)(L) (describing the RDOX routing option under which an order checks the System for available shares, is then sent to the NYSE and can be re-routed by the NYSE. If shares remain unexecuted after routing, they are posted on the NYSE book, unless otherwise instructed by the User).

[12] *See supra* note 5.

[13] *See* Rule 11.9(q)(1).b [sic]

[14] *See supra* note 5.

[15] Implementation of the proposed rule change immediately upon filing is contingent upon the Commission granting a waiver of the 30-day operative delay. 17 CFR 240.19b–4(f)(6)(iii).

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] *See supra* note 11 and accompanying text.

[19] *See supra* note 5.

general, protecting investors and the public interest.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposal will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues but rather avoid investor confusion by eliminating the ROOC routing option that is to be discontinued by the Exchange as well as update the IOCM and ICMT routing options in response to a recent proposed rule change by EDGX.[20]

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the 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, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.[21]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. Waiver of the 30-day operative delay would allow the Exchange to modify its rules in a timely manner by: (i) Eliminating a rule that accounts for a service the Exchange intends to discontinue; and (ii) updating its rules to accurately describe how orders utilizing those routing options function in light of the recent proposed rule change by EDGX, thereby avoiding potential investor confusion during the operative delay period. Based on the foregoing, the Commission believes the waiver of the operative delay is consistent with the protection of investors and the public interest.[22] The Commission hereby grants the waiver and designates the proposal operative upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BYX–2015–33 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–BYX–2015–33. 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 will also 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–BYX–2015–33 and should be submitted on or before August 25, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–19017 Filed 8–3–15; 8:45 am]

BILLING CODE 8011–01–P

[20] *Id.*

[21] In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[22] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Rule 22e–3. SEC File No. 270–603, OMB Control No. 3235–0658.

Notice is hereby given that, under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Section 22(e) of the Investment Company Act [15 U.S.C. 80a–22(e)] (''Act'') generally prohibits funds, including money market funds, from suspending the right of redemption, and from postponing the payment or satisfaction upon redemption of any redeemable security for more than seven days. The provision was designed to prevent funds and their investment advisers from interfering with the

redemption rights of shareholders for improper purposes, such as the preservation of management fees. Although section 22(e) permits funds to postpone the date of payment or satisfaction upon redemption for up to seven days, it does not permit funds to suspend the right of redemption for any amount of time, absent certain specified circumstances or a Commission order.

Rule 22e–3 under the Act [17 CFR 270.22e–3] exempts money market funds from section 22(e) to permit them to suspend redemptions in order to facilitate an orderly liquidation of the fund. Specifically, rule 22e–3 permits a money market fund to suspend redemptions and postpone the payment of proceeds pending board-approved liquidation proceedings if: (i) The fund's board of directors, including a majority of disinterested directors, determines pursuant to § 270.2a–7(c)(8)(ii)(C) that the extent of the deviation between the fund's amortized cost price per share and its current net asset value per share calculated using available market quotations (or an appropriate substitute that reflects current market conditions) may result in material dilution or other unfair results to investors or existing shareholders; (ii) the fund's board of directors, including a majority of disinterested directors, irrevocably approves the liquidation of the fund; and (iii) the fund, prior to suspending redemptions, notifies the Commission of its decision to liquidate and suspend redemptions. Rule 22e–3 also provides an exemption from section 22(e) for registered investment companies that own shares of a money market fund pursuant to section 12(d)(1)(E) of the Act (''conduit funds''), if the underlying money market fund has suspended redemptions pursuant to the rule. A conduit fund that suspends redemptions in reliance on the exemption provided by rule 22e–3 is required to provide prompt notice of the suspension of redemptions to the Commission. Notices required by the rule must be provided by electronic mail, directed to the attention of the Director of the Division of Investment Management or the Director's designee.[1] Compliance with the notification requirement is mandatory for money market funds and conduit funds that rely on rule 22e–3 to suspend redemptions and postpone payment of proceeds pending a liquidation, and are not kept confidential.

Commission staff estimates that, on average, one money market fund would break the buck and liquidate every six years.[2] In addition, Commission staff estimates that there are an average of two conduit funds that may be invested in a money market fund that breaks the buck.[3] Commission staff further estimates that a money market fund or conduit fund would spend approximately one hour of an in-house attorney's time to prepare and submit the notice required by the rule. Given these estimates, the total annual burden of the notification requirement of rule 22e–3 for all money market funds and conduit funds would be approximately 30 minutes, [4] at a cost of $190.[5]

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms.

Compliance with the collection of information requirements of the rule is necessary to obtain the benefit of relying on the rule. 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 control number.

Written comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information 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 in writing within 60 days after this publication.

Please direct your written comments to Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, C/O Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 28, 2015.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–18884 Filed 8–3–15; 8:45 am]

BILLING CODE 8011–01–P

[1] *See* rule 22e–3(a)(3).

[2] This estimate is based upon the Commission's experience with the frequency with which money market funds have historically required sponsor support. Although the vast majority of money market fund sponsors have supported their money market funds in times of market distress, for purposes of this estimate Commission staff conservatively estimates that one or more sponsors may not provide support.

[3] Based on a review of filings with the Commission, Commission staff estimates that 2.3 conduit funds are invested in each master fund. However, master funds account for only 11.3% of all money market funds. Solely for the purposes of this information collection, and to avoid underestimating possible burdens, the Commission conservatively assumes that any money market that breaks the buck and liquidates would be a master fund.

[4] This estimate is based on the following calculations: (1 hour ÷ 6 years) = 10 minutes per year for each fund and conduit fund that is required to provide notice under the rule. 10 minutes per year × 3 (combined number of affected funds and conduit funds) = 30 minutes.

[5] This estimate is based on the following calculation: $380/hour × 30 minutes = $190. The estimated hourly wages used in this PRA analysis were derived from reports prepared by the Securities Industry and Financial Markets Association, modified to account for an 1800-hour work year and multiplied by 5.35 to account for bonuses, firm size, employee benefits and overhead. *See* Securities Industry and Financial Markets Association, *Management & Professional Earnings in the Securities Industry 2013.*

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 31726; File No. 812–14395]

Little Harbor MultiStrategy Composite Fund and Little Harbor Advisors, LLC; Notice of Application

July 28, 2015.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 18(c) and 18(i) of the Act, under sections 6(c) and 23(c)(3) of the Act for an exemption from rule 23c–3 under the Act, and for an order pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end management investment companies to issue multiple classes of shares (''Shares'') and to impose asset-based distribution and service fees and deferred sales charges (''Deferred Sales Charges'').

APPLICANTS: Little Harbor MultiStrategy Composite Fund (''MSC Fund'') and Little Harbor Advisors, LLC (''Investment Manager'').

FILING DATES: The application was filed on December 2, 2014, and amended on April 10, 2015 and June 17, 2015.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving

applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on August 24, 2015 and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants, 30 Doaks Lane, Marblehead, MA 01945.

FOR FURTHER INFORMATION CONTACT: Deepak T. Pai, Senior Counsel, at (202) 551–6876 or Mary Kay Frech, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The MSC Fund is a Delaware statutory trust registered under the Act as a non-diversified, closed-end management investment company. The MSC Fund's investment objective is to realize long-term, risk-adjusted returns that are attractive as compared to those returns of traditional public equity and fixed-income markets. The MSC Fund may invest in U.S. and non-U.S. equities of companies with any market capitalization, fixed income securities of any quality, currencies, derivative instruments, futures contracts, options on futures contracts, and commodities.

2. The Investment Manager is a Delaware limited liability company and is registered as an investment adviser under the Investment Advisers Act of 1940. The Investment Manager serves as the investment manager to the MSC Fund. Foreside Financial Services, LLC, a broker registered under the Securities Exchange Act of 1934 (''Exchange Act'') currently serves as the principal underwriter of the MSC Fund (''Distributor''). In the future, the Distributor may be an affiliated person, as defined in section 2(a)(3) of the Act, of the Investment Manager.

3. Applicants seek an order to permit the MSC Fund to issue multiple classes of Shares, with varying sales charges, and/or asset-based distribution and/or service fees, and Deferred Sales Charges.

4. Applicants request that the order also apply to any continuously offered registered closed-end management investment company existing now or in the future for which the Investment Manager or any entity controlling, controlled by, or under common control with the Investment Manager, or any successor in interest to such entity,[1] serves as investment adviser and which either operates as an ''interval fund'' pursuant to rule 23c–3 under the Act (each, an ''Interval Fund'') or provides periodic liquidity with respect to its Shares pursuant to rule 13e–4 under the Exchange Act (each, a ''New Fund,'' and together with the MSC Fund, the ''Funds'').[2]

5. Since February 1, 2015, the MSC Fund has made a continuous public offering of its single, undesignated class of Shares (the ''Initial Class'').[3] Shares of the MSC Fund currently are not offered or traded in a secondary market and are not listed on any securities exchange or quoted on any quotation medium. Applicants do not expect there to be a secondary trading market for any Fund Shares.

6. The MSC Fund anticipates that Initial Class Shares will continue to be offered at net asset value, subject to a front-end sales load in addition to the current service fee. The MSC Fund and each New Fund propose to offer at least two, and perhaps more than two, classes of Shares. Shares of each new class will be offered at net asset value, and may be subject to a front-end sales load or a Deferred Sales Charge, and/or an asset-based distribution and/or service fee, and/or any early repurchase fee (''Early Repurchase Fee'').[4] Because of the different distribution fees, shareholder service fees, and any other class expenses that may be attributable to the different classes, the net income attributable to, and any dividends payable on, each class of Shares may differ from each other from time to time. As a result, the net asset value per Share of the classes may differ over time.

7. Applicants state that, from time to time, a Fund may create and offer additional classes of Shares of the Fund, or may vary the characteristics of its Shares in the following respects: (i) The amount of fees permitted by a Distribution Plan[5] and/or service plan as to such class; (ii) voting rights with respect to a Distribution Plan and/or service plan as to such class; (iii) different class designations; (iv) the impact of any class expenses directly attributable to a particular class of Shares allocated on a class basis as described in the application; (v) differences in any dividends and net asset values per Share resulting from differences in fees under a Distribution Plan and/or service plan or in class expenses; (vi) any sales load structure; and (vii) any conversion features, as permitted under the Act.

10. Each Fund and its Distributor will comply with any requirements that the Commission or FINRA may adopt regarding disclosure at the point of sale and in transaction confirmations about the costs and conflicts of interest arising out of the distribution of open-end investment company shares, and regarding prospectus disclosure of sales charges and revenue sharing arrangements, as if those requirements applied to the Fund and the Distributor. In addition, each Fund or its Distributor will contractually require that any other distributor of the Fund's Shares comply with such requirements in connection with the distribution of Shares of the New Fund.

11. Each Fund will allocate all expenses incurred by it among its various classes of Shares based on the respective net assets of the Fund attributable to each such class, except

[1] A successor in interest is limited to an entity that results from a reorganization of the entity under the laws of another jurisdiction or in a change in the form of business organization.

[2] Any Fund relying on the requested relief will do so in a manner consistent with the terms and conditions of the application. Applicants represent that any person presently intending to rely on the order requested is listed as an applicant.

[3] Shares of the MSC Fund are currently, and in the future will be, sold only to investors who meet the definition of ''accredited investor'' in Regulator D under the Securities Act of 1933.

[4] Shares may be subject to an Early Repurchase Fee at a rate of 2% of the aggregate net asset value of a shareholder's Shares repurchased by the Fund if the interval between the date of purchase of the Shares and the valuation date with respect to the repurchase of those Shares is less than one year. Any Early Repurchase Fee imposed by a Fund will apply to all classes of Shares of the Fund, consistent with section 18 of the Act and rule 18f–3 thereunder. To the extent the Fund determines to waive, impose scheduled variations of, or eliminate any Early Repurchase Fee, it will do so consistently with the requirements of rule 22d–1 under the Act and the Fund's waiver of, scheduled variation in, or elimination of, any such Early Repurchase Fee will apply uniformly to all shareholders of the Fund.

[5] Distribution fees with respect to any class of Shares of a Fund would be paid pursuant to a plan of distribution adopted by the Fund with respect to the applicable class in compliance with rules 12b–1 and 17d–3 under the Act, as if those rules applied to closed-end management investment companies (a ''Distribution Plan'').

that the net asset value and expenses of each class will reflect the fees associated with the Distribution Plan of that class (if any), shareholder service fees attributable to a particular class (including transfer agency fees, if any), and any other incremental expenses of that class. Expenses of a Fund, respectively allocated to a particular class of the Fund's Shares, will be borne on a pro rata basis by each outstanding Share of that class. Applicants state that the Fund will comply with the provisions of rule 18f–3 under the Act as if it were an open-end investment company.

12. Applicants state that the Interval Funds may impose Deferred Sales Charges on Shares submitted for repurchase that have been held less than a specified period and may waive the Deferred Sales Charge for certain categories of shareholders or transactions to be established from time to time. Applicants represent that each Interval Fund would apply the Deferred Sales Charge (and any waivers or scheduled variations of the Deferred Sales Charge) uniformly to all shareholders in a given class and consistently with the requirements of rule 22d–1 under the Act as if the Interval Fund were an open-end investment company.

13. Each Interval Fund may offer its shareholders an exchange feature under which the shareholders of the Interval Fund may, in connection with such Interval Fund's repurchase offers, exchange their Shares of the Interval Fund for Shares of the same class of (i) registered open-end investment companies or (ii) other Funds that continuously offer their Shares at net asset value, and that in either case are in the Interval Fund's group of investment companies (collectively, ''Other Funds''). Shares of an Interval Fund that are exchanged for Shares of Other Funds will be included as part of the amount of the repurchase offer amount for such Interval Fund as specified in rule 23c–3 under the Act. Any exchange option will comply with rule 11a–1, 11a–3 and rule 18f–3 under the Act, as if the Interval Fund were an open-end investment company. In complying with rule 11a–3, each Interval Fund will treat any Deferred Sales Charge as if it were a contingent deferred sales charge (''CDSC'').

Applicants' Legal Analysis

Multiple Classes of Shares

1. Section 18(c) of the Act provides, in relevant part, that a closed-end investment company may not issue or sell any senior security if, immediately thereafter, the company has outstanding more than one class of senior security. Applicants state that the creation of multiple classes of Shares of the Funds may be prohibited by section 18(c), as a class may have priority over another class as to payment of dividends because shareholders of different classes would pay different fees and expenses.

2. Section 18(i) of the Act provides that each share of stock issued by a registered management investment company will be a voting stock and have equal voting rights with every other outstanding voting stock. Applicants state that multiple classes of Shares of the Funds may violate section 18(i) of the Act because each class would be entitled to exclusive voting rights with respect to matters solely related to that class.

3. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction or any class or classes of persons, securities or transactions from any provision of the Act, or from any rule thereunder, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an exemption under section 6(c) from sections 18(c) and 18(i) to permit the Funds to issue multiple classes of Shares.

4. Applicants submit that the proposed allocation of expenses and voting rights among multiple classes is equitable and will not discriminate against any group or class of shareholders. Applicants submit that the proposed arrangements would permit a Fund to facilitate the distribution of its Shares and provide investors with a broader choice of shareholder services. Applicants assert that the proposed closed-end investment company multiple class structure does not raise the concerns underlying section 18 of the Act to any greater degree than open-end investment companies' multiple class structures that are permitted by rule 18f–3 under the Act. Applicants state that each Fund will comply with the provisions of rule 18f–3 as if it were an open-end investment company.

Deferred Sales Charge

1. Section 23(c) of the Act provides, in relevant part, that no registered closed-end investment company will purchase securities of which it is the issuer, except: (a) On a securities exchange or other open market; (b) pursuant to tenders, after reasonable opportunity to submit tenders given to all holders of securities of the class to be purchased; or (c) under such other circumstances as the Commission may permit by rules and regulations or orders for the protection of investors.

2. Rule 23c–3 under the Act permits a registered closed-end investment company (an ''interval fund'') to make repurchase offers of between five and twenty-five percent of its outstanding shares at net asset value at periodic intervals pursuant to a fundamental policy of the interval fund. Rule 23c–3(b)(1) under the Act provides that an interval fund may deduct from repurchase proceeds only a repurchase fee, not to exceed two percent of the proceeds, that is paid to the interval fund and is reasonably intended to compensate the fund for expenses directly related to the repurchase.

3. Section 23(c)(3) provides that the Commission may issue an order that would permit a closed-end investment company to repurchase its shares in circumstances in which the repurchase is made in a manner or on a basis that does not unfairly discriminate against any holders of the class or classes of securities to be purchased.

4. Applicants request relief under sections 6(c), discussed above, and 23(c)(3) from rule 23c–3 to the extent necessary for the Interval Funds to impose a Deferred Sales Charge on Shares submitted for repurchase that have been held for less than a specified period.

5. Applicants state that the Deferred Sales Charge they intend to impose is functionally similar to a CDSC imposed by an open-end investment company under rule 6c–10 under the Act. Rule 6c–10 permits open-end investment companies to impose CDSCs, subject to certain conditions. Applicants note that rule 6c–10 is grounded in policy considerations supporting the employment of CDSCs where there are adequate safeguards for the investor and state that the same policy considerations support imposition of Deferred Sales Charges in the interval fund context. In addition, applicants state that Deferred Sales Charges may be necessary for the distributor to recover distribution costs. Applicants represent that any Deferred Sales Charge imposed by the Interval Funds will comply with rule 6c–10 under the Act as if that rule were applicable to closed-end investment companies. Each Interval Fund will disclose Deferred Sales Charges in accordance with the requirements of Form N–1A concerning CDSCs. Applicants further state that each Interval Fund will apply the Deferred Sales Charge (and any waivers or scheduled variations of the Deferred

Sales Charge) uniformly to all shareholders in a given class and consistently with the requirements of rule 22d–1 under the Act.

Asset-Based Distribution Fees

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit an affiliated person of a registered investment company or an affiliated person of such person, acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates unless the Commission issues an order permitting the transaction. In reviewing applications submitted under section 17(d) and rule 17d–1, the Commission considers whether the participation of the investment company in a joint enterprise or joint arrangement is consistent with the provisions, policies and purposes of the Act, and the extent to which the participation is on a basis different from or less advantageous than that of other participants.

2. Rule 17d–3 under the Act provides an exemption from section 17(d) and rule 17d–1 to permit open-end investment companies to enter into distribution arrangements pursuant to rule 12b–1 under the Act. Applicants request an order under section 17(d) and rule 17d–1 under the Act to the extent necessary to permit the Fund to impose asset-based service and/or distribution fees. Applicants have agreed to comply with rules 12b–1 and 17d–3 as if those rules applied to closed-end investment companies, which they believe will resolve any concerns that might arise in connection with a Fund financing the distribution of its Shares through asset-based distribution fees.

3. For the reasons stated above, applicants submit that the exemptions requested under section 6(c) are necessary and appropriate in the public interest and are consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants further submit that the relief requested pursuant to section 23(c)(3) is consistent with the protection of investors and insures that applicants do not unfairly discriminate against any holders of the class or classes of securities to be purchased. Finally, applicants submit that the requested relief meets the standards for relief in section 17(d) of the Act and rule 17d–1 thereunder. Applicants state that the Funds' imposition of asset-based distribution fees is consistent with the provisions, policies and purposes of the Act and does not involve participation on a basis different from or less advantageous than that of other participants.

Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the following condition:

Applicants will comply with the provisions of rules 6c–10, 12b–1, 17d–3, 18f–3, and 22d–1 under the Act, as amended from time to time or replaced, as if those rules applied to closed-end management investment companies, and will comply with the NASD Conduct Rule 2830, as amended from time to time, as if that rule applied to all closed-end management investment companies.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–19014 Filed 8–3–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on Thursday, August 6, 2015 at 2 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matter at the Closed Meeting.

Commissioner Gallagher, as duty officer, voted to consider the items listed for the Closed Meeting in closed session.

The subject matter of the Closed Meeting will be: Settlement of injunctive actions; Institution and settlement of administrative proceedings; Consideration of amicus participation; and Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact the Office of the Secretary at (202) 551–5400.

Dated: July 30, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–19188 Filed 7–31–15; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549–2736.

Extension:

Rule 23c–3 and Form N–23c–3, SEC File No. 270–373, OMB Control No. 3235–0422.

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et. seq.*), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 23c–3 (17 CFR 270.23c–3) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) permits a registered closed-end investment company (''closed-end fund'' or ''fund'') that meets certain requirements to repurchase common stock of which it is the issuer from shareholders at periodic intervals, pursuant to repurchase offers made to all holders of the stock. The rule enables these funds to offer their shareholders a limited ability to resell their shares in a manner that previously was available only to open-end investment company shareholders. To protect shareholders, a closed-end fund that relies on rule 23c–3 must send shareholders a notification that contains specified information each time the fund makes a repurchase offer (on a quarterly, semi-annual, or annual basis, or, for certain funds, on a discretionary basis not more often than every two years). The fund also must file copies of the shareholder notification with the Commission (electronically through the Commission's Electronic Data Gathering, Analysis, and Retrieval System (''EDGAR'')) on Form N–23c–3, a filing that provides certain information about the fund and the type of offer the fund is making.[1] The fund

[1] Form N–23c–3, entitled ''Notification of Repurchase Offer Pursuant to Rule 23c–3,'' requires

Continued

must describe in its annual report to shareholders the fund's policy concerning repurchase offers and the results of any repurchase offers made during the reporting period. The fund's board of directors must adopt written procedures designed to ensure that the fund's investment portfolio is sufficiently liquid to meet its repurchase obligations and other obligations under the rule. The board periodically must review the composition of the fund's portfolio and change the liquidity procedures as necessary. The fund also must file copies of advertisements and other sales literature with the Commission as if it were an open-end investment company subject to section 24 of the Investment Company Act (15 U.S.C. 80a–24) and the rules that implement section 24. Rule 24b–3 under the Investment Company Act (17 CFR 270.24b–3), however, exempts the fund from that requirement if the materials are filed instead with the Financial Industry Regulatory Authority (''FINRA'').

The requirement that the fund send a notification to shareholders of each offer is intended to ensure that a fund provides material information to shareholders about the terms of each offer. The requirement that copies be sent to the Commission is intended to enable the Commission to monitor the fund's compliance with the notification requirement. The requirement that the shareholder notification be attached to Form N–23c–3 is intended to ensure that the fund provides basic information necessary for the Commission to process the notification and to monitor the fund's use of repurchase offers. The requirement that the fund describe its current policy on repurchase offers and the results of recent offers in the annual shareholder report is intended to provide shareholders current information about the fund's repurchase policies and its recent experience. The requirement that the board approve and review written procedures designed to maintain portfolio liquidity is intended to ensure that the fund has enough cash or liquid securities to meet its repurchase obligations, and that written procedures are available for review by shareholders and examination by the Commission. The requirement that the fund file advertisements and sales literature as if it were an open-end fund is intended to facilitate the review of these materials by the Commission or FINRA to prevent incomplete, inaccurate, or misleading disclosure about the special characteristics of a closed-end fund that makes periodic repurchase offers.

Based on staff experience, the Commission staff estimates that 21 funds make use of rule 23c–3 annually, including six funds that are relying upon rule 23c–3 for the first time. The Commission staff estimates that on average a fund spends 89 hours annually in complying with the requirements of the rule and Form N–23c–3, with funds relying upon rule 23c–3 for the first time incurring an additional one-time burden of 28 hours. The Commission therefore estimates the total annual burden of the rule's and form's paperwork requirements to be 2,037 hours. In addition to the burden hours, the Commission estimates that the average yearly cost to each fund that relies on rule 23c–3 to print and mail repurchase offers to shareholders is approximately $29,966.50. The Commission estimates total annual cost is therefore approximately $629,297.

Estimates of the average burden hours and costs are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even representative survey or study of the costs of Commission rules and forms. Compliance with the collection of information requirements of the rule and form is mandatory only for those funds that rely on the rule in order to repurchase shares of the fund. The information provided to the Commission on Form N–23c–3 will not be kept confidential. 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 public may view the background documentation for this information collection at the following Web site, *www.reginfo.gov.* Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta_Ahmed@omb.eop.gov;* and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Comments must be submitted to OMB within 30 days of this notice.

Dated: July 28, 2015.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–18886 Filed 8–3–15; 08:45 am]

BILLING CODE 8011–01–P

the fund to state its registration number, its full name and address, the date of the accompanying shareholder notification, and the type of offer being made (periodic, discretionary, or both).

SMALL BUSINESS ADMINISTRATION

Announcement of 2016 InnovateHER: Innovating for Women Business Challenge

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: The U.S. Small Business Administration (SBA) is conducting the second year of the InnovateHER: Innovating for Women Challenge (the Challenge), pursuant to the America Competes Act, for entrepreneurs to create a product or service that has a measurable impact on the lives of women and families, has the potential for commercialization, and fills a need in the marketplace.

DATES: The Challenge launches on August 4, 2015. The initial round of the Challenge will take the form of local competitions that will be run across the country beginning August 5, 2015 and ending no later than December 2, 2015. The host organizations running the local competitions must select and submit one winner from each local competition to SBA, along with a Nomination package, no later than December 3, 2015. SBA will then select up to ten Finalists. The Top 3 Winners will be announced no later than March 17, 2016 following a live pitch competition.

FOR FURTHER INFORMATION CONTACT: Heather Young, Office of Entrepreneurial Development, U.S. Small Business Administration, 409 Third Street SW., 6th Floor, Washington, DC 20416, (202) 205–7430, *womenbusiness@sba.gov.*

SUPPLEMENTARY INFORMATION:

1. *Subject of Challenge Competition:* The SBA is looking for innovative products and services that help impact and empower the lives of women and families. We know that our workforce looks very different from 50 years ago. Women now make up nearly half of the labor force and play a critical role in our nation's economic prosperity. Most children live in households where all parents work. And as our population ages, families are increasingly caring for aging parents while balancing the needs of work and home. As the demands on women and families grow, the need for products and services that address these unique challenges increases. This

Challenge will provide a platform to fulfill that need.

Contestants must develop a product or service that meets the following competition criteria:

- Has a measurable impact on the lives of women and families (30%);
- Has the potential for commercialization (40%); and
- Fills a need in the marketplace (30%)

2. *Eligibility Rules for Participating in the Challenge:* This Challenge is open only to: (1) Citizens or permanent residents of the United States who are at least eighteen (18) years of age at the time of their submission of an entry (or teams of such individuals); and (2) private entities, such as corporations or other organizations, that are incorporated in and maintain a primary place of business in the United States. Individuals submitting on behalf of corporations, nonprofits, or groups of individuals (such as an academic class or other team) must meet the eligibility requirements for individual contestants. An individual may belong to more than one team submitting an entry in this Challenge. SBA employees are not eligible, nor are Federal entities or Federal employees acting within the scope of their employment. Individuals or organizations that are currently suspended or disbarred by the federal government are not eligible for this Challenge.

3. *Registration Process for Participants:* The Challenge launches on August 4, 2015. The initial round of the Challenge will take the form of local competitions that will be run across the country from August 5, 2015 and ending no later than December 2, 2015 by host organizations such as universities, accelerators, clusters, scale-up communities, and SBA Resource Partners. For more information regarding these local competitions as it becomes available, please visit *sba.gov/InnovateHER.* SBA will continue to update the list of local competitions as details are confirmed. While these local competitions will be identified as part of the national InnovateHER Challenge and will be conducted in a manner that is consistent with these Challenge rules, they will be administered solely by the local host organizations and will be judged by individuals selected by each host in their sole discretion. At a minimum, however, each application must contain a business plan covering the contestant's proposed product or service and must satisfy the Challenge criteria identified by SBA in this notice.

Following the completion of the local competitions, each host organization will identify one winner that will advance to the semi-final round of the Challenge. For a winning entry that has been submitted by a team of competitors, the host organization must list the team's self-identified project leader as the winner who will advance to the semi-final round. No later than December 3, 2015, each host organization will submit a nomination package containing the winning individual/team's business plan and other required information to SBA, which will administer the semi-final and final rounds of the Challenge. Selection as a semi-finalist following a local competition is the only means of registering for the Challenge. All nominations will be screened by SBA for eligibility. Contestants cannot submit entries directly to SBA.

4. *Prize for Winners:* Cash prizes totaling $70,000 will be awarded to the three highest-rated contestants in the final round of the competition in the following amounts:

- 1st Place—$40,000
- 2nd Place—$20,000
- 3rd Place—$10,000

For winning entries submitted by teams of competitors, prize money will be awarded to the self-identified project leader for distribution to the rest of the team at their discretion and independently from SBA.

5. *Process for Host Organizations:*

Initial Round—Local Competitions. Organizations that wish to host a local competition as part of the initial round of this Challenge must send a request to the SBA at *womenbusiness@sba.gov* no later than September 3, 2015 with the following information:

- The organization's official legal name, street address, city, state;
- Web site of the organization (if applicable);
- The name of the organization's designated Point Of Contact (POC) for the competition, his/her email address, and phone number.

SBA will evaluate all requests to host a local InnovateHER competition in its sole discretion and will confirm a host's participation in writing. Additionally, with some exceptions, organizations that wish to host an InnovateHER competition will be required to agree to the terms of a Co-sponsorship Agreement with the SBA that defines the scope of the relationship for the purposes of InnovateHER and outlines the co-promotion and marketing terms. SBA will notify prospective hosts if such agreement is required. SBA will reject any nomination package submitted to the SBA by an organization that has not been officially confirmed by SBA to participate in the InnovateHER Challenge.

Additionally, each host organization will determine the type of local competition, conducted in a manner that is consistent with these Challenge Rules, that will best identify the most innovative and entrepreneurial business ideas, including the type of application that individuals need to prepare in order to compete, and will publicize the competition locally. Host organizations should also notify SBA of the date and location of the local competitions for the purposes of publication at *sba.gov/InnovateHER.*

Semi-Final Round—Submission of Local Winners. No later than December 3, 2015, host organizations must select and submit one winner from the local competition along with a Nomination Package to SBA through the *www.Challenge.gov* Web site. The Nomination Package must contain all of the following items:

(a) A single cover page detailing—

(i) The Name of the winning individual (in the case of a winning team, please provide the name of the team's self-identified project lead); Company name (if applicable); Product/Service Name; Company Address, City, State, and Place of Incorporation (if applicable); Product/Service Web site (if applicable); telephone number of winning individual; and his/her email address;

(ii) The host organization's official legal name, street address, city, state, designated POC, and his/her best contact number and email address (*Note:* this information must match the information provided by the organization as part of its request to SBA to host a local competition);

(iii) A concise, two-sentence description of the product or service (*Note:* this description may also be also in promotional or informational materials in connection with InnovateHER).

(b) A Business Plan from the winning individual/team (maximum length: 20 pages, including attachments).

(c) A signed Statement of Support prepared by the host organization that explains why the winner of the local competition best satisfied the competition criteria and presented the greatest potential for success (maximum length: 2 pages).

Each host organization is responsible for preparing the complete Nomination Package, including obtaining a copy of the relevant Business Plan from the winner and ensuring that the full package is timely submitted to the SBA via the *www.Challenge.gov* Web site.

6. *Selection of Winners.*

Semi-Final Round. In the semi-final round of the Challenge, SBA will review

the semi-finalist nomination packages submitted by the local competition host organizations and select up to 10 finalists whose products or services, in SBA's sole judgment, best satisfy the competition criteria identified in Paragraph 1 of this Challenge announcement and present the greatest potential for success. In addition, in order to achieve nationwide distribution of prizes for the purpose of stimulating the growth and development of new products and services across the entire United States and across a diverse range of project types, SBA may take into account nominees' geographic locations when selecting winners, including support to geographic regions that traditionally have limited access to capital, as well as diversity in the types of products and services. Finalists selected by SBA will be required to sign a form certifying that they meet the eligibility requirements identified in Paragraph 2 above and have complied with these Challenge Rules.

Final Round. Each finalist will be offered the opportunity to participate in the InnovateHER Final Challenge to be held on March 17, 2016 in the Washington, DC metro area where they will make a live marketing pitch to a panel of expert judges drawn from the private sector. The panel of judges will select the three finalists whose pitches, in their sole judgment, best satisfy the competition criteria and present the greatest potential for success and rank them in descending order. Finalists will be responsible for covering their own travel costs for the national competition.

7. *Applicable Law:* This Challenge is being conducted by SBA pursuant to the America Competes Act (15 U.S.C. 3719) and is subject to all applicable federal laws and regulations. By participating in this Challenge, each contestant gives its full and unconditional agreement to the Official Rules and the related administrative decisions described in this notice, which are final and binding in all matters related to the Challenge. A contestant's eligibility for a prize award is contingent upon their fulfilling all requirements identified in this notice. Publication of this notice is not an obligation of funds on the part of SBA. All prize monies are funded through private sector sources. The private sector source is liable to the winners for payment of the prize. SBA, however, will coordinate with the private sector source regarding instructions for award of the prize purse. SBA reserves the right to modify or cancel this Challenge, in whole or in part, at any time prior to the award of prizes.

8. *Conflicts of Interest:* No individual acting as a judge at any stage of this Challenge may have personal or financial interests in, or be an employee, officer, director, or agent of any contestant or have a familial or financial relationship with a contestant.

9. *Intellectual Property Rights:* All entries submitted in response to this Challenge will remain the sole intellectual property of the individuals or organizations that developed them. By registering and entering a submission, each contestant represents and warrants that it is the sole author and copyright owner of the submission, and that the submission is an original work of the contestant, or if the submission is a work based on an existing application, that the contestant has acquired sufficient rights to use and to authorize others to use the submission, and that the submission does not infringe upon any copyright or upon any other third party rights of which the contestant is aware.

10. *Publicity Rights:* By registering and entering a submission, each contestant consents to SBA's and its agents' use, in perpetuity, of its name, likeness, photograph, voice, opinions, and/or hometown and state information for promotional or informational purposes through any form of media, worldwide, without further payment or consideration.

11. *Liability and Insurance Requirements:* By registering and entering a submission, each contestant agrees to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from their participation in this Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise. By registering and entering a submission, each contestant further represents and warrants that it possesses sufficient liability insurance or financial resources to cover claims by a third party for death, bodily injury, or property damage or loss resulting from any activity it carries out in connection with its participation in this Challenge, or claims by the Federal Government for damage or loss to Government property resulting from such an activity. Contest winners should be prepared to demonstrate proof of insurance or financial responsibility in the event SBA deems it necessary.

12. *Record Retention and Disclosure:* All nomination packages and related materials provided to SBA in the semi-final and final rounds of the Challenge automatically become SBA records and cannot be returned. Contestants should identify any confidential commercial information contained in their entries at the time of their submission to the local Host Organization. SBA will notify contestants of any Freedom of Information Act requests the Agency receives related to their submissions in accordance with 13 CFR part 102.

Award Approving Official: Erin Andrew, Assistant Administrator, Office of Women's Business Ownership, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416.

Erin Andrew,

Assistant Administrator, Office of Women's Business Ownership.

[FR Doc. 2015–18708 Filed 8–3–15; 8:45 a.m.]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 9211]

30-Day Notice of Proposed Information Collection: Risk Analysis and Management (RAM)

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 30 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to September 3, 2015.

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

- *Web:* Persons with access to the Internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2015–0036'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: FARRELLLM1@state.gov.*
- *Regular Mail:* Send written comments to: U.S. Department of State, Office of Risk Analysis and Management, 2201 C St. NW., Washington, DC 20520.
- *Fax:* 202–647–7082.
- *Hand Delivery or Courier:* U.S. Department of State, Office of Risk

Analysis and Management, 2201 C St. NW., Washington, DC 20520.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Lisa M. Farrell, US Department of State, Office of Risk Analysis and Management, 2201 C Street NW., Washington, DC 20520; who may be reached on 202–647–6020 or at *FARRELLLM1@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Risk Analysis and Management.
- *OMB Control Number:* 1405–0204.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Bureau of Administration, Office of Logistics Management (A/LM).
- *Form Number:* DS–4184.
- *Respondents:* Potential Contractors and Grantees.
- *Estimated Number of Respondents:* 850.
- *Estimated Number of Responses:* 850.
- *Average Time per Response:* 75 minutes.
- *Total Estimated Burden Time:* 1008 hours.
- *Frequency:* On occasion.
- *Obligation to Respond:* Voluntary.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of proposed collection: The information collected from individuals and organizations is specifically used to conduct screening to ensure that State funded activities do not provide support to entities or individuals deemed to be a risk to national security.

Methodology: The State Department has implemented a Risk Analysis and Management Program to vet potential contractors and grantees seeking funding from the Department of State to mitigate the risk that such funds might benefit entities or individuals who present a national security risk. To conduct this vetting program the Department collects information from contractors, sub-contractors, grantees and sub-grantees regarding their directors, officers and/or key employees through mail, fax or electronic submission. The Department published a 30-day notice on April 23, 2015 (80 FR 22764). The Department is publishing this additional notice to announce our intent to collect additional information from former civilian government and military officials of the current Syria regime. Concerns have been raised regarding the possibility of the United States Government inadvertently funding individuals guilty of human rights abuses. The questions we plan to add to the information collection are necessary to help identify the activities and former affiliations of these individuals. The information collected is compared to information gathered from commercial, public, and U.S. government databases to determine the risk that the applying organization, entity or individual might use Department funds or programs in a way that presents a threat to national security. This program will continue as a pilot program as directed by Congress in the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2015 (Div. J, Pub. L. 113–235).

Dated: July 17, 2015.

Catherine I. Ebert-Gray,

Deputy Assistant Secretary, Bureau of Administration, Department of State.

[FR Doc. 2015–19098 Filed 8–3–15; 8:45 am]

BILLING CODE 4710–24–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Release of Airport Property at Upper Cumberland Regional Airport, Sparta, Tennessee

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Request for Public Comment.

SUMMARY: The Federal Aviation Administration is requesting public comment on a request by the Upper Cumberland Regional Airport, Sparta, TN, to release land at the Upper Cumberland Regional Airport. The request consists of approximately 10.3 acres of property non-contiguous to the airport located on Breeding Swamp Road approximately 3 miles southeast of the airport and 36.84 acres of property non-contiguous to the airport on Franks Ferry Road approximately 13 miles southwest of the airport. This release will allow the property to be sold to serve as wetland mitigation for a projects unrelated to the airport. This action is taken under the provisions of Section 125 of the Wendell H. Ford Aviation Investment Reform Act for the 21st Century (AIR 21).

DATES: Comments must be received on or before September 3, 2015.

ADDRESSES: Documents are available for review at the Upper Cumberland Regional Airport, 750 Airport Road, Sparta, TN 38583; and the FAA Memphis Airports District Office, 2600 Thousand Oaks Boulevard, Suite 2250, Memphis, TN 38118–2482. Written comments on the Sponsor's request must be delivered or mailed to: Mr. Phillip J. Braden, Manager, Memphis Airports District Office, 2600 Thousand Oaks Boulevard, Suite 2250, Memphis, TN 38118–2482. Mr. Braden can be contacted at telephone number 901–322–8181.

In addition, a copy of any comments submitted to the FAA must be mailed or delivered to Mr. Jason Baker, Airport Manager at Upper Cumberland Regional Airport, 750 Airport Road, Sparta, TN 38583. Mr. Baker can be contacted at 931–739–7000.

FOR FURTHER INFORMATION CONTACT: Mr. Michael L. Thompson, Program Manager, Federal Aviation Administration, Memphis Airports District Office, 2600, Thousand Oaks Boulevard, Suite 2250, Memphis, TN 38118–2482. The application may be reviewed in person at this same location, by appointment. Mr. Thompson can be contacted at 901–322–8188.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the request to release airport property at the Upper Cumberland Regional Airport, Sparta, TN under the provisions of AIR 21(49 U.S.C. 47107(h)(2)).

On July 28, 2015, the FAA determined that the request to release property at Upper Cumberland Regional Airport meets the procedural requirements of the Federal Aviation Administration. The FAA may approve the request, in

whole or in part, no later September 3, 2015.

The following is a brief overview of the request:

The Upper Cumberland Regional Airport is proposing the release of two tracts of property consisting of 10.33 acres and 36.84 acres to allow the property to be used as wetland mitigation for projects in the area unrelated to the airport. These properties are non-contiguous to the airport and located on Breeding Swamp Road approximately 3 miles southeast of the airport and Franks Ferry Road approximately 13 miles southwest of the airport.

Any person may inspect, by appointment, the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**.

Issued in Memphis, TN on July 28, 2015.

Phillip J. Braden,

Manager, Memphis Airports District Office.

[FR Doc. 2015–19141 Filed 8–3–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2015–2836]

Guidance on the Procedures and Process To Petition the Secretary Under the Airport and Airways Improvement Act

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The Federal Aviation Administration (FAA) is issuing guidance on the procedures and process to petition the Secretary under 49 U.S.C. 47106(c)(1)(A)(ii) of the Airport and Airways Improvement Act of 1982, as amended. Although this provision has been in effect since 1992, the FAA did not receive the first petition under this provision until 2010. This guidance is intended to provide detail and clarity about who may petition the Secretary, when such a petition may be filed, how the petition may be made, and the procedures and process to petition the Secretary under this Section of the Airport and Airways Improvement Act.

DATES: Written comments must be received on or before October 5, 2015.

ADDRESSES: Send comments identified by docket number FAA–2015–2836 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations 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.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://www.regulations.gov,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations 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: Ms. Daphne Fuller, Assistant Chief Counsel. Mailing address: Federal Aviation Administration, 800 Independence Ave. SW., Washington, DC 20591. Telephone: (202) 267–3199. Email address: *Daphne.Fuller@faa.gov*

SUPPLEMENTARY INFORMATION: FAA requests comments, suggestions and recommendations that will assist the agency in assessing and understanding the potential effects and implications of providing guidance on the procedures for and process of the right to petition the Secretary under 49 U.S.C. Section 47106(c)(1)(A)(ii).

I. Background

In 1982, Congress enacted the Airport and Airway Improvement Act (AAIA) (Pub. L. 97–248). Relevant portions of the AAIA are codified in 49 U.S.C. Chapter 471, Subchapter I, Airport Improvement. The AAIA, among other items, established the current-day Airport Improvement Program (AIP) that is administered by the FAA's Office of Airports. Through the AIP, the FAA provides grants to public agencies — and, in limited cases, to private airport owners and operators—for the planning and development of public-use airports that are included in the National Plan of Integrated Airport Systems (NPIAS). The current AIP program built on earlier grant programs that are funded through a variety of user fees and fuel taxes. For more information on the history of the AIP and predecessor grant programs, see *http://www.faa.gov/airports/aip/.*

The AAIA also provides certain prerequisites and conditions that an airport sponsor must meet in order to be eligible for consideration of AIP funding. In 1992, Congress amended various provisions of the AAIA with the Airport and Airway Safety, Capacity, Noise Improvement, and Intermodal Transportation Act, Pub. L. 102–581. Section 113(b), Public Access and Participation with Respect to Airport Projects, amended Section 509(b)(6)(A) of the AAIA (49 U.S.C. 47106(c)(1)(A)) by inserting the following:

> (ii) the sponsor of the project certifies to the Secretary that the airport management board either has voting representation from the communities where the project is located or has advised the communities that they have the right to petition the Secretary concerning a proposed project.

The Secretary of the U.S. Department of Transportation has delegated the responsibility to respond to a petition under Section 47106 to the Administrator of the FAA, 49 CFR 1.83(a)(9). The Administrator has further delegated the authority to administer this provision to the Associate Administrator for the Office of Airports (ARP–1). Order 1100.154A.[1] The requirement for a sponsor to provide such certification to the FAA is incorporated into FAA Order 5050.4B, National Environmental Policy Act (NEPA) Implementing Instructions for Airport Actions, par. 1203.

II. Purpose

After receiving a small number of submissions under this provision, the Associate Administrator for the Office of Airports has determined it would be helpful and appropriate to provide the public with more guidance on the procedures and processes associated with this provision:

> The Secretary may approve an application under this subchapter for an airport development project involving the location of an airport or runway or a major runway extension only if the sponsor certifies to the Secretary that the airport management board

[1] For clarity, this guidance will continue to use the term ''Secretary'' in this context.

has voting representation from the communities in which the project is located or has advised the communities that they have the right to petition the Secretary about a proposed project[.]

49 U.S.C. Section 47106(c)(1)(A)(ii).[2]

III. Proposed Guidance

A. Where To File

The Secretary of the U.S. Department of Transportation has delegated the responsibility to respond to a petition under Section 47106 to the Administrator of the FAA. Accordingly, any petition under this statutory provision should be addressed to the Associate Administrator for the Office of Airports, 800 Independence Avenue SW., Washington, DC 20591.

B. Form and Substance

The statute does not prescribe any specific format prescribed for the submission of a petition. The petition should be a concise statement describing the project to which the petitioner objects, and clearly indicating the petitioner's specific objection to the project. The petition must also include a description of the result the petitioner is seeking. The petition should normally not exceed ten (10) pages. Upon application from the petitioner, the Administrator will consider extending the length of a petition for a large, complex project. Petitions must be legible and must be signed by the petitioner(s), who must be a duly authorized representative(s) of the community (see Section III.D.4 of this **Federal Register** notice). The FAA will not consider any petition that is not signed by the petitioner(s).

C. Time To File a Petition

A petition filed under section 47106(c)(1)(A)(ii) should be filed only after the Airport Sponsor notifies a community of its right to file a petition.

Petitions to the Secretary pursuant to Section 47106(c)(1)(A)(ii) must be submitted within thirty (30) days after the FAA gives notice that the sponsor has presented evidence that the requirements of Section 47106(c)(1)(A)(ii) have been fulfilled. Although the environmental analysis and the grant decisions are separate processes and decision, grant-related findings that are preconditions of issuing a grant are often made in the environmental ROD. Typically, the FAA demonstrates that the sponsor has satisfied the requirements of Section 47106(c)(1)(A)(ii) in its Final Environmental Impact Statement (FEIS). Generally, the FEIS will contain a certification from the Airport Sponsor either that each community in which the project is located has a voting member on its airport management board, or that each community in which the project is located has been advised of its right to petition the Secretary. Normally the Airport Sponsor will have notified each of the communities prior to the publication of an FEIS, allowing communities at least 30 days to prepare and file a petition.[3] The thirty-day time to file ensures that communities without voting representation on the airport management board have the same ability to object to or provide input on a project prior to a final decision that grant-related preconditions have been met as those communities that do have voting representation on the airport management board. Additionally, the 30-day period coincides with the Council on Environmental Quality's (CEQ) requirement that imposes a 30-day ''cooling off'' period on federal agencies between the publication of an FEIS and a Record of Decision (ROD). However, the FAA may also provide notice that the sponsor has fulfilled the requirements of Section 47106(c)(1)(A)(ii) through a Draft EA, a Final EA, a Draft EIS, or via a separate **Federal Register** Notice. This type of FAA notice would also start the 30-day time limit for a community to file a petition pursuant to Section 47106(c)(1)(A)(ii).

D. Definitions

(1) Location of an Airport

For purposes of Section 47106(c)(1)(A)(ii), location of an airport means approval of an airport at a location where no airport exists. This definition is consistent with the definition of the term airport location approval found in FAA Order 5050.4B, National Environmental Policy Act (NEPA) Implementing Instructions for Airport Actions (April 2006). Order 5050.4B defines airport location approval as approval of a new public use airport at a location where no airport exists. (Order 5050.4B, ¶¶ 9.p and 203). In interpreting Section 47106(c)(1)(A)(ii), it is appropriate to be consistent with other FAA interpretations of similar terms. Defining the term location of an airport consistently with the definition in the most current version of Order 5050.4B avoids confusion that could be caused by applying different definitions depending on the circumstances of the inquiry.

(2) Location of a Runway

While other FAA documents have referred to the location of a runway, none have defined the term. Because the term is similar to the term ''location of an airport,'' it is appropriate to define the terms in a similar manner. For purposes of Section 47106(c)(1)(A)(ii), location of a runway refers to decisions approving the site of a new or relocated runway where a runway does not currently exist.

(3) Major Runway Extension

Order 5050.4B defines a major runway extension as one that creates a significant impact to an affected environmental resource (including noise), or one that permanently removes a relocated threshold.[4] Removal of a dislocated threshold is not considered a runway extension.[5] The definition of major runway extension that appears in Order 5050.4B, ¶9.l will be used in interpreting Section 47106(c)(1)(A)(ii).

(4) Communities in Which the Project Is Located

The term community is not defined in the statute. In the enabling legislation, this provision was entitled ''Public Participation With Respect to Airport Projects.'' The term ''community'' will be defined as a jurisdictional authority, that is, a political subdivision of a state, such as a town, township, city, or county. Defining community as a jurisdictional authority is consistent with the context of Section 47106(c). For example, in subsection (A)(i) the statute speaks of ''objectives of any planning that the community has carried out.'' Typically, only political subdivisions of a state, such as those described above, would have planning authority. Similarly, in the FAA's experience, only a jurisdictional authority or political subdivision would be considered for voting representation on the airport's governing authority. It is only in the absence of such voting representation of a jurisdictional authority or political subdivision that

[2] As a starting point, the FAA notes that it is unable to locate any legislative history for Section 47106(c) that would be helpful in determining the Congressional intent with respect with requirements of the statute. In interpreting this section, the Secretary is guided by context and the common meaning of the terms as informed by his understanding of airports and the airport development process.

[3] Should the FAA prepare an Environmental Assessment (EA) for a project to which § 47106(c)(1)(A)(ii) applies, or an EIS under MAP–21, Section 1319, the time to file a petition to the Secretary will begin to run when the community is informed of its right to file such a petition by the airport sponsor and will expire 30 days after such notification.

[4] A relocated threshold leaves the pavement usable only for taxiing.

[5] Pavement beyond a dislocated threshold is available for takeoff.

the statute provides the opportunity to petition the Secretary.

Defining community as a jurisdictional authority or political subdivision is also consistent with the definition of community in Order 5050.4B, ¶1203(b)(1).

Accordingly, only a political subdivision of a state that enjoys general jurisdiction, or a Tribal government meets the definition of community in this context. Political subdivisions of a state that have a specific, substantive authority, such as water districts or school districts, do not adequately represent the interests of the community at large. They are not required to balance the interests of the whole community on a wide range of issues. Rather, they seek to promote their specific substantive interest. Additionally, water districts or school districts would not normally be invited to sit on an airport management board. Thus, only a political subdivision of a state which enjoys general jurisdiction is a community entitled to file a petition under Section 47106(c)(1)(A)(ii).

Finally, under the statute, a community is only eligible to petition under Section 47106(c)(1)(A)(ii) if the project is located in the community. If land is disturbed in the community, then the project is considered to be located in that community. The courts have also provided instruction on when a project is located in a community. In *City of Bridgeton* v. *FAA,* 212 F. 3d 448 (8th Cir. 2000), the court determined that a community in which there was no construction and no significant noise impact could not challenge the failure to notify it that it could petition the Secretary. Thus, outside the construction context, a project may be located in a community only if the project will have a significant impact on the community. For example, where a project will cause a significant noise impact on a community, the project is located in that community. If the project does not create a significant impact in the community, the community will have no right to petition the Secretary.

E. Other Considerations

There are currently ten states that participate in the FAA's State Block Grant Program (SBGP). Under the program, the State agency (usually the aviation division of the state Department of Transportation) assumes responsibility for administering AIP grants and if applicable, discretionary grants for non-primary airports. See 49 U.S.C. Section 47128. As part of the responsibility, the state assumes various responsibilities for the FAA including reviewing and approving proposed changes to the Airport Layout Plan (ALP) and compliance with the National Environmental Policy Act (NEPA).

The FAA interprets 49 U.S.C. Section 47106(c)(1)(A)(ii) as not being applicable to a project approved and administered as part of a state block grant. The plain language of this statutory provision states that this Section is triggered when a proponent submits a project grant application to the FAA. In the case of the SBGP, no such request is made as the funds are given to the states as a block and the state assumes responsibility for administering those funds. Participants in the SBGP are required to engage communities according to FAA guidance and to circulate the draft EA if warranted. Some who have sought to use this provision have argued that it should apply to State Block Grant projects. The FAA invites comments on this interpretation.

F. Agency Response

The FAA will provide a written response to a petition to the Secretary. The FAA may respond by outlining the issues raised in the petition and providing its responses either within the environmental record of decision, or it may elect to respond in a separate document.

Authority: 49 U.S.C. 47106(c)(1)(A)(ii), 14 CFR part 1.

Issued in Washington, DC, on July 29, 2015.

Elliott Black,

Director, Office of Airport Planning and Programming APP–001.

[FR Doc. 2015–19144 Filed 8–3–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Availability of the Record of Decision (ROD) for the Cal Black Memorial Airport, Halls Crossing Replacement Airport

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA, 42 U.S.C. 4321 *et seq.*) and Council on Environmental Quality regulations (40 CFR parts 1500–1508), the Federal Aviation Administration announces the availability of the Record of Decision for the Cal Black Memorial Airport, replacement airport for the Halls Crossing Airport.

ADDRESSES: Copies of the ROD may be viewed during regular business hours at the following locations:

1. Federal Aviation Administration Airports Division, Suite 315, 1601 Lind Avenue SW., Renton, WA 98057.

2. Federal Aviation Administration, Airports District Office, Suite 224, 26805 East 68th Avenue, Denver, CO 80249.

3. San Juan County Courthouse, County Executive Office, 117 S. Main, Monticello, Utah 84535.

The ROD will also be available on the following Web site: *http://halls.crossing.airportnetwork.com/.*

FOR FURTHER INFORMATION CONTACT: Janell Barrilleaux, Environmental Program Manager, Federal Aviation Administration Airports Division, Northwest Mountain Region, 1601 Lind Avenue SW., Renton, WA 98057. Mrs. Barrilleaux may be contacted during business hours at (425) 227–2611 (phone), (425) 227–1600 (fax), or via email at *Janell.Barrilleaux@faa.gov.*

SUPPLEMENTARY INFORMATION: The Halls Crossing replacement airport was originally proposed in 1966 due to the inadequacy of the existing Halls Crossing airstrip. After completion of numerous planning studies, the Federal Aviation Administration completed an Environmental Impact Statement (EIS) (June, 1990) with the cooperation of the National Park Service (NPS) and the Bureau of Land Management (BLM). A Record of Decision (ROD) was issued in August 1990 approving the development of what is now named the Cal Black Memorial Airport. Concurrently, the BLM approved an amendment of a land plan which allowed the conveyance of land to San Juan County for the construction of the new airport.

In 1990, the National Parks Conservation Association (NPCA),[1] et al.[2] brought suit concerning the adequacy of the 1990 Final EIS and the adequacy of the BLM plan amendment and land transfer process. In its July 7, 1993 decision, the U.S. Court of Appeals for the Tenth Circuit concluded that ''the action of FAA approving the project based on a finding of 'no significant impact' and 'no significant adverse impact' [was] arbitrary and capricious.'' The court proceeding stated:

[1] **Note:** The title of the organization as documented in the 1993 United States Court of Appeals case *National Parks Conservation Association, et al. v Federal Aviation Administration, et al.*

[2] Other parties to the suit included the Southern Utah Wilderness Alliance, the Sierra Club, and Deborah L. Threedy.

We therefore REVERSE the BLM's plan amendment and the transfer of land. We REMAND for further proceedings to determine whether the land should be retained under BLM control and management or reconveyed to San Juan County under a newly proposed land use plan amendment. In the case of the FAA, the airport has already been built. This does not mean that a remand would be meaningless, however. On remand, the FAA should re-analyze the impact of the airport under section 4(f) and section 2208.[3] The FAA may determine that it must make use of studies not utilized in the current FEIS. If a ''significant'' impact is found, section 4(f) and section 2208 require that all reasonable steps be taken to mitigate the damage or adverse impact. We therefore REVERSE the FAA's determination of no significant impact and REMAND to the FAA for further proceedings consistent with this decision.

In response to the court remand, FAA, in cooperation with BLM and NPS prepared a Supplemental EIS (SEIS).[4] The Draft SEIS for the Cal Black Memorial Airport (Replacement Airport for Halls Crossing Airport) was published on December 12, 2014. The 45-day comment period included an opportunity to request a public hearing; however, no responses were received requesting a hearing. The following parties submitted comments to the FAA on the Draft SEIS during the comment period: U.S. Department of the Interior, U.S. Environmental Protection Agency, BLM, and the NPCA. An errata sheet was drafted to identify changes that were made to the Draft SEIS in response to comments received. Additionally, an appendix was added (Appendix J) to document each comment received, and FAA's response to each comment. These additional documents, in combination with a CD containing the Draft SEIS, constitute the Final SEIS for the Replacement Airport at Halls Crossing. The Final SEIS for the Cal Black Memorial Airport (replacement airport for the Halls Crossing Airport) was published on May 8, 2015.

The SEIS described potential environmental consequences that could result from the continued operation of the Cal Black Memorial Airport to resources located within the Project Area. Direct effects of the new airport (its construction) as well as indirect effects (airport operations) were identified in the 1990 FEIS. The SEIS provided further evaluation of actual and potential aircraft noise impacts, as well as Section 4(f) impacts and cumulative impacts. Evaluation of noise impacts focused exclusively on the effect of aircraft noise on GCNRA and surrounding lands. Chapter III, Environmental Consequences, presents the analysis for noise impacts, Section 4(f) impacts, and Cumulative Effects resulting from the operation of the Cal Black Memorial Airport.

The FAA has determined, based on the noise analysis conducted for the SEIS that as there are no significant impacts related to the continued operation of the Cal Black Memorial Airport, there is no need for any mitigation measures under either Section 4(f) or Section 2208.

In addition, the FAA has confirmed that the ROD for the 1990 EIS included the FAA determinations made for the project based upon evidence set forth in the FEIS, public input, and the supporting administrative record. These determinations are not changed by any new information developed for this SEIS.

Issued in Renton, Washington, July 28, 2015.

Stanley C. Allison,

Acting Division Manager, Airports Division, Northwest Mountain Region.

[FR Doc. 2015–19145 Filed 8–3–15; 8:45 am]

BILLING CODE 4910–13–P

[3] **Note:** In 1994, the provisions of the Airport and Airway Improvement Act of 1982 were codified in U.S. Code Title 49, chapter 471, subchapter I.

[4] BLM addressed its requirements through its revisions to their Resource Management Plan in 2008. Bureau of Land Management Monticello Field Office, *Record of Decision and Approved Resource Management Plan* (November 2008).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Request To Release Property at the Morgantown Municipal Airport, Morgantown, WV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of request to release airport property.

SUMMARY: The FAA proposes to rule and invite public comment on the land release at the Morgantown Municipal Airport, Morgantown, WV, under the provision 49 U.S.C. 47125(a).

DATES: Comments must be received on or before September 3, 2015.

ADDRESSES: Comments on this application may be mailed or delivered to the following address: Glen Kelly, Assistant City Manager, City of Morgantown, Sponsor for Morgantown Municipal Airport, 389 Spruce Street, Morgantown, WV, 304–291–7461, and at the FAA Beckley Airports Field Office: Matthew DiGiulian, Manager, Beckley Airports Field Office, 176 Airport Circle, Room 101, Beaver, WV 25813, (304) 252–6216.

FOR FURTHER INFORMATION CONTACT: Connie Boley-Lilly, Airports Program Specialist, Beckley Airports Field Office, location listed above.

The request to release airport property may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release property at the Morgantown Municipal Airport under the provisions of Section 47125(a) of Title 49 U.S.C. On July 21, 2015, the FAA determined that the request to release property at the Morgantown Municipal Airport (MGW), WV, submitted by the City of Morgantown, Sponsor for the Morgantown Municipal Airport, met the procedural requirements.

The following is a brief overview of the request:

The Morgantown Municipal Airport is proposing the release of approximately 95.70 acres of fee simple release to permit the transfer of such Property to the Monongalia County Development Authority (''MCDA''). Thereafter, ''MCDA'' will construct, or cause the construction, and operate, or cause the operation, of a Business Park on the Property. The Property to which this request relates is not a viral part of, or necessary for, the Sponsor's operation and development of Morgantown Municipal Airport (MGW). Therefore, it has been determined by the Sponsor that the most productive use of the Property is commercial development subsequent to its transfer to the ''MCDA''. The development of the Property demonstrates that significant private investment can occur at MGW and shall serve to establish quality standards for future investments. The release and transfer of this property will allow the Sponsor to develop the roadway and utilities which will benefit this property, the hangar site, and the landside development site. This release will enhance the development of private aviation and commercial development of the east side of the airport.

Issued in Beckley, West Virginia, on July 16, 2015.

Matthew P. DiGiulian,

Manager, Beckley Airport Field Office, Eastern Region.

Any person may inspect the request by appointment at the FAA office address listed above. Interested persons are invited to comment on the proposed lease. All comments will be considered by the FAA to the extent practicable.

Issued in Beaver, West Virginia, July 21, 2015.

Matthew DiGiulian,

Manager, Beckley Airports Field Office.

[FR Doc. 2015–18596 Filed 8–3–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Receipt of Noise Compatibility Program and Request for Review; Laughlin/Bullhead International Airport, Bullhead City, Arizona

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces that it is reviewing a proposed noise compatibility program that was submitted for Laughlin/Bullhead International Airport under the provisions of Title 49 United States Code, Section 47501 *et seq.* (the Aviation Safety and Noise Abatement Act, hereinafter referred to as ''the Act'') and 14 Code of Federal Regulations (CFR) Part 150 by the Mohave County Airport Authority. This program was submitted subsequent to a determination by FAA that associated noise exposure maps submitted under 14 CFR part 150 for Laughlin/Bullhead International Airport were in compliance with applicable requirements, effective November 21, 2013 (**Federal Register** Volume 78, No. 230, 11–29–2013). The proposed noise compatibility program will be approved or disapproved on or before January 18, 2016.

DATES: *Effective Date:* This notice is effective August 4, 2015 and is applicable beginning July 23, 2015. The public comment period ends September 21, 2015.

FOR FURTHER INFORMATION CONTACT: Jared M. Raymond, Airport Planner, Phoenix Airports District Office, Phoenix, Arizona, (602) 792–1072. Comments on the proposed noise compatibility program should also be submitted to the above office.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA is reviewing a proposed noise compatibility program for Laughlin/Bullhead International Airport which will be approved or disapproved on or before January 18, 2016. This notice also announces the availability of this program for public review and comment.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) Part 150, promulgated pursuant to the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes to reduce existing non-compatible uses and prevent the introduction of additional non-compatible uses.

The FAA has formally received the noise compatibility program for Laughlin/Bullhead International Airport, effective on July 23, 2015. The airport operator has requested that the FAA review this material and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a noise compatibility program under section 47504 of the Act. Preliminary review of the submitted material indicates that it conforms to FAR Part 150 requirements for the submittal of noise compatibility programs, but that further review will be necessary prior to approval or disapproval of the program. The formal review period, limited by law to a maximum of 180 days, will be completed on or before January 18, 2016.

The FAA's detailed evaluation will be conducted under the provisions of 14 CFR part 150, Section 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety or create an undue burden on interstate or foreign commerce, and whether they are reasonably consistent with obtaining the goal of reducing existing non-compatible land uses and preventing the introduction of additional non-compatible land uses.

Interested persons are invited to comment on the proposed program with specific reference to these factors. All comments relating to these factors, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Copies of the noise exposure maps and the proposed noise compatibility program are available for examination at the following locations during normal business hours:

Federal Aviation Administration, Western Pacific Region, Airports Division, Room 3012, 15000 Aviation Boulevard, Hawthorne, California, 90261

Federal Aviation Administration, Phoenix Airports District Office, 3800 N. Central Ave., Suite 1025, Phoenix, Arizona 85012

Laughlin/Bullhead International Airport, 2250 Laughlin View Drive, Bullhead City, Arizona 86429

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT**.

Issued in Hawthorne, California, on July 23, 2015.

Mark A. McClardy,

Manager, Airports Division, AWP–600, Western-Pacific Region.

[FR Doc. 2015–19142 Filed 8–3–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Buy America Waiver Notification

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice provides information regarding FHWA's finding that a Buy America waiver is appropriate for the obligation of Federal-aid funds for 57 State projects involving the acquisition of vehicles and equipment on the condition that they be assembled in the U.S.

DATES: The effective date of the waiver is August 5, 2015.

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Mr. Gerald Yakowenko, FHWA Office of Program Administration, 202–366–1562, or via email at *gerald.yakowenko@dot.gov*. For legal questions, please contact Mr. Jomar Maldonado, FHWA Office of the Chief Counsel, 202–366–1373, or via email at *jomar.maldonado@dot.gov*. Office hours for the FHWA are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded from the **Federal Register**'s home page at *http://www.archives.gov* and the Government Publishing Office's database at *http://www.access.gpo.gov/nara.*

Background

This notice provides information regarding FHWA's finding that a Buy America waiver is appropriate for the obligation of Federal-aid funds for 57 State projects involving the acquisition of vehicles (including sedans, vans, pickups, trucks, buses, and street sweepers) and equipment (such as Bridge snooper truck and trail grooming equipment) on the condition that they be assembled in the U.S. The waiver would apply to approximately 349 vehicles. The requests, available at *http://www.fhwa.dot.gov/construction/contracts/cmaq150611.cfm,* are

incorporated by reference into this notice. These projects are being undertaken to implement air quality improvement, safety, and mobility goals under FHWA's Congestion Mitigation and Air Quality Improvement Program; National Bridge and Tunnel Inventory and Inspection Program; and the Recreational Trails Program.

Title 23, Code of Federal Regulations, section 635.410 requires that steel or iron materials (including protective coatings) that will be permanently incorporated in a Federal-aid project must be manufactured in the U.S. For FHWA, this means that all the processes that modified the chemical content, physical shape or size, or final finish of the material (from initial melting and mixing, continuing through the bending and coating) occurred in the U.S. The statute and regulations create a process for granting waivers from the Buy America requirements when its application would be inconsistent with the public interest or when satisfactory quality domestic steel and iron products are not sufficiently available. In 1983, FHWA determined that it was both in the public interest and consistent with the legislative intent to waive Buy America for manufactured products other than steel manufactured products. However, FHWA's national waiver for manufactured products does not apply to the requests in this notice because they involve predominately steel and iron manufactured products. The FHWA's Buy America requirements do not have special provisions for applying Buy America to ''rolling stock'' such as vehicles or vehicle components (see 49 U.S.C. 5323(j)(2)(C), 49 CFR 661.11, and 49 U.S.C. 24405(a)(2)(C) for examples of Buy America rolling stock provisions for other DOT agencies).

Based on all the information available to the agency, FHWA concludes that there are no domestic manufacturers that produce the vehicles and vehicle components identified in this notice in such a way that their steel and iron elements are manufactured domestically. The FHWA's Buy America requirements were tailored to the types of products that are typically used in highway construction, which generally meet the requirement that steel and iron materials be manufactured domestically. In today's global industry, vehicles are assembled with iron and steel components that are manufactured all over the world. The FHWA is not aware of any domestically produced vehicle on the market that meets FHWA's Buy America requirement to have all its iron and steel be manufactured exclusively in the U.S. For example, the Chevrolet Volt, which was identified by many commenters in a November 21, 2011, **Federal Register** Notice (76 FR 72027) as a car that is made in the U.S., is comprised of only 45 percent of U.S. and Canadian content according to the National Highway Traffic Safety Administration's Part 583 American Automobile Labeling Act Report Web page *(http://www.nhtsa.gov/Laws+&+Regulations/Part+583+American+Automobile+Labeling+Act+(AALA)+Reports*). Moreover, there is no indication of how much of this 45 percent content is U.S.-manufactured (from initial melting and mixing) iron and steel content.

In accordance with Division K, section 122 of the ''Consolidated and Further Continuing Appropriations Act, 2015'' (Pub. L. 113–235), FHWA published a notice of intent to issue a waiver on its Web site at *http://www.fhwa.dot.gov/construction/contracts/waivers.cfm?id=108* on une 12, 2015. The FHWA received five comments in response to the publication. All commenters expressed support for granting the waiver with suggestions. Richard Chaput suggested that the waiver should be limited and only granted when there is no comparable product in America to justify a waiver. Allen W. Miller supports the waiver but suggested that the only long term solution would be for the U.S. to reinvigorate manufacturing through incentive; as well as the U.S. workforce being re-educated which will require the act of Congress. The Puget Sound Clean Air Agency, Port of Seattle and Port of Tacoma support granting the waiver based on the efficiency and benefits of CMAQ programs. The Puget Sound Clean Air Agency strongly urges issuance of this waiver request to enable them to continue reduction of toxic diesel emissions from trucks serving the Port of Seattle and the Port of Tacoma and also reduce exposure to such toxics for area residents.

Based on FHWA's conclusion that there are no domestic manufacturers that can produce the vehicles and equipment identified in this notice in such a way that steel and iron materials are manufactured domestically, and after consideration of the comments received, FHWA finds that application of FHWA's Buy America requirements to these products is inconsistent with the public interest (23 U.S.C. 313(b)(1) and 23 CFR 635.410(c)(2)(i)). However, FHWA believes that it is in the public interest and consistent with the Buy America requirements to impose the condition that the vehicles and the vehicle components be assembled in the U.S. Requiring final assembly to be performed in the U.S. is consistent with past guidance to FHWA Division Offices on manufactured products (see Memorandum on Buy America Policy Response, Dec. 22, 1997, *http://www.fhwa.dot.gov/programadmin/contracts/122297.cfm*). A waiver of the Buy America requirement without any regard to where the vehicle is assembled would diminish the purpose of the Buy America requirement. Moreover, in today's economic environment, the Buy America requirement is especially significant in that it will ensure that Federal Highway Trust Fund dollars are used to support and create jobs in the U.S. This approach is similar to the conditional waivers previously given for various vehicle projects. Thus, so long as the final assembly of the 57 State projects occurs in the U.S., applicants to this waiver request may proceed to purchase these vehicles and equipment consistent with the Buy America requirement.

In accordance with the provisions of section 117 of the ''Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users, Technical Corrections Act of 2008'' (Pub. L. 110–244), FHWA is providing this notice of its finding that a public interest waiver of Buy America requirements is appropriate on the condition that the vehicles and equipment identified in the notice be assembled in the U.S. The FHWA invites public comment on this finding for an additional 15 days following the effective date of the finding. Comments may be submitted to FHWA's Web site via the link provided to the waiver page noted above.

Authority: 23 U.S.C. 313; Pub. L. 110–161, 23 CFR 635.410.

Issued on: July 28, 2015.

Gregory G. Nadeau,

Acting Administrator, Federal Highway Administration.

[FR Doc. 2015–19137 Filed 8–3–15; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2015–0070]

Petition for Waiver of Compliance

In accordance with part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated June 24, 2015, Florida East Coast Railway (FECR) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part

240–Qualification and Certification of Locomotive Engineers, and Part 242–Qualification and Certification of Conductors. The relief is contingent on FECR's implementation of and participation in the Confidential Close Call Reporting System (C^3RS) pilot project. FRA assigned the petition Docket Number FRA–2015–0070.

FECR seeks to shield reporting employees and the railroad from mandatory punitive sanctions that would otherwise arise as provided in 49 CFR 240.117(e)(1)–(4); 240.305(a)(l)–(4) and (a)(6); 240.307; 242.403(b), (c), (e)(l)–(4), (e)(6)–(11), (f)(l)–(2); and 242.407. The C^3RS pilot project encourages certified operating crew members to report close calls and protects employees and the railroad from discipline or sanctions arising from the incidents reported per the C^3RS Implementing Memorandum of Understanding.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by September 18, 2015 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov.

Issued in Washington, DC, on July 29, 2015.

Ron Hynes,

Director, Office of Technical Oversight.

[FR Doc. 2015–19086 Filed 8–3–15; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

July 30, 2015.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before September 3, 2015 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestion for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.GOV* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at *PRA@treasury.gov*.

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927–5331, email at *PRA@treasury.gov,* or the entire information collection request maybe found at *www.reginfo.gov*.

Departmental Offices (DO)

OMB Number: 1505–XXXX.
Type of Review: New Clearance.
Title: Ramp It Up Survey.
Abstract: This Treasury-funded research will be the first evaluation of the Ramp It Up app. The primary goal of the 500-person evaluation is to assess the tool's impact on students' mental models about their ability to attend and finance higher education. The evaluation will examine changes in students' confidence in their choices related to college financing, knowledge of college financial tools and concepts, and decision-making skills related to college financing.
Affected Public: Individuals.
Estimated Total Burden Hours: 2.

Robert Dahl,

Treasury PRA Clearance Officer.

[FR Doc. 2015–19052 Filed 8–3–15; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Disability Compensation, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the Advisory Committee on Disability Compensation (Committee) will meet on September 14–15, 2015, at the U.S. Department of Veterans Affairs, 425 Eye Street NW., Washinginton, DC 20001. The Committee will meet in the Fourth Floor Conference Room 4E400. The sessions will begin at 8:30 a.m. and end at 4:30 p.m. each day. The meeting is open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on the maintenance and periodic readjustment of the VA Schedule for Rating Disabilities. The Committee is to assemble and review relevant information relating to the nature and character of disabilities arising during service in the Armed Forces, provide an ongoing assessment of the effectiveness of the rating schedule, and give advice on the most appropriate means of responding to the needs of Veterans relating to disability compensation.

The Committee will receive briefings on issues related to compensation for Veterans with service-connected disabilities and other VA benefits programs. Time will be allocated for receiving public comments. Public comments will be limited to three minutes each. Individuals wishing to make oral statements before the Committee will be accommodated on a

first-come, first-served basis. Individuals who speak are invited to submit 1–2 page summaries of their comments at the time of the meeting for inclusion in the official meeting record.

The public may submit written statements for the Committee's review to Dr. Ioulia Vvedenskaya, Department of Veterans Affairs, Veterans Benefits Administration, Compensation Service, Policy Staff (211C), 810 Vermont Avenue NW, Washington, DC 20420 or email at *Ioulia.Vvedenskaya@va.gov.* Because the meeting is being held in a government building, a photo I.D. must be presented at the Guard's Desk as a part of the clearance process. Therefore, you should allow an additional 15 minutes before the meeting begins. Any member of the public wishing to attend the meeting or seeking additional information should email Dr. Vvedenskaya or call her at (202) 461–9882.

Dated: July 30, 2015.

Jelessa Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2015–19044 Filed 8–3–15; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Women Veterans; Solicitation of Nomination for Appointment to the Advisory Committee on Women Veterans

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) is seeking nominees to be considered for membership on the Advisory Committee on Women Veterans (Committee) for the 2015 membership cycle. The Committee is authorized by 38 U.S.C. 542 (the statute), to provide advice to the Secretary of Veterans Affairs (Secretary) on the administration of VA's benefits and services (health care, rehabilitation benefits, compensation, outreach, and other relevant programs) for women Veterans. In accordance with the statute and the Committee's current charter, the majority of the membership shall consist of non-Federal employees appointed by the Secretary from the general public, serving as special government employees. The Committee provides a Congressionally-mandated report to the Secretary each even-numbered year, which includes: An assessment of the needs of women Veterans, with respect to compensation, health care, rehabilitation, outreach, and other benefits and programs administered by VA; a review of the programs and activities of VA designed to meet such needs; and other recommendations (including recommendations for administrative and legislative action), as the Committee considers appropriate. The Committee reports to the Secretary, through the Director of the Center for Women Veterans.

The Secretary appoints Committee members, and determines the length of terms in which Committee members serve. A term of service for any member may not exceed 3 years. The Secretary can reappoint members for additional terms. Each year, there are several vacancies on the Committee, as members' terms expire.

Self-nominations and nominations of non-Veterans are accepted. Any letters of nomination from organizations or other individuals should accompany the package when it is submitted.

In accordance with OMB guidance, federally registered lobbyists may not serve on Federal advisory committees in their individual capacity. Additional information regarding this issue can be found at *www.federalregister.gov/articles/2014/08/13/2014-19140/revised-guidance-on-appointment-of-lobbyists-to-federal-advisory-committees-boards-and-commissions*.

SUPPLEMENTARY INFORMATION: The Committee is currently comprised of 12 members. In accordance with the statute, the Committee consists of members appointed by the Secretary from the general public, including: Representatives of women Veterans; individuals who are recognized authorities in fields pertinent to the needs of women Veterans, including the gender specific health-care needs of women; representatives of both female and male Veterans with service-connected disabilities, including at least one female Veteran with a service-connected disability and at least one male Veteran with a service-connected disability; and women Veterans who are recently separated from service in the Armed Forces.

The Committee meets at least two times annually, which may include a site visit to a VA field location. In accordance with Federal Travel Regulation, VA will cover travel expenses—to include per diem—for all members of the Committee, for any travel associated with official Committee duties. A copy of the Committee's most recent charter and a list of the current membership can be found at *www.va.gov/ADVISORY/* or *www.va.gov/womenvet/*.

The Department makes every effort to ensure that the membership of its advisory committees is fairly balanced, in terms of points of view represented. In the review process, consideration is given to nominees' potential to address the Committee's demographic needs (regional representation, race/ethnicity representation, professional expertise, war era service, gender, former enlisted or officer status, branch of service, etc.). Other considerations to promote a balanced membership include longevity of military service, significant deployment experience, ability to handle complex issues, experience running large organizations, and ability to contribute to the gender-specific health care and benefits needs of women Veterans.

Nomination Package Requirements

Nomination packages must be typed (12 point font) and include: (1) A cover letter from the nominee, and (2) a current resume that is no more than four pages in length. The cover letter must summarize: The nominees' interest in serving on the committee and contributions she/he can make to the work of the committee; any relevant Veterans service activities she/he is currently engaged in; the military branch affiliation and timeframe of military service (if applicable). To promote a balanced membership, please provide information about your personal and professional qualifications and background that would give you a diverse perspective on women Veterans matters. Finally, please include in the cover letter the nominee's complete contact information (name, address, email address, and phone number); and a statement confirming that she/he is not a Federally-registered lobbyist. The resume should show professional work experience, and Veterans service involvement, especially service that involves women Veterans' issues.

Nominations for membership on the Committee must be received by August 31, 2015, no later than 4:00 p.m., Eastern Standard Time. Packages received after this time will not be considered for the current membership cycle. All nomination packages should be sent to the Advisory Committee Management Office by email (recommended) or mail. Please see contact information below.

Advisory Committee Management Office (00AC), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC, 20420, *VA.Advisory.Cmte@va.gov*.

Dated: July 30, 2015.

Jelessa Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2015–19045 Filed 8–3–15; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0319]

Proposed Information Collection (Fiduciary Agreement) Activity: Comment Request

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision with extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information provided by VA federal fiduciaries management of beneficiary funds.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before October 5, 2015.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email to *nancy.kessinger@va.gov*. Please refer to ''OMB Control No. 2900–0319'' in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 632–8924 or FAX (202) 632–8925.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Fiduciary Agreement (VA Form 21P–4703).

OMB Control Number: 2900–0319.

Type of Review: Revision of a currently approved collection.

Abstract: VA maintains supervision of the distribution and use of VA benefits paid to fiduciaries on behalf of VA claimants who are incompetent, a minor, or under legal disability. This form is used as a legal contract between VA and a federal fiduciary. It outlines the responsibilities of the fiduciary with respect to the uses of VA funds.

Affected Public: Individuals or households.

Estimated Annual Burden: 3,917.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 47,000.

By direction of the Secretary.

Kathleen M. Manwell,

Program Analyst, VA Privacy Service, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2015–19070 Filed 8–3–15; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 483

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 483

[CMS–1622–F]

RIN 0938–AS44

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2016. In addition, it specifies a SNF all-cause all-condition hospital readmission measure, as well as adopts that measure for a new SNF Value-Based Purchasing (VBP) Program, and includes a discussion of SNF VBP Program policies we are considering for future rulemaking to promote higher quality and more efficient health care for Medicare beneficiaries. Additionally, this final rule will implement a new quality reporting program for SNFs as specified in the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act). It also amends the requirements that a long-term care (LTC) facility must meet to qualify to participate as a skilled nursing facility (SNF) in the Medicare program, or a nursing facility (NF) in the Medicaid program, by establishing requirements that implement the provision in the Affordable Care Act regarding the submission of staffing information based on payroll data.

DATES: *Effective date:* The provisions of this final rule are effective on October 1, 2015 with the exception of provisions in § 483.75(u) which are effective on July 1, 2016.

FOR FURTHER INFORMATION CONTACT:

Penny Gershman, (410) 786–6643, for information related to SNF PPS clinical issues (excluding any issues raised in section III.D. of this final rule).

John Kane, (410) 786–0557, for information related to the development of the payment rates and case-mix indexes.

Kia Sidbury, (410) 786–7816, for information related to the wage index.

Bill Ullman, (410) 786–5667, for information related to level of care determinations, consolidated billing, and general information.

Shannon Kerr, (410) 786–0666, for information related to skilled nursing facility value-based purchasing.

Charlayne Van, (410) 786–8659, for information related to skilled nursing facility quality reporting.

Lorelei Chapman, (410) 786–9254, for information related to staffing data collection.

SUPPLEMENTARY INFORMATION:

Availability of Certain Tables Exclusively Through the Internet on the CMS Web Site

As discussed in the FY 2016 SNF PPS proposed rule (80 FR 22044), tables setting forth the Wage Index for Urban Areas Based on CBSA Labor Market Areas and the Wage Index Based on CBSA Labor Market Areas for Rural Areas are no longer published in the **Federal Register**. Instead, these tables are available exclusively through the Internet on the CMS Web site. The wage index tables for this final rule can be accessed on the SNF PPS Wage Index homepage, at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html*.

Readers who experience any problems accessing any of these online SNF PPS wage index tables should contact Kia Sidbury at (410) 786–7816.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

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Acronyms

In addition, because of the many terms to which we refer by acronym in this final rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

AIDS Acquired Immune Deficiency Syndrome
ARD Assessment reference date
BBA Balanced Budget Act of 1997, Pub. L. 105–33
BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 106–554
CAH Critical access hospital
CASPER Certification and Survey Provider Enhanced Reports
CBSA Core-based statistical area
CCN CMS Certification Number
CFR Code of Federal Regulations
CMI Case-mix index
CMS Centers for Medicare & Medicaid Services
COT Change of therapy
ECI Employment Cost Index
EHR Electronic health record
EOT End of therapy
EOT–R End of therapy—resumption
ESRDQIP End-Stage Renal Disease Quality Incentive Program
FAQ Frequently Asked Questions
FFS Fee-for-service
FR Federal Register
FY Fiscal year
GAO Government Accountability Office
HAC Hospital-Acquired Conditions
HACRP Hospital-Acquired Condition Reduction Program
HCPCS Healthcare Common Procedure Coding System
HIQR Hospital Inpatient Quality Reporting
HOQR Hospital Outpatient Quality Reporting
HRRP Hospital Readmissions Reduction Program
HVBP Hospital Value-Based Purchasing
ICR Information Collection Requirements
IGI IHS (Information Handling Services) Global Insight, Inc.
IMPACT Improving Medicare Post-Acute Care Transformation Act of 2014, Public Law 113–185
IPPS Inpatient prospective payment system
IRF Inpatient Rehabilitation Facility
LTC Long-term care
LTCH Long-term care hospital
MAP Measures Application Partnership
MDS Minimum data set
MFP Multifactor productivity
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MSA Metropolitan statistical area
NAICS North American Industrial Classification System
NF Nursing facility
NH Nursing Home
NQF National Quality Forum
OBRA Omnibus Budget Reconciliation Act of 1987, Public Law 100–203
OMB Office of Management and Budget
OMRA Other Medicare-Required Assessment
PAC Post-acute care
PAMA Protecting Access to Medicare Act of 2014, Public Law 113–93
PBJ Payroll-Based Journal
PPS Prospective Payment System
PQRS Physician Quality Reporting System
QIES Quality Improvement Evaluation System
QIES ASAP Quality Improvement and Evaluation System Assessment Submission and Processing
QRP Quality Reporting Program
RAI Resident assessment instrument
RAVEN Resident assessment validation entry
RFA Regulatory Flexibility Act, Public Law 96–354
RIA Regulatory impact analysis
RUG–III Resource Utilization Groups, Version 3
RUG–IV Resource Utilization Groups, Version 4
RUG–53 Refined 53-Group RUG–III Case-Mix Classification System
SCHIP State Children's Health Insurance Program
sDTI Suspected deep tissue injuries
SNF Skilled nursing facility
SNFRM Skilled Nursing Facility 30-Day All-Cause Readmission Measure
STM Staff time measurement
STRIVE Staff time and resource intensity verification
TEP Technical expert panel
UMRA Unfunded Mandates Reform Act, Public Law 104–4
VBP Value-based purchasing

I. Executive Summary

A. Purpose

This final rule updates the SNF prospective payment rates for FY 2016 as required under section 1888(e)(4)(E) of the Social Security Act (the Act). It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each fiscal year (FY), certain specified information relating to the payment update (see section II.C.). In addition, it implements a new quality reporting program (QRP) for SNFs required under section 1888(e)(6) of the Act. The final rule also specifies a SNF all-cause all-condition hospital readmission measure required under section 1888(g)(1) of the Act, and adopts that measure for a new SNF value-based purchasing (VBP) program as required under section 1888(h) of the Act. Further, this final rule establishes new regulatory reporting requirements for SNFs and NFs to implement the statutory obligation to submit staffing information based on payroll data under section 1128I(g) of the Act.

B. Summary of Major Provisions

In accordance with sections 1888(e)(4)(E)(ii)(IV) and 1888(e)(5) of the Act, the federal rates in this final rule reflect an update to the rates that we published in the SNF PPS final rule for FY 2015 (79 FR 45628), which reflects the SNF market basket index as adjusted by the applicable forecast error correction and by the multifactor productivity adjustment for FY 2016. We are also finalizing a SNF all-cause all-condition hospital readmission measure under section 1888(g)(1) of the

Act, as well as adopting that measure for a new SNF VBP Program as required under section 1888(h) of the Act. We are also implementing a new QRP for SNFs under section 1888(e)(6) of the Act, which was added by section 2(c)(4) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, Pub. L. 113–185).

For payment determinations beginning with FY 2018, we are adopting measures meeting three quality domains specified in section 1899B(c)(1) of the Act: Functional status, skin integrity, and incidence of major falls.

In addition, we are adding new language at 42 CFR, part 483 to implement section 1128I(g) of the Act. Specifically, beginning on July 1, 2016, long-term care (LTC) facilities that participate in Medicare or Medicaid will be required to submit electronically direct care staffing information (including information for agency and contract staff) based on payroll and other verifiable and auditable data in a uniform format.

C. Summary of Cost and Benefits

Provision description	Total transfers
FY 2016 SNF PPS payment rate update.	The overall economic impact of this final rule will be an estimated increase of $430 million in aggregate payments to SNFs during FY 2016.

II. Background on SNF PPS

A. Statutory Basis and Scope

As amended by section 4432 of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33), section 1888(e) of the Act provides for the implementation of a PPS for SNFs. This methodology uses prospective, case-mix adjusted per diem payment rates applicable to all covered SNF services defined in section 1888(e)(2)(A) of the Act. The SNF PPS is effective for cost reporting periods beginning on or after July 1, 1998, and covers all costs of furnishing covered SNF services (routine, ancillary, and capital-related costs) other than costs associated with approved educational activities and bad debts. Under section 1888(e)(2)(A)(i) of the Act, covered SNF services include post-hospital extended care services for which benefits are provided under Part A, as well as those items and services (other than a small number of excluded services, such as physician services) for which payment may otherwise be made under Part B and which are furnished to Medicare beneficiaries who are residents in a SNF during a covered Part A stay. A comprehensive discussion of these provisions appears in the May 12, 1998 interim final rule (63 FR 26252). In addition, a detailed discussion of the legislative history of the SNF PPS is available online at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_07302013.pdf*.

Section 215(a) of the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93, enacted on April 1, 2014), added section 1888(g) to the Act, requiring the Secretary to specify certain quality measures for the SNF setting. Additionally, section 215(b) of PAMA added section 1888(h) to the Act, requiring the Secretary to implement a VBP program for SNFs. Finally, section 2(a) of the IMPACT Act added section 1899B to the Act that, among other things, requires SNFs to report standardized data for measures in specified quality and resource use domains. In addition, the IMPACT Act added section 1888(e)(6) to the Act, which requires the Secretary to implement a QRP for SNFs, under which SNFs that do not report certain data will receive a reduction in their payments under the SNF PPS of 2 percentage points for FYs beginning with FY 2018.

B. Initial Transition for the SNF PPS

Under sections 1888(e)(1)(A) and 1888(e)(11) of the Act, the SNF PPS included an initial, three-phase transition that blended a facility-specific rate (reflecting the individual facility's historical cost experience) with the federal case-mix adjusted rate. The transition extended through the facility's first three cost reporting periods under the PPS, up to and including the one that began in FY 2001. Thus, the SNF PPS is no longer operating under the transition, as all facilities have been paid at the full federal rate effective with cost reporting periods beginning in FY 2002. As we now base payments for SNFs entirely on the adjusted federal per diem rates, we no longer include adjustment factors under the transition related to facility-specific rates for the upcoming FY.

C. Required Annual Rate Updates

Section 1888(e)(4)(E) of the Act requires the SNF PPS payment rates to be updated annually. The most recent annual update occurred in a final rule that set forth updates to the SNF PPS payment rates for FY 2015 (79 FR 45628, August 5, 2014).

Section 1888(e)(4)(H) of the Act specifies that we provide for publication annually in the **Federal Register** of the following:

- The unadjusted federal per diem rates to be applied to days of covered SNF services furnished during the upcoming FY.
- The case-mix classification system to be applied for these services during the upcoming FY.
- The factors to be applied in making the area wage adjustment for these services.

Along with other revisions discussed later in this preamble, this final rule provides the required annual updates to the per diem payment rates for SNFs for FY 2016.

III. Analysis of and Responses to Public Comments on the FY 2016 SNF PPS Proposed Rule

In response to the publication of the FY 2016 SNF PPS proposed rule, we received 53 timely public comments from individuals, providers, corporations, government agencies, private citizens, trade associations, and major organizations. The following are brief summaries of each proposed provision, a summary of the public comments that we received related to that proposal, and our responses to the comments.

A. General Comments on the FY 2016 SNF PPS Proposed Rule

In addition to the comments we received on specific proposals contained within the proposed rule (which we address later in this final rule), commenters also submitted the following, more general observations on the SNF PPS and SNF care generally. A discussion of these comments, along with our responses, appears below.

Comment: One commenter expressed concern regarding the recent evolution of SNF care, stating that, in the commenter's opinion, while resident acuity is increasing, facilities worry more about money than about actual resident care. The commenter further stated that fewer staff hours should be focused on determining a resident's particular Resource Utilization Group (RUG) level for the purpose of managing facility budgets, and instead should be focused on resident care. Additionally, the commenter asked that we establish standards of practice to eliminate unwarranted variability in care, such as residents sharing various health characteristics but receiving very different amounts of care.

Response: We appreciate the commenter raising these points and are mindful of the commenter's concern regarding the apparent tension between profit and resident care. We also agree

that SNF care appropriately should focus on the resident's unique characteristics and goals, and note that RUG determinations should be based on the type and amount of nursing and therapy care required by the resident, rather than on facility budget considerations. We will consider the concerns the commenter raised as we identify future areas for analysis and program monitoring.

Comment: One commenter recommended that we address the need for CMS to broaden the categories of healthcare professionals who may order patient diets. The commenter stated that such a change would improve patient health and allow SNFs to respond more quickly to resident nutritional needs.

Response: We appreciate this comment, but would note as we did in the FY 2015 SNF PPS final rule (79 FR 45630) that the specific issues the commenter raised about who may prescribe diets for SNF residents do not relate to payment policy, but rather to certification standards for long-term care facilities more generally. Therefore, while we once again note that such comments lie outside of the scope of this final rule, we will share them with the relevant CMS staff that works on survey and certification issues.

Comment: Several commenters made comments related to potential refinements or revisions of the existing SNF PPS. Some commenters expressed concern regarding compensation for non-therapy ancillary services, with one commenter stating specifically that the SNF PPS emphasizes therapy services and deemphasizes the care needs for medically complex residents, particularly in hospital-based SNFs. A second commenter stated that the current RUG system does not appropriately capture the intensity or cost of services for residents in certain non-therapy RUG groups, most notably those resident living with Alzheimer's disease and dementia. Both commenters urged CMS to revise the SNF PPS to account for the potentially increased intensity or cost of services for medically complex residents, some of which may result from the provision of non-therapy ancillary services. One commenter expressed a ''growing impatience'' with CMS's lack of progress in implementing a revised SNF PPS and urged CMS to move forward with a revised PPS design or provide a timeline for when such revisions will be ready given that the flaws with the current system are already well known. A different commenter expressed support for CMS's current efforts to revise the SNF PPS, while at the same time cautioning CMS to proceed gradually by considering an approach that would transition to a revised PPS design over time.

Response: We appreciate the commenters raising these points and share the commenters' interest in exploring ways to revise the SNF PPS that may improve payment policy as well as promote appropriate resident care. We believe that our SNF payment model research (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*) will help us establish a strong basis for examining potential improvements and refinements to the overall SNF PPS, most notably given that we recently expanded the scope of this research to focus not only on therapy payment but nursing and non-therapy ancillary payments as well. With regard to comments on the overall approach CMS is taking in developing a revised PPS design, and specifically, the two comments that presented contrasting views on the pace of our progress, we would agree with the commenter who urged a certain degree of caution in moving to a revised SNF PPS. While we also agree that many of the issues with the current system are well known at this point, we believe that arriving at appropriate solutions to issues of this complexity will, of necessity, entail an investment of time and effort that goes considerably beyond simply identifying the issues themselves. That said, we do believe that we should continue to move as quickly as possible to address the issues with the existing SNF PPS design, though without compromising the overall integrity of our research and analysis for the sake of time. We also welcome additional comments and feedback on this research, which may be submitted to: *SNFTherapyPayments@cms.hhs.gov*.

Comment: One commenter raised a concern regarding the potential impact of current Minimum Data Set (MDS) 3.0 assessment rules and policies during facility audits of completed MDS assessments. Specifically, the commenter stated that during an audit of assessments completed by a given facility, it might be discovered that correcting a given error (for example, an error in the number of therapy minutes coded on a given assessment) also means that a Change-of-Therapy (COT) Other Medicare-Required Assessment (OMRA) may have been missed during that timeframe when the original error occurred. Due to the missed assessment policy outlined in Chapters 2 and 6 of the MDS 3.0 manual, this could mean that the days associated with that missed assessment could be considered provider liable, which could have a significant financial impact on the facility. The commenter recommended that CMS re-evaluate the potentially punitive impact of not being able to complete an MDS after the resident's Medicare-covered SNF stay has ended.

Response: The consequences associated with coding errors and the use of audits to identify these errors are necessary to ensure that SNFs take seriously the responsibility of ensuring that accurate information is coded on the MDS. While we appreciate that errors are always possible, we do not believe that this is sufficient to warrant a change in policy at this time. We will continue to consider this issue as part of our ongoing evaluation of potential refinements and improvements to the overall SNF PPS.

B. SNF PPS Rate Setting Methodology and FY 2016 Update

1. Federal Base Rates

Under section 1888(e)(4) of the Act, the SNF PPS uses per diem federal payment rates based on mean SNF costs in a base year (FY 1995) updated for inflation to the first effective period of the PPS. We developed the federal payment rates using allowable costs from hospital-based and freestanding SNF cost reports for reporting periods beginning in FY 1995. The data used in developing the federal rates also incorporated a Part B add-on, which is an estimate of the amounts that, prior to the SNF PPS, would have been payable under Part B for covered SNF services furnished to individuals during the course of a covered Part A stay in a SNF.

In developing the rates for the initial period, we updated costs to the first effective year of the PPS (the 15-month period beginning July 1, 1998) using a SNF market basket index, and then standardized for geographic variations in wages and for the costs of facility differences in case mix. In compiling the database used to compute the federal payment rates, we excluded those providers that received new provider exemptions from the routine cost limits, as well as costs related to payments for exceptions to the routine cost limits. Using the formula that the BBA prescribed, we set the federal rates at a level equal to the weighted mean of freestanding costs plus 50 percent of the difference between the freestanding mean and weighted mean of all SNF costs (hospital-based and freestanding) combined. We computed and applied separately the payment rates for facilities located in urban and rural areas, and adjusted the portion of the federal rate attributable to wage-related

costs by a wage index to reflect geographic variations in wages.

2. SNF Market Basket Update

a. SNF Market Basket Index

Section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket index that encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses. We use the SNF market basket index, adjusted in the manner described below, to update the federal rates on an annual basis. In the SNF PPS final rule for FY 2014 (78 FR 47939 through 47946), we revised and rebased the market basket, which included updating the base year from FY 2004 to FY 2010.

For the FY 2016 proposed rule, the FY 2010-based SNF market basket growth rate was estimated to be 2.6 percent, which was based on the IHS Global Insight, Inc. (IGI) first quarter 2015 forecast with historical data through fourth quarter 2014. However, as discussed in the FY 2016 SNF PPS proposed rule (80 FR 22049), we proposed that if more recent data become available (for example, a more recent estimate of the FY 2010-based SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine the FY 2016 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in this final rule. Since that time we have received an updated FY 2016 market basket percentage increase, which is based on the second quarter 2015 IHS Global Insight forecast of the FY 2010-based SNF market basket. The revised market basket growth rate is 2.3 percent. In section III.B.2.e. of this final rule, we discuss the specific application of this adjustment to the forthcoming annual update of the SNF PPS payment rates.

b. Use of the SNF Market Basket Percentage

Section 1888(e)(5)(B) of the Act defines the SNF market basket percentage as the percentage change in the SNF market basket index from the midpoint of the previous FY to the midpoint of the current FY. For the federal rates set forth in this final rule, we use the percentage change in the SNF market basket index to compute the update factor for FY 2016. This is based on the IGI second quarter 2015 forecast (with historical data through the first quarter 2015) of the FY 2016 percentage increase in the FY 2010-based SNF market basket index for routine, ancillary, and capital-related expenses, which is used to compute the update factor in this final rule. As discussed in sections III.B.2.c. and III.B.2.d. of this final rule, this market basket percentage change is reduced by the applicable forecast error correction (as described in § 413.337(d)(2)) and by the multifactor productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act. Finally, as discussed in section II.B. of this final rule, we no longer compute update factors to adjust a facility-specific portion of the SNF PPS rates, because the initial three-phase transition period from facility-specific to full federal rates that started with cost reporting periods beginning in July 1998 has expired.

c. Forecast Error Adjustment

As discussed in the June 10, 2003 supplemental proposed rule (68 FR 34768) and finalized in the August 4, 2003, final rule (68 FR 46057 through 46059), the regulations at § 413.337(d)(2) provide for an adjustment to account for market basket forecast error. The initial adjustment for market basket forecast error applied to the update of the FY 2003 rate for FY 2004, and took into account the cumulative forecast error for the period from FY 2000 through FY 2002, resulting in an increase of 3.26 percent to the FY 2004 update. Subsequent adjustments in succeeding FYs take into account the forecast error from the most recently available FY for which there is final data, and apply the difference between the forecasted and actual change in the market basket when the difference exceeds a specified threshold. We originally used a 0.25 percentage point threshold for this purpose; however, for the reasons specified in the FY 2008 SNF PPS final rule (72 FR 43425, August 3, 2007), we adopted a 0.5 percentage point threshold effective for FY 2008 and subsequent FYs. As we stated in the final rule for FY 2004 that first issued the market basket forecast error adjustment (68 FR 46058, August 4, 2003), the adjustment will reflect both upward and downward adjustments, as appropriate.

For FY 2014 (the most recently available FY for which there is final data), the estimated increase in the market basket index was 2.3 percentage points, while the actual increase for FY 2014 was 1.7 percentage points, resulting in the actual increase being 0.6 percentage point lower than the estimated increase. Accordingly, as the difference between the estimated and actual amount of change in the market basket index exceeds the 0.5 percentage point threshold and because, in this instance, the estimated amount of change exceeded the actual amount of change, the FY 2016 market basket percentage change of 2.3 percent would be adjusted downward by the forecast error correction of 0.6 percentage point, resulting in a SNF market basket increase of 1.7 percent, before application of the productivity adjustment discussed in this section. Table 1 shows the forecasted and actual market basket amounts for FY 2014.

TABLE 1—DIFFERENCE BETWEEN THE FORECASTED AND ACTUAL MARKET BASKET INCREASES FOR FY 2014

Index	Forecasted FY 2014 increase *	Actual FY 2014 increase **	FY 2014 Difference
SNF	2.3	1.7	−0.6

* Published in **Federal Register**; based on second quarter 2013 IGI forecast (2010-based index).
** Based on the first quarter 2015 IGI forecast, with historical data through the fourth quarter 2014 (2010-based index).

A discussion of the general comments that we received on the forecast error adjustment, and our responses to those comments, appears below.

Comment: One commenter requested that in determining the need for a market basket forecast error adjustment in a given year, CMS consider recalculating the wage index budget neutrality factor (discussed in section III.B.4 of this final rule) based on more recent data and utilize any error found in the original budget neutrality factor calculation in CMS's determination of the need for a market basket forecast error adjustment.

Response: The commenter appears to be requesting a wage index budget

neutrality factor error adjustment. However, we note at the outset that given the limited year-to-year variance in the wage index budget neutrality factor, any calculation of a budget neutrality factor error would likely represent an error of no more than a few thousandths of a percentage point, and thus we do not believe a wage index budget neutrality factor error adjustment would be necessary. Moreover, the market basket forecast error adjustment and the wage index budget neutrality factor serve fundamentally different purposes and involve entirely separate aspects of the SNF PPS. As such, we do not believe it would be appropriate to apply a wage index budget neutrality factor error to a market basket forecast error in order to determine if the market basket forecast error adjustment should be made.

Comment: One commenter stated that the forecast error adjustment of 0.6 percentage point represents a significant reduction and recommended that we implement the forecast error correction over a 2-year period.

Response: The forecast error adjustment is an essential aspect of ensuring that SNF PPS payments are as accurate as possible. Therefore, consistent with the way we have applied forecast error adjustments in the past, we do not believe that it is either appropriate or beneficial to the overall integrity of the SNF PPS to implement this adjustment over a multiple-year period.

d. Multifactor Productivity Adjustment

Section 3401(b) of the Affordable Care Act requires that, in FY 2012 (and in subsequent FYs), the market basket percentage under the SNF payment system as described in section 1888(e)(5)(B)(i) of the Act is to be reduced annually by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, added by section 3401(a) of the Affordable Care Act, sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable FY, 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 multifactor productivity (MFP). We refer readers to the BLS Web site at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. To generate a forecast of MFP, IGI replicates the MFP measure calculated by the BLS, using a series of proxy variables derived from IGI's U.S. macroeconomic models. In section III.F.3. of the FY 2012 SNF PPS final rule (76 FR 48527 through 48529), we identified each of the major MFP component series employed by the BLS to measure MFP as well as provided the corresponding concepts determined to be the best available proxies for the BLS series.

Beginning with the FY 2016 rulemaking cycle, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs. Specifically, IGI has replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of BLS aggregate capital inputs recently developed by IGI using a regression model. This series provides a better fit to the BLS capital inputs as measured by the differences between the actual BLS capital input growth rates and the estimated model growth rates over the historical time period. Therefore, we are using IGI's most recent forecast of the BLS capital inputs series in the MFP calculations beginning with the FY 2016 rulemaking cycle. A complete description of the MFP projection methodology is available on our Web site at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.* Although we discuss the IGI changes to the MFP proxy series in this final rule, in the future, when IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

(1) Incorporating the Multifactor Productivity Adjustment Into the Market Basket Update

According to section 1888(e)(5)(A) of the Act, the Secretary shall establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Section 1888(e)(5)(B)(ii) of the Act, added by section 3401(b) of the Affordable Care Act, requires that for FY 2012 and each subsequent FY, after determining the market basket percentage described in section 1888(e)(5)(B)(i) of the Act, the Secretary shall reduce such percentage by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) (which we refer to as the MFP adjustment). Section 1888(e)(5)(B)(ii) of the Act further states that the reduction of the market basket percentage by the MFP adjustment may result in the market basket percentage being less than zero for a FY, and may result in payment rates under section 1888(e) of the Act for a FY being less than such payment rates for the preceding FY. Thus, if the application of the MFP adjustment to the market basket percentage calculated under section 1888(e)(5)(B)(i) of the Act results in an MFP-adjusted market basket percentage that is less than zero, then the annual update to the unadjusted federal per diem rates under section 1888(e)(4)(E)(ii) of the Act would be negative, and such rates would decrease relative to the prior FY.

For the FY 2016 update, the MFP adjustment is calculated as the 10-year moving average of changes in MFP for the period ending September 30, 2016. In the FY 2016 SNF PPS proposed rule, this adjustment was calculated to be 0.6 percent. However, as discussed in the FY 2016 SNF PPS proposed rule (80 FR 22049), we proposed that if more recent data become available (for example, a more recent estimate of the FY 2010-based SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine, among other things, the FY 2016 SNF market basket percentage change and the MFP adjustment in this final rule. Therefore, based on IGI's most recent second quarter 2015 forecast (with historical data through first quarter 2015), the MFP adjustment for FY 2016 is 0.5 percent. Consistent with section 1888(e)(5)(B)(i) of the Act and § 413.337(d)(2) of the regulations, the market basket percentage for FY 2016 for the SNF PPS is based on IGI's second quarter 2015 forecast of the SNF market basket update (2.3 percent) as adjusted by the forecast error adjustment (0.6 percentage point), and is estimated to be 1.7 percent. In accordance with section 1888(e)(5)(B)(ii) of the Act (as added by section 3401(b) of the Affordable Care Act) and § 413.337(d)(3), this market basket percentage is then reduced by the MFP adjustment (the 10-year moving average of changes in MFP for the period ending September 30, 2016) of 0.5 percent, which is calculated as described above and based on IGI's second quarter 2015 forecast. The

resulting MFP-adjusted SNF market basket update is equal to 1.2 percent, or 1.7 percent less 0.5 percentage point.

e. Market Basket Update Factor for FY 2016

Sections 1888(e)(4)(E)(ii)(IV) and 1888(e)(5)(i) of the Act require that the update factor used to establish the FY 2016 unadjusted federal rates be at a level equal to the market basket index percentage change. Accordingly, we determined the total growth from the average market basket level for the period of October 1, 2014 through September 30, 2015 to the average market basket level for the period of October 1, 2015 through September 30, 2016. This process yields a percentage change in the market basket of 2.3 percent.

As further explained in section III.B.2.c. of this final rule, as applicable, we adjust the market basket percentage change by the forecast error from the most recently available FY for which there is final data and apply this adjustment whenever the difference between the forecasted and actual percentage change in the market basket exceeds a 0.5 percentage point threshold. Since the forecasted FY 2014 SNF market basket percentage change exceeded the actual FY 2014 SNF market basket percentage change (FY 2014 is the most recently available FY for which there is final data) by more than 0.5 percentage point, the FY 2016 market basket percentage change of 2.3 percent would be adjusted downward by the applicable difference, which for FY 2014 is 0.6 percent.

In addition, for FY 2016, section 1888(e)(5)(B)(ii) of the Act requires us to reduce the market basket percentage change by the MFP adjustment (the 10-year moving average of changes in MFP for the period ending September 30, 2016) of 0.5 percent, as described in section III.B.2.d. of this final rule. The resulting net SNF market basket update would equal 1.2 percent, or 2.3 percent less the 0.6 percentage point forecast error adjustment, less the 0.5 percentage point MFP adjustment. We proposed in the FY 2016 SNF PPS proposed rule (80 FR 22049) that if more recent data become available (for example, a more recent estimate of the FY 2010-based SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine the FY 2016 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in this final rule. As noted above, more recent data were used to update the market basket update and MFP adjustment in this final rule.

A discussion of the general comments that we received on the market basket update factor for FY 2016, and our responses to those comments, appears below.

Comment: We received a number of comments in relation to applying the FY 2016 market basket update factor in the determination of the FY 2016 unadjusted federal per diem rates, with some commenters supporting its application in determining the FY 2016 unadjusted per diem rates, while others opposed its application. In their March 2015 report (available at: *http://www.medpac.gov/documents/reports/chapter-8-skilled-nursing-facility-services-(march-2015-report).pdf?sfvrsn=0*) and in their comment on the FY 2016 SNF PPS proposed rule, MedPAC recommended that CMS eliminate the market basket update for SNFs altogether and rebase payments for the SNF PPS, beginning with a 4 percent reduction in the base payment rates.

Response: We appreciate all of the comments received on the proposed market basket update for FY 2016. In response to those comments which opposed our applying the FY 2016 market basket update factor in determining the FY 2016 unadjusted federal per diem rates, specifically MedPAC's proposal to eliminate the market basket update for SNFs and to implement a 4 percent reduction to the SNF PPS base rates, we would need statutory authority to act on these proposals at the current time.

Comment: One commenter stated that in their preliminary analyses, they observed a gap between the market basket and costs indexed to 2001 dollars (which we assume to mean an index based on 2001 dollars) which occurs even in rebasing years. They also observed a growing gap in non-labor components. They stated that further research is needed to understand the gap and they respectfully request that CMS engage in an ongoing dialogue.

Response: We appreciate the commenter's review of the SNF market basket methodology and look forward to the commenter's analysis. While any comments on the SNF market basket methodology, including any analyses, can be emailed to *DNHS@cms.hhs.gov*, we would be happy to engage in further dialogue on this issue.

Comment: One commenter noted that the weights used in calculating the market basket update should continue to use the most updated cost data available. They suggested that the market basket be revised and reweighted with greater frequency—on the same schedule as the hospital market basket, particularly given the new Medicare provisions, such as the IMPACT Act and also if the SNF wage index continues to be directly linked to the hospital wage index. The commenter also suggested that CMS update the market basket each year; alternatively, should such a process be too onerous, CMS should calculate the six major cost weights derived from the Medicare cost report (wages and salaries, employee benefits, contract labor, pharmaceuticals, professional liability insurance and capital-related) every year and update the market basket every 4 years (rather than every 6), as well as whenever the aggregate percentage change of the six major cost weights, when taken together, exceeds some set amount.

Response: We appreciate the commenter's request for the SNF market basket to be revised and reweighted more frequently. As discussed in the FY 2006 IPPS final rule (70 FR 47387), we established a rebasing frequency of every 4 years for the hospital market basket, in accordance with section 404 of Public Law 108–173. We typically rebase and revise the SNF market baskets approximately every 6 years. Our prior analysis has shown that the major cost weights do not vary that much from year to year. However, we do understand the commenter's concern for more frequent rebasings given that any changes in the Medicare law could alter the way in which SNFs provide Medicare services—which, in turn, potentially could affect the SNF cost structures (that is, the market basket cost weights). Accordingly, we will consider the methodology presented by the commenter and evaluate the possible impact on the SNF market basket update by monitoring the percent change of the six major cost weights derived from the Medicare cost report (wages and salaries, employee benefits, contract labor, pharmaceuticals, professional liability insurance and capital-related).

Accordingly, for the reasons specified in this final rule and in the FY 2016 SNF PPS proposed rule (80 FR 22047 through 22049), we are applying the FY 2016 market basket increase factor, as adjusted by the forecast error correction and MFP adjustment as described above, in our determination of the FY 2016 SNF PPS unadjusted federal per diem rates. We used the SNF market basket, adjusted as described in this section, to adjust each per diem component of the federal rates forward to reflect the change in the average prices for FY 2016 from average prices for FY 2015. We would further adjust the rates by a wage index budget neutrality factor, described later in this

section. Tables 2 and 3 reflect the updated components of the unadjusted federal rates for FY 2016, prior to adjustment for case-mix.

TABLE 2—FY 2016 UNADJUSTED FEDERAL RATE PER DIEM URBAN

Rate component	Nursing—case-mix	Therapy—case-mix	Therapy—non-case-mix	Non-case-mix
Per Diem Amount	$171.17	$128.94	$16.98	$87.36

TABLE 3—FY 2016 UNADJUSTED FEDERAL RATE PER DIEM RURAL

Rate component	Nursing—case-mix	Therapy—case-mix	Therapy—non-case-mix	Non-case-mix
Per Diem Amount	$163.53	$148.67	$18.14	$88.97

3. Case-Mix Adjustment

Under section 1888(e)(4)(G)(i) of the Act, the federal rate also incorporates an adjustment to account for facility case-mix, using a classification system that accounts for the relative resource utilization of different patient types. The statute specifies that the adjustment is to reflect both a resident classification system that the Secretary establishes to account for the relative resource use of different patient types, as well as resident assessment data and other data that the Secretary considers appropriate. In the interim final rule with comment period that initially implemented the SNF PPS (63 FR 26252, May 12, 1998), we developed the RUG–III case-mix classification system, which tied the amount of payment to resident resource use in combination with resident characteristic information. Staff time measurement (STM) studies conducted in 1990, 1995, and 1997 provided information on resource use (time spent by staff members on residents) and resident characteristics that enabled us not only to establish RUG–III, but also to create case-mix indexes (CMIs). The original RUG–III grouper logic was based on clinical data collected in 1990, 1995, and 1997. As discussed in the SNF PPS proposed rule for FY 2010 (74 FR 22208), we subsequently conducted a multi-year data collection and analysis under the Staff Time and Resource Intensity Verification (STRIVE) project to update the case-mix classification system for FY 2011. The resulting Resource Utilization Groups, Version 4 (RUG–IV) case-mix classification system reflected the data collected in 2006 through 2007 during the STRIVE project, and was finalized in the FY 2010 SNF PPS final rule (74 FR 40288) to take effect in FY 2011 concurrently with an updated new resident assessment instrument, version 3.0 of the Minimum Data Set (MDS 3.0), which collects the clinical data used for case-mix classification under RUG–IV.

We note that case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy services. The case-mix classification system uses clinical data from the MDS to assign a case-mix group to each patient that is then used to calculate a per diem payment under the SNF PPS. As discussed in section III.C.1. of this final rule, the clinical orientation of the case-mix classification system supports the SNF PPS's use of an administrative presumption that considers a beneficiary's initial case-mix classification to assist in making certain SNF level of care determinations. Further, because the MDS is used as a basis for payment, as well as a clinical assessment, we have provided extensive training on proper coding and the time frames for MDS completion in our Resident Assessment Instrument (RAI) Manual. For an MDS to be considered valid for use in determining payment, the MDS assessment must be completed in compliance with the instructions in the RAI Manual in effect at the time the assessment is completed. For payment and quality monitoring purposes, the RAI Manual consists of both the Manual instructions and the interpretive guidance and policy clarifications posted on the appropriate MDS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html*.

In addition, we note that section 511 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, Pub. L. 108–173) amended section 1888(e)(12) of the Act to provide for a temporary increase of 128 percent in the PPS per diem payment for any SNF residents with Acquired Immune Deficiency Syndrome (AIDS), effective with services furnished on or after October 1, 2004. This special add-on for SNF residents with AIDS was to remain in effect until the Secretary certifies that there is an appropriate adjustment in the case mix to compensate for the increased costs associated with such residents. The add-on for SNF residents with AIDS is also discussed in Program Transmittal #160 (Change Request #3291), issued on April 30, 2004, which is available online at *www.cms.gov/transmittals/downloads/r160cp.pdf*. In the SNF PPS final rule for FY 2010 (74 FR 40288), we did not address the certification related to the add-on for SNF residents with AIDS in that final rule's implementation of the case-mix refinements for RUG–IV, thus allowing the add-on payment required by section 511 of the MMA to remain in effect. For the limited number of SNF residents that qualify for this add-on, there is a significant increase in payments. For example, using FY 2013 data, we identified fewer than 4,800 SNF residents with a diagnosis code of 042 (Human Immunodeficiency Virus (HIV) Infection). For FY 2016, an urban facility with a resident with AIDS in RUG–IV group ''HC2'' would have a case-mix adjusted per diem payment of $427.85 (see Table 4) before the application of the MMA adjustment. After an increase of 128 percent, this urban facility would receive a case-mix adjusted per diem payment of approximately $975.50.

Currently, we use the International Classification of Diseases, 9th revision, Clinical Modification (ICD–9–CM) code 042 to identify those residents for whom it is appropriate to apply the AIDS add-on established by section 511 of the MMA. In this context, we note that the Department published a final rule in the September 5, 2012 **Federal Register** (77 FR 54664) which requires us to stop using ICD–9–CM on September 30, 2014, and begin using the International Classification of Diseases, 10th revision, Clinical Modification (ICD–10–CM), on October 1, 2014. Regarding the above-referenced ICD–9–CM diagnosis code of

042, in the FY 2014 SNF PPS proposed rule (78 FR 26444, May 6, 2013), we proposed to transition to the equivalent ICD–10–CM diagnosis code of B20 upon the overall conversion to ICD–10–CM on October 1, 2014, and we subsequently finalized that proposal in the FY 2014 SNF PPS final rule (78 FR 47951 through 47952).

However, on April 1, 2014, PAMA was enacted. Section 212 of PAMA, titled ''Delay in Transition from ICD–9 to ICD–10 Code Sets,'' provides that the 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 Act (42 U.S.C. 1320d–2(c)) and 45 CFR 162.1002. In the FY 2015 SNF PPS final rule (79 FR 45633), we stated that the Department expected to release an interim final rule in the near future that would include a new compliance date that would require the use of ICD–10 beginning October 1, 2015. In light of this, in the FY 2015 SNF PPS final rule, we stated that the effective date of the change from ICD–9–CM code 042 to ICD–10–CM code B20 for purposes of applying the AIDS add-on is October 1, 2015, and that until that time we would continue to use the ICD–9–CM code 042 for this purpose. On August 4, 2014, HHS released a final rule in the **Federal Register** (79 FR 45128 through 45134) that included a new compliance date that requires the use of ICD–10 beginning October 1, 2015. The August 4, 2014 final rule is available for viewing on the Internet at *http://www.gpo.gov/fdsys/pkg/FR–2014–08–04/pdf/2014–18347.pdf*. That final rule also requires HIPAA covered entities to continue to use ICD–9–CM through September 30, 2015. Thus, as we finalized in the FY 2015 SNF PPS final rule, the effective date of the change from ICD–9–CM code 042 to ICD–10–CM code B20 for the purpose of applying the AIDS add-on enacted by section 511 of the MMA is October 1, 2015.

Under section 1888(e)(4)(H), each update of the payment rates must include the case-mix classification methodology applicable for the upcoming FY. The payment rates set forth in this final rule reflect the use of the RUG–IV case-mix classification system from October 1, 2015, through September 30, 2016. We list the proposed case-mix adjusted RUG–IV payment rates, provided separately for urban and rural SNFs, in Tables 4 and 5 with corresponding case-mix values. We use the revised OMB delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634) to identify a facility's urban or rural status for the purpose of determining which set of rate tables apply to the facility. These tables do not reflect the add-on for SNF residents with AIDS enacted by section 511 of the MMA, which we apply only after making all other adjustments (such as wage index and case-mix).

TABLE 4—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES URBAN

RUG–IV Category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
RUX	2.67	1.87	$457.02	$241.12		$87.36	$785.50
RUL	2.57	1.87	439.91	241.12		87.36	768.39
RVX	2.61	1.28	446.75	165.04		87.36	699.15
RVL	2.19	1.28	374.86	165.04		87.36	627.26
RHX	2.55	0.85	436.48	109.60		87.36	633.44
RHL	2.15	0.85	368.02	109.60		87.36	564.98
RMX	2.47	0.55	422.79	70.92		87.36	581.07
RML	2.19	0.55	374.86	70.92		87.36	533.14
RLX	2.26	0.28	386.84	36.10		87.36	510.30
RUC	1.56	1.87	267.03	241.12		87.36	595.51
RUB	1.56	1.87	267.03	241.12		87.36	595.51
RUA	0.99	1.87	169.46	241.12		87.36	497.94
RVC	1.51	1.28	258.47	165.04		87.36	510.87
RVB	1.11	1.28	190.00	165.04		87.36	442.40
RVA	1.10	1.28	188.29	165.04		87.36	440.69
RHC	1.45	0.85	248.20	109.60		87.36	445.16
RHB	1.19	0.85	203.69	109.60		87.36	400.65
RHA	0.91	0.85	155.76	109.60		87.36	352.72
RMC	1.36	0.55	232.79	70.92		87.36	391.07
RMB	1.22	0.55	208.83	70.92		87.36	367.11
RMA	0.84	0.55	143.78	70.92		87.36	302.06
RLB	1.50	0.28	256.76	36.10		87.36	380.22
RLA	0.71	0.28	121.53	36.10		87.36	244.99
ES3	3.58		612.79		16.98	87.36	717.13
ES2	2.67		457.02		16.98	87.36	561.36
ES1	2.32		397.11		16.98	87.36	501.45
HE2	2.22		380.00		16.98	87.36	484.34
HE1	1.74		297.84		16.98	87.36	402.18
HD2	2.04		349.19		16.98	87.36	453.53
HD1	1.60		273.87		16.98	87.36	378.21
HC2	1.89		323.51		16.98	87.36	427.85
HC1	1.48		253.33		16.98	87.36	357.67
HB2	1.86		318.38		16.98	87.36	422.72
HB1	1.46		249.91		16.98	87.36	354.25
LE2	1.96		335.49		16.98	87.36	439.83
LE1	1.54		263.60		16.98	87.36	367.94
LD2	1.86		318.38		16.98	87.36	422.72
LD1	1.46		249.91		16.98	87.36	354.25
LC2	1.56		267.03		16.98	87.36	371.37
LC1	1.22		208.83		16.98	87.36	313.17
LB2	1.45		248.20		16.98	87.36	352.54
LB1	1.14		195.13		16.98	87.36	299.47

TABLE 4—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES URBAN—Continued

RUG–IV Category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
CE2	1.68		287.57		16.98	87.36	391.91
CE1	1.50		256.76		16.98	87.36	361.10
CD2	1.56		267.03		16.98	87.36	371.37
CD1	1.38		236.21		16.98	87.36	340.55
CC2	1.29		220.81		16.98	87.36	325.15
CC1	1.15		196.85		16.98	87.36	301.19
CB2	1.15		196.85		16.98	87.36	301.19
CB1	1.02		174.59		16.98	87.36	278.93
CA2	0.88		150.63		16.98	87.36	254.97
CA1	0.78		133.51		16.98	87.36	237.85
BB2	0.97		166.03		16.98	87.36	270.37
BB1	0.90		154.05		16.98	87.36	258.39
BA2	0.70		119.82		16.98	87.36	224.16
BA1	0.64		109.55		16.98	87.36	213.89
PE2	1.50		256.76		16.98	87.36	361.10
PE1	1.40		239.64		16.98	87.36	343.98
PD2	1.38		236.21		16.98	87.36	340.55
PD1	1.28		219.10		16.98	87.36	323.44
PC2	1.10		188.29		16.98	87.36	292.63
PC1	1.02		174.59		16.98	87.36	278.93
PB2	0.84		143.78		16.98	87.36	248.12
PB1	0.78		133.51		16.98	87.36	237.85
PA2	0.59		100.99		16.98	87.36	205.33
PA1	0.54		92.43		16.98	87.36	196.77

TABLE 5—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES RURAL

RUG–IV Category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
RUX	2.67	1.87	$436.63	$278.01		$88.97	$803.61
RUL	2.57	1.87	420.27	278.01		88.97	787.25
RVX	2.61	1.28	426.81	190.30		88.97	706.08
RVL	2.19	1.28	358.13	190.30		88.97	637.40
RHX	2.55	0.85	417.00	126.37		88.97	632.34
RHL	2.15	0.85	351.59	126.37		88.97	566.93
RMX	2.47	0.55	403.92	81.77		88.97	574.66
RML	2.19	0.55	358.13	81.77		88.97	528.87
RLX	2.26	0.28	369.58	41.63		88.97	500.18
RUC	1.56	1.87	255.11	278.01		88.97	622.09
RUB	1.56	1.87	255.11	278.01		88.97	622.09
RUA	0.99	1.87	161.89	278.01		88.97	528.87
RVC	1.51	1.28	246.93	190.30		88.97	526.20
RVB	1.11	1.28	181.52	190.30		88.97	460.79
RVA	1.10	1.28	179.88	190.30		88.97	459.15
RHC	1.45	0.85	237.12	126.37		88.97	452.46
RHB	1.19	0.85	194.60	126.37		88.97	409.94
RHA	0.91	0.85	148.81	126.37		88.97	364.15
RMC	1.36	0.55	222.40	81.77		88.97	393.14
RMB	1.22	0.55	199.51	81.77		88.97	370.25
RMA	0.84	0.55	137.37	81.77		88.97	308.11
RLB	1.50	0.28	245.30	41.63		88.97	375.90
RLA	0.71	0.28	116.11	41.63		88.97	246.71
ES3	3.58		585.44		18.14	88.97	692.55
ES2	2.67		436.63		18.14	88.97	543.74
ES1	2.32		379.39		18.14	88.97	486.50
HE2	2.22		363.04		18.14	88.97	470.15
HE1	1.74		284.54		18.14	88.97	391.65
HD2	2.04		333.60		18.14	88.97	440.71
HD1	1.60		261.65		18.14	88.97	368.76
HC2	1.89		309.07		18.14	88.97	416.18
HC1	1.48		242.02		18.14	88.97	349.13
HB2	1.86		304.17		18.14	88.97	411.28
HB1	1.46		238.75		18.14	88.97	345.86
LE2	1.96		320.52		18.14	88.97	427.63
LE1	1.54		251.84		18.14	88.97	358.95
LD2	1.86		304.17		18.14	88.97	411.28
LD1	1.46		238.75		18.14	88.97	345.86
LC2	1.56		255.11		18.14	88.97	362.22
LC1	1.22		199.51		18.14	88.97	306.62

TABLE 5—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES RURAL—Continued

RUG–IV Category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
LB2	1.45		237.12		18.14	88.97	344.23
LB1	1.14		186.42		18.14	88.97	293.53
CE2	1.68		274.73		18.14	88.97	381.84
CE1	1.50		245.30		18.14	88.97	352.41
CD2	1.56		255.11		18.14	88.97	362.22
CD1	1.38		225.67		18.14	88.97	332.78
CC2	1.29		210.95		18.14	88.97	318.06
CC1	1.15		188.06		18.14	88.97	295.17
CB2	1.15		188.06		18.14	88.97	295.17
CB1	1.02		166.80		18.14	88.97	273.91
CA2	0.88		143.91		18.14	88.97	251.02
CA1	0.78		127.55		18.14	88.97	234.66
BB2	0.97		158.62		18.14	88.97	265.73
BB1	0.90		147.18		18.14	88.97	254.29
BA2	0.70		114.47		18.14	88.97	221.58
BA1	0.64		104.66		18.14	88.97	211.77
PE2	1.50		245.30		18.14	88.97	352.41
PE1	1.40		228.94		18.14	88.97	336.05
PD2	1.38		225.67		18.14	88.97	332.78
PD1	1.28		209.32		18.14	88.97	316.43
PC2	1.10		179.88		18.14	88.97	286.99
PC1	1.02		166.80		18.14	88.97	273.91
PB2	0.84		137.37		18.14	88.97	244.48
PB1	0.78		127.55		18.14	88.97	234.66
PA2	0.59		96.48		18.14	88.97	203.59
PA1	0.54		88.31		18.14	88.97	195.42

4. Wage Index Adjustment

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the federal rates to account for differences in area wage levels, using a wage index that the Secretary determines appropriate. Since the inception of the SNF PPS, we have used hospital inpatient wage data in developing a wage index to be applied to SNFs. We proposed to continue this practice for FY 2016, as we continue to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage index data is appropriate and reasonable for the SNF PPS. As explained in the update notice for FY 2005 (69 FR 45786), the SNF PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the occupational wage data also excludes any wage data related to SNFs. Therefore, we believe that using the updated wage data exclusive of the occupational mix adjustment continues to be appropriate for SNF payments. For FY 2016, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2011 and before October 1, 2012 (FY 2012 cost report data).

We note that section 315 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) authorized us to establish a geographic reclassification procedure that is specific to SNFs, but only after collecting the data necessary to establish a SNF wage index that is based on wage data from nursing homes. However, to date, this has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of that data.

In addition, we proposed to continue to use the same methodology discussed in the SNF PPS final rule for FY 2008 (72 FR 43423) to address those geographic areas in which there are no hospitals, and thus, no hospital wage index data on which to base the calculation of the FY 2016 SNF PPS wage index. For rural geographic areas that do not have hospitals, and therefore, lack hospital wage data on which to base an area wage adjustment, we would use the average wage index from all contiguous Core-Based Statistical Areas (CBSAs) as a reasonable proxy. For FY 2016, there are no rural geographic areas that do not have hospitals, and thus, this methodology will not be applied. For rural Puerto Rico, we will 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 will continue to use the most recent wage index previously available for that area. For urban areas without specific hospital wage index data, we will use the average wage indexes of all of the urban areas within the state to serve as a reasonable proxy for the wage index of that urban CBSA. For FY 2016, the only urban area without wage index data available is CBSA 25980, Hinesville-Fort Stewart, GA. The wage index applicable to FY 2016 is set forth in Table A available on the CMS Web site at *http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html*.

Once calculated, we will apply the wage index adjustment to the labor-related portion of the federal rate. Each year, we calculate a revised labor-related share, based on the relative importance of labor-related cost categories (that is, those cost categories that are labor-intensive and vary with the local labor market) in the input price index. In the SNF PPS final rule for FY 2014 (78 FR 47944 through 47946), we finalized a proposal to revise the labor-related share to reflect the relative importance of the revised FY 2010-based SNF market basket cost weights for the following cost categories: Wages and salaries; employee benefits; the labor-related portion of nonmedical professional fees; administrative and facilities support services; all other:

Labor-related services; and a proportion of capital-related expenses.

We calculate the labor-related relative importance from the SNF market basket, and it approximates the labor-related portion of the total costs after taking into account historical and projected price changes between the base year and FY 2016. The price proxies that move the different cost categories in the market basket do not necessarily change at the same rate, and the relative importance captures these changes. Accordingly, the relative importance figure more closely reflects the cost share weights for FY 2016 than the base year weights from the SNF market basket.

We calculate the labor-related relative importance for FY 2016 in four steps. First, we compute the FY 2016 price index level for the total market basket and each cost category of the market basket. Second, we calculate a ratio for each cost category by dividing the FY 2016 price index level for that cost category by the total market basket price index level. Third, we determine the FY 2016 relative importance for each cost category by multiplying this ratio by the base year (FY 2010) weight. Finally, we add the FY 2016 relative importance for each of the labor-related cost categories (wages and salaries, employee benefits, the labor-related portion of non-medical professional fees, administrative and facilities support services, all other: labor-related services, and a portion of capital-related expenses) to produce the FY 2016 labor-related relative importance. Table 6 summarizes the updated labor-related share for FY 2016, compared to the labor-related share that was used for the FY 2015 SNF PPS final rule.

We proposed for FY 2016 and subsequent FYs, to report and apply the SNF PPS labor-related share at a tenth of a percentage point (rather than at a thousandth of a percentage point) consistent with the manner in which we report and apply the market basket update percentage under the SNF PPS and the IPPS and the manner in which we report and apply the IPPS labor-related share. The level of precision specified for the IPPS labor-related share is three decimal places or a tenth of a percentage point (0.696 or 69.6 percent), which we believe provides a reasonable level of precision. We believe it is appropriate to maintain such consistency across all payment systems so that the level of precision specified is both reasonable and similar for all providers. Additionally, we proposed in the FY 2016 SNF PPS proposed rule (80 FR 22049) that if more recent data become available (for example, a more recent estimate of the FY 2010-based SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine the FY 2016 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in this final rule. We note that more recent data did become available and that the proposed labor related share for FY 2016 of 69.2 percent has been updated, based on IGI's second quarter 2015 forecast, to an FY 2016 labor related share of 69.1 percent.

We invited public comments on these proposals. A discussion of the comments we received on these proposals, as well as a discussion of the general comments that we received on the wage index adjustment, and our responses to those comments, appears below.

Comment: Several commenters stated that hospital cost data may not be the most reliable resource when determining geographical differences in salary structure for SNFs. These commenters urged CMS to establish a SNF-specific wage index. One commenter stated that new SNF cost reports, required by section 6104 of the Affordable Care Act, provide the requisite data in order for CMS to establish a SNF-specific wage index that could replace the current use of the inpatient hospital wage index data as the basis for the current SNF wage index.

Response: We appreciate the commenters raising these concerns, particularly the one commenter who provided significant details on how new SNF cost-report data could be used to develop a SNF-specific wage index. While CMS may consider this new data source as a potential stepping-stone towards developing a SNF-specific wage index, we note that consistent with our previous responses to these recurring comments (most recently published in the FY 2015 SNF PPS final rule (79 FR 45636)), developing such a wage index would require a resource-intensive audit process similar to that used for IPPS hospital data, to improve the quality of the SNF cost report data in order for it to be used as part of this analysis. Ultimately, while we continue to review all available data and contemplate the potential methodological approaches for a SNF-specific wage index in the future, we do not believe that the current state of the data is sufficiently refined to permit any such use of this data at this time.

Comment: Some commenters urged that CMS, to the extent that we plan to continue to use hospital cost data as the basis for SNF wage index adjustments, consider adopting certain wage index policies in use under the IPPS, such as reclassification or rural floor, because SNFs compete in a similar labor pool as acute care hospitals. Commenters also stated that CMS should use post-reclassification hospital wage data to influence SNF PPS wage index policy decisions. These commenters further stated that in addition to considering such policies as reclassification and a rural floor, CMS should consider implementing a floor and ceiling for annual changes to the wage index in order to smooth perceived volatility of such changes.

Response: Consistent with our previous responses to these recurring comments (most recently published in the FY 2015 SNF PPS final rule (79 FR 45636 through 45637), we continue to believe that in the absence of the appropriate SNF-specific wage data, using the pre-reclassified hospital inpatient wage data (without the occupational mix adjustment) is appropriate and reasonable for the SNF PPS. As discussed above, section 315 of BIPA authorized us to establish a geographic reclassification procedure that is specific to SNFs, only after collecting the data necessary to establish a SNF-specific wage index that is based on data from nursing homes. However, to date this has been infeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of that data. Furthermore, we do not believe that using hospital reclassification data would be appropriate as this data is specific to the requesting hospitals and it may or may not apply to a given SNF in a given instance. With regard to implementing a rural floor, we do not believe it would be prudent at this time to adopt such a policy, because MedPAC has recommended eliminating the rural floor policy from the calculation of the IPPS wage index (see, for example, Chapter 3 of MedPAC's March 2013 Report to Congress on Medicare Payment Policy, available at *http://medpac.gov/documents/reports/mar13_entirereport.pdf*, which *notes on page 65 that* in 2007, MedPAC had ''. . . recommended eliminating these special wage index adjustments and adopting a new wage index system to avoid geographic inequities that can occur due to current wage index policies (Medicare Payment Advisory Commission 2007b.'') If we adopted the rural floor at this time under the SNF PPS, we believe that, the SNF PPS wage index could become vulnerable to

problems similar to those that MedPAC identified in its March 2013 Report to Congress. Additionally, at this time, we do not believe it would be appropriate to establish a floor and ceiling for annual wage index changes. Any perceived volatility in the wage index is predicated upon volatility in actual wages in that area and reflects real differences in area wage levels that should be accounted for timely. As stated above, under 1888(e)(4)(G)(ii) of the Act and § 413.337(a)(1)(ii) of the regulations, we adjust the SNF PPS rates to account for differences in area wage levels. We believe that applying a ceiling or floor to annual wage index changes would make the wage index for a given area less reflective of the area wage levels and changes. Additionally, we note that establishing an artificial ceiling for annual changes in the wage index could not only result in an inaccurate wage index, but also potentially have an adverse impact on those providers that would otherwise experience a larger increase in their wage index absent such a ceiling.

Comment: One commenter requested that CMS provide more detail on the processes and procedures that are used in determining what hospital data may be excluded from forming the inpatient hospital wage index, which serves as the basis for the SNF wage index.

Response: The processes and procedures for how the inpatient hospital wage index is developed are discussed in the Inpatient Prospective Payment System (IPPS) rule each year, with the most recent discussion appearing in the FY 2016 IPPS proposed rule (80 FR 24463 through 24477) and subsequent FY 2016 IPPS final rule.

After considering the comments received and for the reasons discussed above and in the FY 2016 SNF PPS proposed rule (80 FR 22052 through 22056), we are finalizing the FY 2016 wage index adjustment and related policies as proposed in the FY 2016 SNF PPS proposed rule without modification. For FY 2016, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2011 and before October 1, 2012 (FY 2012 cost report data). We are also finalizing our proposal that for FY 2016 and subsequent FYs, we will report and apply the SNF PPS labor-related share at a tenth of a percentage point (rather than at a thousandth of a percentage point) consistent with the manner in which we report and apply the market basket update percentage under the SNF PPS and the IPPS and the manner in which we report and apply the IPPS labor-related share. Table 6 summarizes the updated labor-related share for FY 2016, compared to the labor-related share that was used for the FY 2015 SNF PPS final rule.

TABLE 6—LABOR-RELATED RELATIVE IMPORTANCE, FY 2015 AND FY 2016

	Relative importance, labor-related, FY 2015 14:2 forecast [1]	Relative importance, labor-related, FY 2016 15:2 forecast [2]
Wages and salaries	48.816	48.8
Employee benefits	11.365	11.3
Nonmedical Professional fees: labor-related	3.450	3.5
Administrative and facilities support services	0.502	0.5
All Other: Labor-related services	2.276	2.3
Capital-related (.391)	2.771	2.7
Total	69.180	69.1

[1] Published in the **Federal Register**; based on second quarter 2014 IGI forecast
[2] Based on second quarter 2015 IGI forecast, with historical data through first quarter 2015.

Tables 7 and 8 show the RUG–IV case-mix adjusted federal rates by labor-related and non-labor-related components.

TABLE 7—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES FOR URBAN SNFS BY LABOR AND NON-LABOR COMPONENT

RUG–IV Category	Total rate	Labor portion	Non-labor portion
RUX	785.50	$542.78	$242.72
RUL	768.39	530.96	237.43
RVX	699.15	483.11	216.04
RVL	627.26	433.44	193.82
RHX	633.44	437.71	195.73
RHL	564.98	390.40	174.58
RMX	581.07	401.52	179.55
RML	533.14	368.40	164.74
RLX	510.30	352.62	157.68
RUC	595.51	411.50	184.01
RUB	595.51	411.50	184.01
RUA	497.94	344.08	153.86
RVC	510.87	353.01	157.86
RVB	442.40	305.70	136.70
RVA	440.69	304.52	136.17
RHC	445.16	307.61	137.55
RHB	400.65	276.85	123.80
RHA	352.72	243.73	108.99
RMC	391.07	270.23	120.84
RMB	367.11	253.67	113.44
RMA	302.06	208.72	93.34
RLB	380.22	262.73	117.49

TABLE 7—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES FOR URBAN SNFS BY LABOR AND NON-LABOR COMPONENT—Continued

RUG–IV Category	Total rate	Labor portion	Non-labor portion
RLA	244.99	169.29	75.70
ES3	717.13	495.54	221.59
ES2	561.36	387.90	173.46
ES1	501.45	346.50	154.95
HE2	484.34	334.68	149.66
HE1	402.18	277.91	124.27
HD2	453.53	313.39	140.14
HD1	378.21	261.34	116.87
HC2	427.85	295.64	132.21
HC1	357.67	247.15	110.52
HB2	422.72	292.10	130.62
HB1	354.25	244.79	109.46
LE2	439.83	303.92	135.91
LE1	367.94	254.25	113.69
LD2	422.72	292.10	130.62
LD1	354.25	244.79	109.46
LC2	371.37	256.62	114.75
LC1	313.17	216.40	96.77
LB2	352.54	243.61	108.93
LB1	299.47	206.93	92.54
CE2	391.91	270.81	121.10
CE1	361.10	249.52	111.58
CD2	371.37	256.62	114.75
CD1	340.55	235.32	105.23
CC2	325.15	224.68	100.47
CC1	301.19	208.12	93.07
CB2	301.19	208.12	93.07
CB1	278.93	192.74	86.19
CA2	254.97	176.18	78.79
CA1	237.85	164.35	73.50
BB2	270.37	186.83	83.54
BB1	258.39	178.55	79.84
BA2	224.16	154.89	69.27
BA1	213.89	147.80	66.09
PE2	361.10	249.52	111.58
PE1	343.98	237.69	106.29
PD2	340.55	235.32	105.23
PD1	323.44	223.50	99.94
PC2	292.63	202.21	90.42
PC1	278.93	192.74	86.19
PB2	248.12	171.45	76.67
PB1	237.85	164.35	73.50
PA2	205.33	141.88	63.45
PA1	196.77	135.97	60.80

TABLE 8—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES FOR RURAL SNFS BY LABOR AND NON-LABOR COMPONENT

RUG–IV category	Total rate	Labor portion	Non-labor portion
RUX	803.61	$555.29	$248.32
RUL	787.25	543.99	243.26
RVX	706.08	487.90	218.18
RVL	637.40	440.44	196.96
RHX	632.34	436.95	195.39
RHL	566.93	391.75	175.18
RMX	574.66	397.09	177.57
RML	528.87	365.45	163.42
RLX	500.18	345.62	154.56
RUC	622.09	429.86	192.23
RUB	622.09	429.86	192.23
RUA	528.87	365.45	163.42
RVC	526.20	363.60	162.60
RVB	460.79	318.41	142.38
RVA	459.15	317.27	141.88
RHC	452.46	312.65	139.81
RHB	409.94	283.27	126.67
RHA	364.15	251.63	112.52
RMC	393.14	271.66	121.48
RMB	370.25	255.84	114.41
RMA	308.11	212.90	95.21

TABLE 8—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES FOR RURAL SNFS BY LABOR AND NON-LABOR COMPONENT—Continued

RUG–IV category	Total rate	Labor portion	Non-labor portion
RLB	375.90	259.75	116.15
RLA	246.71	170.48	76.23
ES3	692.55	478.55	214.00
ES2	543.74	375.72	168.02
ES1	486.50	336.17	150.33
HE2	470.15	324.87	145.28
HE1	391.65	270.63	121.02
HD2	440.71	304.53	136.18
HD1	368.76	254.81	113.95
HC2	416.18	287.58	128.60
HC1	349.13	241.25	107.88
HB2	411.28	284.19	127.09
HB1	345.86	238.99	106.87
LE2	427.63	295.49	132.14
LE1	358.95	248.03	110.92
LD2	411.28	284.19	127.09
LD1	345.86	238.99	106.87
LC2	362.22	250.29	111.93
LC1	306.62	211.87	94.75
LB2	344.23	237.86	106.37
LB1	293.53	202.83	90.70
CE2	381.84	263.85	117.99
CE1	352.41	243.52	108.89
CD2	362.22	250.29	111.93
CD1	332.78	229.95	102.83
CC2	318.06	219.78	98.28
CC1	295.17	203.96	91.21
CB2	295.17	203.96	91.21
CB1	273.91	189.27	84.64
CA2	251.02	173.45	77.57
CA1	234.66	162.15	72.51
BB2	265.73	183.62	82.11
BB1	254.29	175.71	78.58
BA2	221.58	153.11	68.47
BA1	211.77	146.33	65.44
PE2	352.41	243.52	108.89
PE1	336.05	232.21	103.84
PD2	332.78	229.95	102.83
PD1	316.43	218.65	97.78
PC2	286.99	198.31	88.68
PC1	273.91	189.27	84.64
PB2	244.48	168.94	75.54
PB1	234.66	162.15	72.51
PA2	203.59	140.68	62.91
PA1	195.42	135.04	60.38

Section 1888(e)(4)(G)(ii) of the Act also requires that we apply this wage index in a manner that does not result in aggregate payments under the SNF PPS that are greater or less than would otherwise be made if the wage adjustment had not been made. For FY 2016 (federal rates effective October 1, 2015), we will apply an adjustment to fulfill the budget neutrality requirement. We meet this requirement by multiplying each of the components of the unadjusted federal rates by a budget neutrality factor equal to the ratio of the weighted average wage adjustment factor for FY 2015 to the weighted average wage adjustment factor for FY 2016. For this calculation, we use the same FY 2014 claims utilization data for both the numerator and denominator of this ratio. We define the wage adjustment factor used in this calculation as the labor share of the rate component multiplied by the wage index plus the non-labor share of the rate component. The budget neutrality factor for FY 2016 would be 0.9992.

In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in the OMB Bulletin No. 03–04 (June 6, 2003), available online at *www.whitehouse.gov/omb/bulletins/b03-04.html*, which announced revised definitions for MSAs and the creation of micropolitan statistical areas and combined statistical areas.

In adopting the CBSA geographic designations, we provided for a 1-year transition in FY 2006 with a blended wage index for all providers. For FY 2006, the wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the FY 2006 SNF PPS transition wage index. As discussed in the SNF PPS final rule for FY 2006 (70 FR 45041), since the expiration of this 1-year transition on September 30, 2006, we have used the full CBSA-based wage index values.

On February 28, 2013, OMB issued OMB Bulletin No. 13–01, announcing revisions to the delineation of MSAs, Micropolitan Statistical Areas, and Combined Statistical Areas, and guidance on uses of the delineation of

these areas. This bulletin, which is available online at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf*, 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.

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 FY 2006, the February 28, 2013 bulletin does contain a number of significant changes. For example, there are new CBSAs, urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart.

In the FY 2015 SNF PPS final rule (79 FR 45644 through 45646), we finalized changes to the SNF PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01, beginning in FY 2015, including a 1-year transition with a blended wage index for FY 2015. Because the 1-year transition period expires at the end of FY 2015, the SNF PPS wage index for FY 2016 is fully based on the revised OMB delineations adopted in FY 2015. As noted in this section, the wage index applicable to FY 2016 is set forth in Table A available on the CMS Web site at *http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html*.

5. Adjusted Rate Computation Example

Using the hypothetical SNF XYZ described below, Table 9 shows the adjustments made to the federal per diem rates to compute the provider's actual per diem PPS payment. We derive the Labor and Non-labor columns from Table 7. The wage index used in this example is based on the wage index found in Table A as referenced in this section. As illustrated in Table 9, SNF XYZ's total PPS payment would equal $45,256.24.

TABLE 9—ADJUSTED RATE COMPUTATION EXAMPLE SNF XYZ: LOCATED IN FREDERICK, MD (URBAN CBSA 43524) WAGE INDEX: 0.9640

[See wage index in table A] [1]

RUG–IV Group	Labor	Wage index	Adjusted labor	Non-labor	Adjusted rate	Percent adjustment	Medicare days	Payment
RVX	$483.11	0.9640	$465.72	$216.04	$681.76	$681.76	14	$9,544.64
ES2	387.90	0.9640	373.94	173.46	547.40	547.40	30	16,422.00
RHA	243.73	0.9640	234.96	108.99	343.95	343.95	16	5,503.20
CC2*	224.68	0.9640	216.59	100.47	317.06	722.90	10	7,229.00
BA2	154.89	0.9640	149.31	69.27	218.58	218.58	30	6,557.40
							100	45,256.24

* Reflects a 128 percent adjustment from section 511 of the MMA.
[1] Available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html*.

C. Additional Aspects of the SNF PPS

1. SNF Level of Care—Administrative Presumption

The establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage. However, because the case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy, we have attempted, where possible, to coordinate claims review procedures with the existing resident assessment process and case-mix classification system discussed in section III.B.3 of this final rule. This approach includes an administrative presumption that utilizes a beneficiary's initial classification in one of the upper 52 RUGs of the 66-group RUG–IV case-mix classification system to assist in making certain SNF level of care determinations.

In accordance with section 1888(e)(4)(H)(ii) of the Act and the regulations at § 413.345, we include in each update of the federal payment rates in the **Federal Register** the designation of those specific RUGs under the classification system that represent the required SNF level of care, as provided in § 409.30. As set forth in the FY 2011 SNF PPS update notice (75 FR 42910), this designation reflects an administrative presumption under the 66-group RUG–IV system that beneficiaries who are correctly assigned to one of the upper 52 RUG–IV groups on the initial 5-day, Medicare-required assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date on the five-day Medicare-required assessment.

A beneficiary assigned to any of the lower 14 RUG–IV groups is not automatically classified as either meeting or not meeting the definition, but instead receives an individual level of care determination using the existing administrative criteria. This presumption recognizes the strong likelihood that beneficiaries assigned to one of the upper 52 RUG–IV groups during the immediate post-hospital period require a covered level of care, which would be less likely for those beneficiaries assigned to one of the lower 14 RUG–IV groups.

In the July 30, 1999 final rule (64 FR 41670), we indicated that we would announce any changes to the guidelines for Medicare level of care determinations related to modifications in the case-mix classification structure. In this final rule, we will continue to designate the upper 52 RUG–IV groups for purposes of this administrative presumption, consisting of all groups encompassed by the following RUG–IV categories:

- Rehabilitation plus Extensive Services.
- Ultra High Rehabilitation.
- Very High Rehabilitation.
- High Rehabilitation.
- Medium Rehabilitation.
- Low Rehabilitation.
- Extensive Services.
- Special Care High.
- Special Care Low.
- Clinically Complex.

However, we note that this administrative presumption policy does not supersede the SNF's responsibility to ensure that its decisions relating to level of care are appropriate and timely, including a review to confirm that the services prompting the beneficiary's assignment to one of the upper 52 RUG–IV groups (which, in turn, serves to trigger the administrative presumption) are themselves medically necessary. As we explained in the FY 2000 SNF PPS final rule (64 FR 41667), the administrative presumption:

. . . is itself rebuttable in those individual cases in which the services actually received by the resident do not meet the basic statutory criterion of being reasonable and necessary to diagnose or treat a beneficiary's condition (according to section 1862(a)(1) of

the Act). Accordingly, the presumption would not apply, for example, in those situations in which a resident's assignment to one of the upper . . . groups is itself based on the receipt of services that are subsequently determined to be not reasonable and necessary.

Moreover, we want to stress the importance of careful monitoring for changes in each patient's condition to determine the continuing need for Part A SNF benefits after the assessment reference date of the 5-day assessment.

We received one comment on this issue, which we discuss below along with our response.

Comment: One commenter requested that CMS consider further analysis of the administrative presumption that utilizes a beneficiary's initial classification in one of the upper 52 RUGs to assist in making certain SNF level of care determinations. The commenter expressed concern that the use of such presumptions could disadvantage members of certain vulnerable specialty populations who might not typically group to one of the upper 52 RUGs, and yet still require a sufficient intensity of services to qualify for coverage.

Response: While it is true that those SNF residents who group to one of the lower 14 RUGs on the initial 5-day, Medicare-required assessment are not automatically *presumed* to require a skilled level of care, neither are they automatically classified as requiring nonskilled care. Instead, as we have noted in this and previous SNF PPS rules, any such resident ''. . . receives an individual level of care determination using the existing administrative criteria.'' We adopted this approach specifically to ensure that the presumption does not disadvantage such residents, by providing them with an individualized level of care determination that fully considers all pertinent factors. Nevertheless, as we noted previously in the FY 2000 SNF PPS final rule (64 FR 41668, July 30, 1999), while we believe that the use of the administrative level of care presumption ''. . . represents a significant advancement toward achieving greater simplicity, predictability, and consistency in the coverage process, we will continue to monitor coverage determinations under the SNF PPS with a view toward the possibility of making further refinements and improvements in the future.'' Accordingly, we will keep the commenter's concerns in mind as we continue our ongoing SNF PPS research and analysis.

2. Consolidated Billing

Sections 1842(b)(6)(E) and 1862(a)(18) of the Act (as added by section 4432(b) of the BBA) require a SNF to submit consolidated Medicare bills to its Medicare Administrative Contractor for almost all of the services that its residents receive during the course of a covered Part A stay. In addition, section 1862(a)(18) of the Act places the responsibility with the SNF for billing Medicare for physical therapy, occupational therapy, and speech-language pathology services that the resident receives during a noncovered stay. Section 1888(e)(2)(A) of the Act excludes a small list of services from the consolidated billing provision (primarily those services furnished by physicians and certain other types of practitioners), which remain separately billable under Part B when furnished to a SNF's Part A resident. These excluded service categories are discussed in greater detail in section V.B.2. of the May 12, 1998 interim final rule (63 FR 26295 through 26297).

A detailed discussion of the legislative history of the consolidated billing provision is available on the SNF PPS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_07302013.pdf*. In particular, section 103 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113) amended section 1888(e)(2)(A) of the Act by further excluding a number of individual ''high-cost, low probability'' services, identified by Healthcare Common Procedure Coding System (HCPCS) codes, within several broader categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that otherwise remained subject to the provision. We discussed this BBRA amendment in greater detail in the SNF PPS proposed and final rules for FY 2001 (65 FR 19231 through 19232, April 10, 2000, and 65 FR 46790 through 46795, July 31, 2000), as well as in Program Memorandum AB–00–18 (Change Request #1070), issued March 2000, which is available online at *www.cms.gov/transmittals/downloads/ab001860.pdf*.

As explained in the FY 2001 proposed rule (65 FR 19231 through 19232), the amendments enacted in section 103 of the BBRA not only identified for exclusion from this provision a number of particular service codes within four specified categories (that is, chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices), but also gave the Secretary ''. . . the authority to designate additional, individual services for exclusion within each of the specified service categories.'' In the proposed rule for FY 2001, we also noted that the BBRA Conference report (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)) characterizes the individual services that this legislation targets for exclusion as ''. . . high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment [SNFs] receive under the prospective payment system. . . .'' According to the conferees, section 103(a) of the BBRA ''is an attempt to exclude from the PPS certain services and costly items that are provided infrequently in SNFs. . . .'' By contrast, we noted that the Congress declined to designate for exclusion any of the remaining services within those four categories (thus, leaving all of those services subject to SNF consolidated billing), because they are relatively inexpensive and are furnished routinely in SNFs.

As we further explained in the final rule for FY 2001 (65 FR 46790), and as our longstanding policy, any additional service codes that we might designate for exclusion under our discretionary authority must meet the same statutory criteria used in identifying the original codes excluded from consolidated billing under section 103(a) of the BBRA: they must fall within one of the four service categories specified in the BBRA; and they also must meet the same standards of high cost and low probability in the SNF setting, as discussed in the BBRA Conference report. Accordingly, we characterized this statutory authority to identify additional service codes for exclusion ''. . . as essentially affording the flexibility to revise the list of excluded codes in response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice)'' (65 FR 46791), and since that time, we have periodically invited the public to submit comments identifying codes that might meet the criteria for exclusion. In the FY 2016 SNF PPS proposed rule (80 FR 22057–58), we specifically invited public comments identifying HCPCS codes in any of these four service categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) representing recent medical advances that might meet our criteria for exclusion from SNF consolidated billing, and we requested

commenters to identify in their comments the specific HCPCS code that is associated with the service in question, as well as their rationale for requesting that the identified HCPCS code(s) be excluded. A discussion of the public comments received on this topic, along with our responses, appears below.

Comment: One commenter recommended a new chemotherapy drug, BLINCYTO®, as meeting the statutory ''high-cost, low probability'' criteria for exclusion from consolidated billing. After noting that this drug currently is assigned a temporary C code, C9449 (Injection, blinatumomab, 1 mcg.), the commenter referred to our explanation in the FY 2015 SNF PPS final rule that ''. . . a chemotherapy drug's assignment to its own specific code has always served as the mechanism of designating that drug for exclusion, as well as the means by which the claims processing system is able to recognize that exclusion'' (79 FR 45642, August 5, 2014). The commenter then suggested that until such time as this drug may be assigned a permanent J code of its own, CMS should devise an administrative alternative for effectuating its exclusion from consolidated billing, such as utilizing the drug's existing C code for this purpose. The commenter further stated that the exclusion list's current use of C codes for designating the excluded magnetic resonance imaging (MRI) services in Major Category I.C establishes the feasibility of similarly adopting such an approach for chemotherapy drugs like BLINCYTO® under Major Category III.A.

Response: We agree with the commenter that, as described, this drug would appear to meet the ''high-cost, low probability'' criteria to qualify for the statutory carve-out of certain highly intensive chemotherapy drugs from consolidated billing. We note that, as described in the National Institutes of Health's *MedlinePlus* Web site at *www.nlm.nih.gov/medlineplus/druginfo/meds/a614061.html*, this is one of the types of drugs referenced in the BBRA Conference Report's legislative history on the chemotherapy exclusion (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)); namely, those chemotherapy drugs that ''. . . are given as infusions, thus requiring special staff expertise to administer.'' In addition, the comment itself notes that ''In the six months since BLINCYTO® has been approved and available on the market, we are not aware of *any* patients who were treated with BLINCYTO® in the SNF setting'' (emphasis added). However, we are unable to adopt the commenter's suggestion that until a specific J code is assigned, a C code appropriately could be used on an interim basis as a vehicle for designating a chemotherapy drug for exclusion from consolidated billing. While the commenter is correct in pointing out some excluded MRI services that are identified by C code, we note that these C codes are designed specifically for use under the outpatient *hospital* PPS (OPPS), and that in contrast to the administrative exclusion for MRIs—which is a *hospital-specific* exclusion—the statutory chemotherapy exclusion is a *categorical* one that applies equally to hospital and non-hospital settings alike. This means that a temporary C code would not be suitable for the purpose of excluding chemotherapy drugs from consolidated billing and that, as we indicated previously in the FY 2015 SNF PPS final rule, we are unable to designate a chemotherapy drug for exclusion from consolidated billing prior to the point at which it is actually assigned its own permanent J code. Accordingly, we plan to add this drug to the exclusion list, at such time as it may be assigned a specific J code of its own.

Comment: Several commenters expressed their continued support for the longstanding statutory exclusion from consolidated billing of certain specified types of customized prosthetic devices, and recommended the exclusion of two additional prosthetic device codes, L5969 (''ankle/foot power assist, including motors'') and L5987 (''all lower extremity prosthesis, shank foot system with vertical loading pylon''). One commenter further recommended that certain customized orthotic devices meeting the statutory ''high-cost, low probability'' criteria be excluded as well.

Response: We note that code L5969 actually appears on the exclusion list already under Major Category III.D (''Customized Prosthetic Devices''), where this particular L code has, in fact, been listed ever since its initial assignment in January 2014. Regarding code L5987, we note that this particular code had been recommended for exclusion previously during the FY 2012 rulemaking cycle, along with two other L codes that, like L5987, already existed—but were not designated by the Congress for exclusion—upon the original 1999 enactment of the customized prosthetic device exclusion in the BBRA. In the FY 2012 SNF PPS final rule (76 FR 48531, August 8, 2011), we issued our decision to ''. . . decline to add these codes to the exclusion list,'' explaining that

> . . . our position has always been that the BBRA's discretionary authority to exclude codes within certain designated service categories applies solely to codes that were created subsequent to the BBRA's enactment, and not to those codes that were already in existence as of July 1, 1999 (the date that the legislation itself uses as the reference point for identifying the codes that it designates for exclusion). As we explained in the FY 2010 final rule (74 FR 40354), this position reflects the assumption that if a particular code was already in existence as of that date but not designated for exclusion, this meant that it was intended to remain within the SNF PPS bundle, subject to the BBRA Conference Report's provision for a GAO review of the code set that was conducted the following year (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)).

Regarding the suggestion on excluding certain customized orthotic devices under this authority, we have explained repeatedly in this and previous rules that the amendments enacted in section 103 of the BBRA *only* allow us to identify additional codes for exclusion *within* each of the four specified service categories: chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices (a category that is separate from and *does not* encompass orthotics). Accordingly, as we have already indicated previously in the SNF PPS final rules for FY 2001 (65 FR 46790, July 31, 2000) and FY 2009 (73 FR 46436, August 8, 2008), because orthotic devices do not fall within any of these four specified service categories, excluding them from consolidated billing would require legislation by the Congress to amend the law.

Comment: Several commenters on the VBP provision additionally alleged that there is an inherent ''tension'' between VBP and consolidated billing (the SNF PPS's bundling requirement), particularly with respect to portable x-rays and other types of diagnostic imaging, services that the commenters characterized as playing a key role in providing high-quality patient care. The commenters stated that the inclusion of these services within the PPS bundle incentivizes SNFs to select suppliers of diagnostic services solely on the basis of price, without considering the quality of the services. They also stated that the current framework allows a practice in which a supplier offers to furnish deeply discounted services to the SNF's Part A residents in return for being selected to handle the Part B services for those of the SNF's Medicare-eligible residents who are in noncovered stays. The commenters recommended that diagnostic imaging services should be unbundled altogether (or, alternatively,

if left within the bundle, that the SNF should be required to pay its supplier the full Part B fee schedule amount for them). They suggested that unbundling these services would enable SNFs to focus more on the quality of the services themselves rather than on the details of the billing process. Some of the commenters additionally noted that certain diagnostic radiology services such as portable x-rays are split between a bundled technical component (TC, representing the diagnostic test itself) and a separately billable professional component (PC, representing the physician's interpretation of the test), and they asserted that the portable x-ray's transportation and setup should appropriately be classified under the separately billable PC rather than the bundled TC, stating that the assignment of a Level II HCPCS code is sufficient in itself to identify a service as being an excluded ''physician'' service in this context.

Response: We have long recognized the incentives to realize efficiencies in providing care that are inherent in *any* bundled payment requirement, along with the attendant concerns about the potential effect of those incentives on quality of care. However, we do not believe that the commenters, in citing the SNF VBP as a new basis for reiterating these recurring concerns, have established sufficient justification for unbundling diagnostic imaging services from consolidated billing—an action that, in any event, would require legislation by the Congress. We also note that the long-term care facility requirements for participation, which long predate the VBP legislation, contain at 42 CFR 483.25 an overall mandate for Medicare SNFs to provide ''. . . the necessary care and services to attain or maintain [each resident's] highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.'' In addition, whenever a SNF elects to obtain such services from an outside source, the requirements at § 483.75(h)(2)(i) further confer on the SNF the specific responsibility to obtain ''. . . services that meet professional standards and principles that apply to professionals providing services in such a facility.'' Thus, a SNF that fails to provide the appropriate quantity *or quality* of care in accordance with this mandate would jeopardize its compliance with the requirements for participation in the Medicare program.

Moreover, we do not accept the commenters' premise that placing the billing responsibility with the SNF itself has the effect of distracting from a focus on quality of care. To the contrary, the consolidated billing provision was itself established precisely to help *promote* the overall coordination of high-quality care in the SNF setting. We note that prior to the enactment of this provision, care for SNF residents could be fragmented among a wide variety of outside suppliers who were not required to bill through the SNF. The resulting dispersal of responsibility for resident care among various outside suppliers adversely affected quality (coordination of care) and program integrity, as documented in reports by both the Office of the Inspector General (OIG) and the Government Accountability Office (GAO) (see OIG report no. OEI–06–92–00863, ''Medicare Services Provided to Residents of Skilled Nursing Facilities'' (October 1994), available online at *https://oig.hhs.gov/oei/reports/oei-06-92-00863.pdf*, and GAO report no. HEHS–96–18, ''Providers Target Medicare Patients in Nursing Facilities'' (January 1996), available online at *http://www.gao.gov/products/HEHS-96-18*). Thus, the enactment of consolidated billing reflected a recognition that fully enabling SNFs to ensure the overall quality of their residents' services necessitated placing with the SNF itself not only the professional but also the *financial* responsibility for those services.

As for the commenters' suggestions on requiring SNFs to pay suppliers the full Part B fee schedule amount for a bundled service, in the FY 2000 SNF PPS final rule (64 FR 41677, July 30, 1999), we noted in response to previous, similar suggestions that

> . . . under current law, an SNF's relationship with its supplier is essentially a private contractual matter, and the terms of the supplier's payment by the SNF must be arrived at through direct negotiations between the two parties themselves. Accordingly, we believe that the most effective way for a supplier to address any concerns that it may have about the adequacy or timeliness of the SNF's payment would be for the supplier to ensure that any terms to which it agrees in such negotiations satisfactorily address those concerns.

In that same final rule (64 FR 41677), we also noted in response to previous, similar concerns regarding supplier discounts that

> . . . our discussion of the relationship between an SNF and its suppliers should not be construed as addressing in any manner the potential applicability of the statutory anti-kickback provisions, since matters relating specifically to the enforcement of these provisions lie exclusively within the purview of the Office of the Inspector General.

Finally, we do not share the view of those commenters who would categorize a portable x-ray service's transportation and setup as part of the separately billable PC; rather, as noted in § 90.5 of the Medicare Claims Processing Manual, Chapter 13 (available online at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c13.pdf*):

> . . . When a SNF resident receives a portable x-ray service during the course of a Medicare-covered stay in the SNF, only the service's professional component (representing the physician's interpretation of the test results) is a separately billable physician service under Part B . . . By contrast, the technical component representing the procedure itself, *including any associated transportation and setup costs,* would be subject to consolidated billing (the SNF ''bundling'' requirement for services furnished to the SNF's Part A residents), and must be included on the SNF's Part A bill for the resident's covered stay (Bill Type 21x) rather than being billed separately under Part B . . . (emphasis added).

Moreover, notwithstanding the commenters' assertions, the assignment of a Level II HCPCS code to a particular service would in no way automatically equate to identifying it as an excluded ''physician'' service in this context. Rather, under the regulations at 42 CFR 411.15(p)(2)(i), the *only* services that can qualify for the physician service exclusion from consolidated billing are those that meet the criteria set forth in 42 CFR 415.102(a) for payment on a fee schedule basis as a *physician* service. Sections 415.102(a)(1) and (a)(3), in turn, specify that such a service must be *furnished personally by* a physician, and must be a type of service that *ordinarily requires* such performance. These are criteria that a portable x-ray service's transportation and setup would never meet, as the service's excluded PC relates solely to *reading* the x-ray rather than *taking* it, and the physician's personal performance clearly would not be required for activities such as driving the supplier's vehicle to the SNF, or setting up the equipment once it arrives there.

3. Payment for SNF-Level Swing-Bed Services

Section 1883 of the Act permits certain small, rural hospitals to enter into a Medicare swing-bed agreement, under which the hospital can use its beds to provide either acute- or SNF-level care, as needed. For critical access hospitals (CAHs), Part A pays on a reasonable cost basis for SNF-level services furnished under a swing-bed agreement. However, in accordance with section 1888(e)(7) of the Act, these services furnished by non-CAH rural

hospitals are paid under the SNF PPS, effective with cost reporting periods beginning on or after July 1, 2002. As explained in the FY 2002 final rule (66 FR 39562), this effective date is consistent with the statutory provision to integrate swing-bed rural hospitals into the SNF PPS by the end of the transition period, June 30, 2002.

Accordingly, all non-CAH swing-bed rural hospitals have now come under the SNF PPS. Therefore, all rates and wage indexes outlined in earlier sections of this final rule for the SNF PPS also apply to all non-CAH swing-bed rural hospitals. A complete discussion of assessment schedules, the MDS, and the transmission software (RAVEN–SB for Swing Beds) appears in the FY 2002 final rule (66 FR 39562) and in the FY 2010 final rule (74 FR 40288). As finalized in the FY 2010 SNF PPS final rule (74 FR 40356 through 40357), effective October 1, 2010, non-CAH swing-bed rural hospitals are required to complete an MDS 3.0 swing-bed assessment which is limited to the required demographic, payment, and quality items. The latest changes in the MDS for swing-bed rural hospitals appear on the SNF PPS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html*. We received no comments on this aspect of the proposed rule.

D. Other Issues

1. SNF Value-Based Purchasing (VBP) Program

a. Background

(1) Overview

In recent years, we have undertaken a number of initiatives to promote higher quality and more efficient health care for Medicare beneficiaries. These initiatives, which include demonstration projects, QRPs, and VBP programs, have been implemented in various health care settings, including physician offices, ambulatory surgical centers (ASCs), hospitals, nursing homes, home health agencies (HHAs), and dialysis facilities. Many of these programs link a portion of Medicare payments to provider reporting or performance on quality measures. The overarching goal of these initiatives is to transform Medicare from a passive payer of claims to an active purchaser of quality health care for its beneficiaries.

We view VBP as an important step toward revamping how care is paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely volume.

(2) SNF VBP Report to Congress

Section 3006(a) of the Affordable Care Act required the Secretary to develop a plan to implement a VBP program under the Medicare program for SNFs (as defined in section 1819(a) of the Act) and to submit that plan to Congress. In developing the plan, this section required the Secretary to consider several issues, including the ongoing development, selection, and modification process for measures, the reporting, collection, and validation of quality data, the structure of value-based payment adjustments, methods for public disclosure of SNF performance, and any other issues determined appropriate by the Secretary. The Secretary was also required to consult with relevant affected parties and consider experience with demonstrations relevant to the SNF VBP Program.

HHS submitted the Report to Congress required under section 3006 of the Affordable Care Act in March 2012. The report explains that a significant number of elderly Americans receive care in SNFs/NFs, either as short-term post-acute care or as long-term custodial care, and that quality of care is a significant concern for a subset of SNFs/NFs. The report also states that the SNF PPS does not strongly incentivize SNFs to furnish high quality care to this very fragile patient population. The report concludes that the Medicare program could incentivize SNFs to improve the quality of care for their patients.

In the report, we explained our belief that the implementation of a SNF VBP Program is a central step in revamping Medicare's payments for health care services to reward better value, outcome, and innovations, rather than the volume of care. We also explained our belief that a SNF VBP Program should promote the development and use of robust quality measures, including measures that assess functional status, to promote timely, safe, and high-quality care for Medicare beneficiaries. We noted that the creation of a SNF VBP Program would align with numerous HHS and CMS efforts to improve care coordination, and would be consistent with the National Quality Strategy and its aims of Better Care, Healthy People and Communities, and Affordable Care.

The full report is available on our Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/SNF-VBP-RTC.pdf*.

b. Statutory Basis for the SNF VBP Program

Section 215 of PAMA added sections 1888(g) and (h) to the Act. Section 1888(g)(1) of the Act requires the Secretary to specify a SNF all-cause all-condition hospital readmission measure (or any successor to such a measure) not later than October 1, 2015. Section 1888(g)(2) of the Act requires the Secretary to specify an all-condition risk-adjusted potentially preventable hospital readmission rate for SNFs not later than October 1, 2016. Section 1888(g)(3) of the Act directs the Secretary to develop a methodology to achieve high reliability and validity for these measures, especially for SNFs with a low volume of readmissions. Section 1888(g)(4) of the Act makes the pre-rulemaking Measure Applications Partnership process of Section 1890A of the Act optional for these measures. Under section 1888(g)(5) of the Act, the Secretary is directed to provide quarterly confidential feedback reports to SNFs on their performance on the readmission or resource use measure beginning on October 1, 2016. Under section 1888(g)(6) of the Act, not later than October 1, 2017, the Secretary must establish procedures for making performance data on readmission and resource use measures public on *Nursing Home Compare* or a successor Web site. That paragraph also requires that the procedures ensure that a SNF has the opportunity to review and submit corrections to the information that is to be made public for it before that information is made public.

Section 1888(h)(1)(A) of the Act requires the Secretary to establish a SNF VBP program under which value-based incentive payments are made in a FY to SNFs, and section 1888(h)(1)(B) of the Act requires that the Program apply to payments for services furnished on or after October 1, 2018. Under section 1888(h)(2)(A) of the Act, the Secretary must apply the readmission measure specified under section 1888(g)(1) of the Act for purposes of the Program, and section 1888(h)(1)(B) of the Act requires the Secretary to apply the resource use measure specified under section 1888(g)(2) of the Act instead of the readmission measure specified under section 1888(g)(1) as soon as practicable. Sections 1888(h)(3)(A) and (B) of the Act require the Secretary to establish performance standards for the measure applied under section 1888(h)(2) of the Act for a performance period for a FY and that those performance standards include levels of achievement and improvement. In addition, in calculating the SNF performance score for the

measure under the Program, section 1888(h)(3)(B) of the Act requires the Secretary to use the higher of achievement or improvement scores. Further, the performance standards established under section 1888(h)(3) of the Act must, under section 1888(h)(3)(C), be established and announced by the Secretary not later than 60 days prior to the beginning of the performance period for the FY involved.

Section 1888(h)(4) of the Act directs the Secretary to develop a methodology to assess each SNF's total performance based on the performance standards for the applicable measure for each performance period. Under section 1888(h)(4)(B) of the Act, SNF performance scores for the performance period for each FY must be ranked from low to high.

Section 1888(h)(5) of the Act outlines several requirements for value-based incentive payments under the SNF VBP Program. Under section 1888(h)(5)(A) of the Act, the Secretary is directed to increase the adjusted federal per diem rate determined under section 1888(e)(4)(G) for services furnished by a SNF by the value-based incentive payment amount determined under section 1888(h)(5)(B). This section also directs that the value-based incentive payment amount be equal to the product of the adjusted federal per diem rate and the value-based incentive payment percentage specified under section 1888(h)(5)(C) of the Act for the SNF for the FY. Section 1888(h)(5)(C) requires the Secretary to specify a value-based incentive payment percentage for a SNF for a FY, which may include a zero percentage. The Secretary is further directed under section 1888(h)(5)(C) to ensure that such percentage is based on the SNF performance score for the performance period for the FY, that the application of all such percentages in a FY results in an appropriate distribution of value-based incentive payments, and that the total amount of value-based incentive payments for all SNFs for a FY be greater than or equal to 50 percent, but not greater than 70 percent, of the total amount of the reductions to payments for the FY under section 1888(h)(6), as estimated by the Secretary.

Section 1888(h)(6) of the Act requires the Secretary to reduce the adjusted federal per diem rate for SNFs otherwise applicable to each SNF for services furnished by that SNF during the applicable FY by the applicable percent, which is defined in paragraph (b) as 2 percent for FY 2019 and subsequent years. Section 1888(h)(7) of the Act requires the Secretary to inform each SNF of its payment adjustments under the Program not later than 60 days prior to the FY involved, and under section 1888(h)(8) of the Act, the value-based incentive payments calculated for a FY apply only for that FY.

Section 1888(h)(9)(A) of the Act requires the Secretary to publish SNF-specific performance information on the *Nursing Home Compare* Web site or a successor Web site, including SNF performance scores and rankings. Section 1888(h)(9)(B) of the Act requires the Secretary to post aggregate information on the SNF VBP Program, including the range of SNF performance scores and the number of SNFs receiving value-based incentive payments and the range and total amount of those payments.

We received a number of general comments on the SNF VBP Program.

Comment: Commenters suggested that we phase-in the SNFRM to ensure that providers are fully capable of reporting the measure accurately and to ensure that it is fully valid and accurate. Commenters suggested that such a phase-in should include a period of ''hold-harmless reporting'' and data collection that does not include penalties or incentive payments.

Response: We do not have the administrative discretion to phase-in the SNF VBP Program as the commenter suggests, since section 1888(h)(1)(B) of the Act requires us to apply the Program to payments for services furnished on or after October 1, 2018. However, section 1888(g)(5) requires us to provide quarterly, confidential feedback reports to SNFs on their performance on measures specified for the program beginning October 1, 2016. We believe those feedback reports will meet the commenter's request that we provide feedback on the measure during a time period that would not involve penalties or incentive payments. Additionally, we would remind commenters that the SNFRM is a claims-based measure, and therefore will not require any additional data to be submitted by SNFs.

Comment: Commenters recommended that proposed measures should align, where possible, with existing quality measures across settings and by payment type (such as ACO or bundled payments).

Response: We will take the recommendation into account as we further develop and implement the Program.

Comment: Commenters urged us to adopt an Extraordinary Circumstances Exception process for the SNF VBP Program to ensure that facilities do not incur penalties under the program during major weather events or other circumstances beyond their control.

Response: We will take the recommendation into account as we further develop and implement the Program.

Comment: Commenters suggested that we set up a regular workgroup to discuss the SNF VBP Program's development with stakeholders.

Response: We intend to continue outreach efforts to the SNF community as we develop the Program.

Comment: Commenters suggested that we should adopt a rule prohibiting value-based incentive payments under the SNF VBP Program to any SNF that does not accurately report staffing data or does not have sufficient nursing staff to meet residents' needs.

Response: We thank the commenters for this suggestion and will consider it, if legally feasible, as part of the Program's scoring policies in the future.

Comment: Commenters suggested that we adopt a nutritional status domain and implement a malnutrition-related quality measure in the future for the SNF VBP Program. Other commenters suggested measures that are currently displayed on *Nursing Home Compare,* those that were part of the SNF VBP demonstration, or those that are part of the new SNF QRP.

Response: We do not believe we have the authority to adopt measures covering additional clinical topics beyond those specified in sections 1888(g)(1) and (2) of the Act at this time.

Comment: Commenters urged us to make SNF VBP Program data as contemporaneous as possible. Commenters noted that more recent hospitalization data allow SNFs to monitor their performance and better realize the connection between their performance rates and their payment rates.

Response: We intend to make SNFs' performance data available as quickly as is practicable to ensure that facilities are able to understand their performance and undertake quality improvement efforts.

Comment: Commenters encouraged us to develop the statutorily-mandated resource use measure specified under section 1888(g)(2) of the Act as soon as possible, and to share a timeline for when the measure will replace the SNFRM. Some commenters also stated that the potentially preventable hospital readmissions measure needs additional testing and more detailed public information.

Response: We thank the commenters for this request. At this time, we have not specified the resource use measure under section 1888(g)(2) of the Act. We

will make all details available, including technical reports presenting results of measure testing and technical expert input, in the future and will seek public comment.

We thank the commenters for this general feedback, and will take it into account in future rulemaking.

c. Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510; Measure Steward: CMS)

(1) Overview

Reducing hospital readmissions is important for quality of care and patient safety. Readmission to a hospital may be an adverse event for patients and in many cases imposes a financial burden on the health care system. Successful efforts to reduce preventable readmission rates will improve the quality of care furnished to beneficiaries while simultaneously decreasing the cost of that care. Hospitals and other health care providers can work with their communities to lower readmission rates and improve patient care in a number of ways, such as by ensuring that patients are clinically ready to be discharged, reducing infection risk, reconciling medications, improving communication with community providers responsible for post-discharge patient care, improving care transitions, and ensuring that patients understand their care plans upon discharge.

Many studies have demonstrated the effectiveness of these types of in-hospital and post-discharge interventions in reducing the risk of readmission, confirming that hospitals and their partners have the ability to lower readmission rates.[1 2 3] These types of efforts during and after a hospitalization have been shown to be effective in reducing readmission rates in geriatric populations generally,[4 5] as well as for multiple specific conditions. Moreover, such interventions can result in cost saving. Financial incentives to reduce readmissions will in turn promote improvement in care transitions and care coordination, as these are important means of reducing preventable readmissions.[6] In its 2007 Report to Congress on Promoting Better Efficiency in Medicare,[7] MedPAC noted the potential benefit to patients of lowering readmissions and suggested payment strategies that would incentivize hospitals to reduce these rates. Readmission rates are important markers of quality of care, particularly of the care of a patient in transition from an acute care setting to a non-acute care setting, and improving readmissions can positively influence patient outcomes and the cost of care.

We proposed to specify the SNF 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) as the SNF all-cause, all-condition hospital readmission measure under section 1888(g)(1) of the Act. This measure assesses the risk-standardized rate of all-cause, all-condition, unplanned inpatient hospital readmissions of Medicare fee-for-service (FFS) SNF patients within 30 days of discharge from an admission to an inpatient prospective payment system (IPPS) hospital, CAH, or psychiatric hospital. This measure is claims-based, requiring no additional data collection or submission burden for SNFs.

We also proposed to apply this measure for purposes of the SNF VBP Program under section 1888(h)(2)(A) of the Act. We believe that this measure will (1) incentivize SNFs to make quality improvements that result in successful transitions of care for patients discharged from the hospital (IPPS, CAH or psychiatric hospital) setting to a SNF, and subsequently to the community or to another post-acute care setting, (2) reduce unplanned readmission rates of these patients to hospitals; and (3) align the SNF VBP Program with the National Quality Strategy priorities of safer, better coordinated care and lower costs.[8]

We developed this measure based upon the NQF-endorsed Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) (NQF #1789) (*http://www.qualityforum.org/QPS/1789*)[9] implemented in the Hospital Inpatient QRP. To the extent methodologically and clinically appropriate, we harmonized the SNFRM with the HWR measure specifications.

A discussion of the general comments that we received on the SNFRM, and our responses to those comments, appears below.

Comment: One commenter expressed concern about our proposal to adopt the SNFRM, stating that it does not align with the unplanned readmission measure for IRFs (NQF #2502), particularly in reporting period duration. The commenter stated that we should strive for alignment between post-acute care settings, particularly given the ongoing implementation of the IMPACT Act.

Response: We thank the commenter for their comments regarding alignment of these measures. The SNFRM (NQF #2510) is based on 12 months of data as this ensures an accurate sample size for calculating the Risk-Standardized Readmission Rate (RSRR). However, 24 months of data were needed to ensure sufficient sample sizes to reliably estimate and develop the all-cause, unplanned hospital readmission measures used in the Inpatient Rehabilitation Facility Quality Reporting Program (NQF #2502) and the Long-Term Care Hospital Quality Reporting Program, due to the substantially lower number of IRF and LTCH stays.

While we recognize that the SNFRM does not align with the unplanned readmission measure for IRFs (#2502), we are currently developing an unplanned readmission measure for IRFs that is analogous to the SNFRM in that it assesses readmissions among IRF patients following discharge from an acute care hospital. This second IRF measure is intended to exist in tandem with the existing IRF measure #2502, which assesses readmissions for 30 days following discharge from the IRF.

Comment: Some commenters supported our proposal to adopt the SNFRM, noting that the measure is consistent with other CMS readmission measures, and that it will decrease costs, improve patient safety, and promote the best possible clinical outcomes. Commenters suggested that we consider adopting additional measures in the future in the SNF VBP Program that cover resource use,

[1] Gwadry-Sridhar FH, Flintoft V, Lee DS, Lee H, Guyatt GH: A systematic review and meta-analysis of studies comparing readmission rates and mortality rates in patients with heart failure. Arch Intern Med. 2004;164(21):2315–2320.

[2] McAlister FA, Lawson FM, Teo KK, Armstrong PW.: A systematic review of randomized trials of disease management programs in heart failure. AmJMed. 2001;110(5):378–384.

[3] Krumholz HM, Amatruda J, Smith GL, et al.: Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. J Am Coll Cardiol. 2002;39(1):83–89.

[4] Coleman EA, Parry C, Chalmers S, Min SJ.: The care transitions intervention: Results of a randomized controlled trial. Arch Intern Med. 2006;166:1822–8.

[5] Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, Schwartz JS.: Comprehensive discharge planning and home follow-up of hospitalized elders: A randomized clinical trial. JAMA. 1999;281:613–20.

[6] Coleman EA.: 2005. Background Paper on Transitional Care Performance Measurement. Appendix I. In: Institute of Medicine, Performance Measurement: Accelerating Improvement. Washington, DC: National Academy Press.

[7] Medicare Payment Advisory Commission (MedPAC). Report to Congress: Promoting Greater Efficiency in Medicare; 2007. Available at *http://www.medpac.gov/documents/Jun07_EntireReport.pdf*. Accessed January 10, 2011.

[8] Wilson, N. U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality. (2014). National quality strategy: Overview.

[9] Adopted for the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS Final Rule (77 FR 53521 through 53528).

functional outcomes, and return to the community following discharge.

Response: We do not have the authority to adopt additional measures in the SNF VBP Program beyond those specified in sections 1888(g)(1) and (2) of the Act.

Comment: Some commenters suggested that we either adopt a readmission measure that includes all SNF patients, regardless of payer, or clarify that the SNFRM is an ''all-cause fee-for-service measure'' because it excludes Medicare Advantage beneficiaries.

Response: This measure is based on FFS claims, consistent with other hospital readmission measures used in other programs. The measure as specified requires Medicare claims to determine if any readmissions are deemed to be planned or unplanned and for comprehensive risk adjustment.

Comment: One commenter recommended that we ask the MAP to review PointRight OnPoint-30 SNF Rehospitalizations (NQF #2375) before taking a final position on the SNFRM (NQF #2510). The commenter explained that #2375 is an MDS-based measure that captures patients regardless of payer type and also includes observation admissions. The commenter further noted that #2375 risk adjusts for functional and clinical symptoms that are strong predictors of readmissions.

Response: We recognize the desirability of implementing an all-payer readmission measure. However, we have some concerns with including the measure (NQF #2375) in the SNF VBP program. The MDS-based measure excludes readmissions that occur after discharge from the SNF, which creates a perverse incentive for SNFs to discharge patients prematurely to avoid being penalized if the patients are considered a high risk for readmission. The MDS-based measure also does not exclude planned readmissions which are not indications of poor quality. Additionally, while NQF #2375 adjusts for functional and clinical symptoms, analyses conducted jointly by the developers of that measure and the SNFRM concluded that there is no substantial distinction in the risk models' capacity to assess readmission rates at the facility level.

Comment: One commenter asked that we clarify that the MAP process is not restricted to reviewing and commenting only on CMS-sponsored measures or measures presented by CMS to the MAP, per section 1890 of the Act. The commenter also requested that we clarify that the input from the MAP is not with the view that the measure is used for VBP, as they believed that a measure for payment should be evaluated in a different manner.

Response: It is correct that other measures are eligible for consideration in the MAP process. While the MAP provides input on measures selected by the Secretary, the pre-rulemaking provisions of the Act do not restrict the MAP from reviewing or recommending measures and methodologies in lieu of those under consideration by the Secretary. Therefore, we refer readers to the MAP Web site at *http://www.qualityforum.org/map/*. Additionally, we intend to provide the commenters' input to the NQF.

In addition, at times we request additional measures from external stakeholders and measure developers, which are also reviewed by the MAP. The MAP's input is responsive to the particular program for which its review was sought. In this case, the SNFRM was submitted via an ad hoc Measures Under Consideration list to the MAP for consideration in SNF–VBP. The MAP's 2015 recommendations, available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711,* show that the MAP supported the SNFRM's adoption for the SNF VBP Program.

Comment: One commenter opposed the proposed SNFRM, stating that the measure is self-reported because it is based on MDS information and that it is industry-developed and controlled.

Response: The proposed SNFRM is based on Medicare claims data and the measure does not use MDS information. Furthermore, the proposed measure was developed by CMS working with an independent CMS contractor, RTI International, and was not industry-developed. The proposed measure was endorsed by the National Quality Forum (NQF), and its specifications are available in our technical report, which is available on our Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNFRM-Technical-Report-3252015.pdf.*

Comment: Some commenters expressed concern that SNFs will not have access to the data used to calculate the SNFRM, and will therefore not be able to validate CMS's calculations.

Response: While we intend to make as much information related to SNFRM performance as possible available to SNFs through confidential quarterly feedback reports required under section 1888(g)(5) of the Act, we understand that claims-based quality measurement is difficult for providers to replicate. It would require familiarity with a number of data sources that are used to develop the risk-adjustment model for SNFRM in order to account for variation across SNFs in case-mix and patient characteristics predictive of readmission (including the MedPAR, Medicare Enrollment Database (EDB), Medicare Denominator files, Agency for Healthcare Research & Quality (AHRQ)'s Clinical Classification Software (CCS) groupings of ICD–9 codes, and CMS's hierarchical condition category (HCC) mappings of ICD–9 codes). We view this as a necessary compromise to minimize reporting burden on participating SNFs by using claims data while ensuring that we obtain timely data for quality measurement.

Comment: One commenter suggested that our longer-term goal should be to align the SNFRM with other relevant hospitalization measures planned for use, such as those being developed by states under section 1115 waivers and new value-based initiatives for the Medicare fee-for-service program.

Response: We thank the commenter for this feedback, and will consider how best to align our programs with these efforts in the future.

Comment: Some commenters expressed concerns about our proposal to adopt the SNFRM, stating that further vetting of the measure is warranted given commenter's belief that research cited on the measure is spare and includes only effectiveness studies limited to certain conditions.

Response: The SNFRM was developed using the Measures Management System (MMS) Blueprint, a process that included input from a TEP and a public comment period. The measure was also reviewed by the NQF, and supported by that body for endorsement in December 2014. We believe that this represents sufficient vetting for the purpose of implementing a measure in a VBP program. We welcome additional input regarding the research supporting or questioning the appropriateness of this, or any other measure.

Comment: One commenter urged us to consider adjusting the SNFRM for situations beyond facilities' control, such as family members insisting on a patient being hospitalized, and for patients with increased risks of hospitalization, including medically complex, frail elderly patients and those with certain primary diagnoses. The commenter also noted that avoidable hospital admissions frequently result from poorly managed transitions, and suggested that we investigate meaningful ways to capture and incentivize care transitions using this measure.

Response: The SNFRM, which was endorsed by the NQF, has been risk

adjusted for case-mix to account for differences in patient populations. The goal of risk adjustment is to account for these differences so that providers who treat sicker or more vulnerable patient populations are not unnecessarily penalized for factors that are outside of their control. The current measure accounts for: Principal diagnosis from the Medicare claim corresponding to the prior proximal hospitalization as categorized by AHRQ's CCS groupings, length of stay during the patient's prior proximal hospitalization, length of stay in the intensive care unit (ICU), end-stage renal disease (ESRD) status, whether the patient was disabled, the number of prior hospitalizations in the previous 365 days, system-specific surgical indicators, individual comorbidities as grouped by HCCs or other comorbidity indices, and a variable counting the number of comorbidities if the patient had more than two HCCs. Many of the factors, such as family preference, suggested by the commenter are not feasibly captured by any existing data source of which we are aware. The medical complexity of patients is captured to the extent possible through the comorbidity data described above. In this way, we are able to capture poorly managed transitions through risk adjusted readmissions rates.

Comment: One commenter encouraged us to consider creating safeguards for SNFs participating in the Program to ensure that patients are fully protected from unintended consequences resulting from the SNFRM's adoption, potentially including functional declines and resident deaths. The commenter suggested that a companion measure of death and decline of residents would determine whether SNFs improperly avoided hospitalizing residents who should have been hospitalized.

Response: We intend to monitor the effects of the SNFRM on clinical care closely, and we intend to take any necessary steps to ensure that SNFs do not avoid hospitalizing patients. Additional measures may be implemented in other SNF-related programs such as the QRP. However, as stated above, we do not have the authority to adopt additional measures under the Program beyond the ones required under sections 1888(g)(1) and (2) of the Act.

(2) Measure Calculation

The SNFRM estimates the risk-standardized rate of all-cause, unplanned, hospital readmissions for SNF Medicare FFS beneficiaries within 30 days of discharge from their prior proximal acute hospitalization. The SNF admission must have occurred within one day after discharge from the prior proximal hospitalization. The prior proximal hospitalization is defined as an inpatient admission to an IPPS, CAH, or a psychiatric hospital. Because the measure denominator is based on SNF admissions, each Medicare beneficiary may be included in the measure multiple times within a given year if they have more than one SNF stay meeting all measure inclusion criteria including a prior proximal hospitalization.

Patient readmissions included in the measure are identified by examining Medicare claims data for readmissions of SNF Medicare FFS beneficiaries to an IPPS, or CAH occurring within 30 days of discharge from the prior proximal hospitalization. If the patient was admitted to the SNF within 1 day of discharge from the prior proximal hospitalization and the hospital readmission occurred within the 30-day risk window, it is counted in the numerator regardless of whether the patient is readmitted directly from the SNF or has been discharged from the SNF. Because patients differ in complexity and morbidity, the measure is risk-adjusted for patient case-mix. The measure also excludes planned readmissions, because these are not considered to be indicative of poor quality of care by the SNF. Details regarding how readmissions are identified are available in our SNFRM Technical Report.[10]

The SNFRM (NQF #2510) assesses readmission rates while accounting for patient demographics, principal diagnosis in the prior hospitalization, comorbidities, and other patient factors. While estimating the predictive power of patient characteristics, the model also estimates a facility-specific effect common to patients treated at that SNF.

The SNFRM is calculated based on the ratio, for each SNF, of the number of risk-adjusted all-cause, unplanned readmissions to an IPPS or CAH that occurred within 30 days of discharge from the prior proximal hospitalization, including the estimated facility effect, to the estimated number of risk-adjusted predicted unplanned inpatient hospital readmissions for the same patients treated at the average SNF. A ratio above 1.0 indicates a higher than expected readmission rate, or lower level of quality, while a ratio below 1.0 indicates a lower than expected readmission rate, or higher level of quality. This ratio is referred to as the standardized risk ratio or SRR. The SRR is then multiplied by the overall national raw readmission rate for all SNF stays. The resulting rate is the risk-standardized readmission rate (RSRR). The full methodology is detailed in the SNFRM Technical Report.

The patient population includes SNF patients who:

- Had a prior hospital discharge (IPPS, CAH or psychiatric hospital) within 1 day of their admission to a SNF.
- Had at least 12 months of Medicare Part A, FFS coverage prior to their discharge date from the prior proximal hospitalization.
- Had Medicare Part A, FFS coverage during the 30 days (the 30-day risk window) following their discharge date from the prior proximal hospitalization.

A discussion of the general comments that we received on the SNFRM measure calculation, and our responses to those comments, appears below.

Comment: One commenter expressed concern about the SNFRM's readmission window, noting that just over one-third of SNF stays exceed the 30-day readmission window. The commenter suggested that adopting the 30-day window as proposed could relieve SNFs of accountability for longer-stay patients and could create incentives for SNFs to delay needed care until after day 30. The commenter further stated that SNFs should be responsible for every readmission that occurs while the beneficiary is in the SNF.

Response: We agree with the commenter's concerns that SNFs should be accountable for longer-stay patients who are admitted to an acute care hospital. The SNFRM is designed to assess failed transitions from an acute care hospital to the SNF, and is not intended to capture all hospitalizations that may occur in a SNF population. Including all admissions beyond 30 days in the population would attenuate the association between the transitions of care at the proximate discharge from an acute care hospital to the readmission.

Comment: Some commenters stated that the SNFRM does not hold SNFs fully accountable for transitions to the next care setting, and suggested that we should adopt separate measures of readmissions after discharge from the SNF and from the hospital. One commenter stated that the SNFRM's measurement period should capture rehospitalizations within 90 days, not just 30 days. The commenter noted that other efforts to reduce rehospitalizations

[10] Available on the Nursing Home Quality Initiative Web site at *https://www.cms.gov/Medicare/Quality-nitiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html?redirect=/nursinghomequalityinits/.*

focus on a 90-day time period, and suggested that the 30-day period may reflect poor hospital care more than care problems in the SNF.

Response: The 30-day readmission window was developed to harmonize with other hospital readmission measures and reflects a transitional time period during which the acute care hospital and SNF are responsible for coordinating the care of a patient moving from one setting to another. While there is no definitive timeframe for which such a measure may be applied, the 30-day window is consistent with similar measures applied in other VBP programs, such as the ESRD Quality Incentive Program and the Hospital Readmission Reduction Program, as well as a number of QRPs. Furthermore, this 30-day post-hospital discharge window was reviewed by a TEP. Analysis of readmission rates showed no patterns indicating that using a shorter or longer period would produce very different comparative results, though the overall rates would change. In addition, the NQF Standing Committee generally agreed that 30 days post-hospital discharge is an accepted standard for measuring readmissions. Longer windows may be subject to greater ''noise'' or statistical variability in the readmission rate. The measure as specified has the potential for this unintended consequence of delaying hospital care beyond the 30-day readmission window, but this issue may occur with any selected day threshold. We will be closely monitoring this and continue to analyze whether there are changes in the number of days to hospital readmission over time to assess whether a change to the readmissions window is needed for this measure in the future.

Comment: One commenter expressed concern about the time lag between the end of the measurement period and the release of clean, adjudicated claims data. The commenter was concerned that these delays could affect timely notice and payment for SNFs participating in the Program.

Response: We share the commenters' concern. As required by statute, we intend to provide quarterly feedback to SNFs to ensure that facilities have as much information as possible to inform their quality improvement efforts.

Comment: Commenters expressed concern that while the SNFRM accounts for principal diagnosis, that diagnosis may not be the reason for admission to a SNF. Commenters suggested that the SNFRM should also account for comorbidities, diagnoses from prior hospitalizations during the prior year, length of stay during the prior proximal hospitalization, length of stay in the ICU, body system specific surgical indicators, ESRD status, disability status, and number of prior hospitalizations during the previous year. Commenters also requested that we develop a list of comorbidities that are being evaluated in the SNFRM's risk adjustment model.

Response: We would like to clarify that the SNFRM is risk-adjusted for all of the factors cited by the commenter. The SNFRM accounts for all of the factors proposed in the comment above, including first diagnosis from the Medicare claim corresponding to the prior proximal hospitalization as coded by the AHRQ's CCS, length of stay during the patient's prior proximal hospitalization, indicator of a stay in the ICU, ESRD status, whether the patient was disabled, the number of prior hospitalizations in the previous 365 days, system-specific surgical indicators, individual comorbidities as grouped by CMS's (HCCs, and a variable counting the number of comorbidities if the patient had more than two HCCs. To capture comorbidities, we used the secondary medical diagnoses listed on the patient's prior proximal hospital claim as well as all diagnoses listed on acute care hospitalizations that occurred in the prior 12 months. We refer the commenter to the Technical Report for the SNFRM for additional information, which can be found on the Nursing Home Quality Initiative Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html.*

Comment: Some commenters disagreed with our proposal to adopt a measure based on claims data, stating that determining readmission rates will be difficult for SNFs since claims data are cumbersome to use or access. Commenters stated that the SNFRM will not provide meaningful insights or otherwise impact quality improvement efforts when facilities are unable to interpret or access the data.

Response: This measure was developed to harmonize with other hospital-based measures that are claims-based. Despite the commenter's concern that these data are difficult to access, the measure developer (RTI) cited evidence that these data are both reliable and valid. Further detail on this evidence is available in the SNFRM Technical Report, Section 3.5 (Validity Testing), available on the Nursing Home Quality Initiative Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/index.html.*

Furthermore, we intend to make performance reports available to facilities that are easy to interpret and present information on the facility-level readmission rates and relative standing on this measure, rather than information from the claims data directly. We intend to make SNFs' performance data available as quickly as is practicable. This will serve to provide information on a facility's performance and aid in informing quality improvement efforts at the facility level.

Comment: One commenter stated that readmission measures should be ''normalized'' instead of reported in simple percentage rates. The commenter believed that reductions in hospital admissions could result in more measured readmissions, even if the normalized readmission rate has remained constant. The commenter also suggested that undue variation may result for smaller facilities and fewer admissions.

Response: The percentages computed by the measure are normalized in the sense that they are computed with risk adjustment and may be compared to one another and to the national rate for SNFs. A ratio of the risk-adjusted predicted rate for each facility to the expected rate for the same patients at the average facility produces a normalized value (referred to as the standardized risk ratio) which is 1.0 for a facility with readmissions at the expected rate for its own patients, and higher or lower than 1.0 if the readmission rate is higher or lower. For ease of interpretation, this standardized risk ratio is converted to a standardized rate by multiplying it by the national raw rate. This is an accepted method for producing standardized rates that are comparable across facilities. There is no external percentage target that every facility must meet and the national mean rate is driven by the data for the measurement period. The national mean may go up or down over time reflecting a changing pool of patients, medical conditions, and treatments.

Variation in rates that may occur in facilities with low volume is dealt with by averaging the volatile facility data with the national mean when the hierarchical models are used. In addition, we will consider appropriate facility volume thresholds for reporting depending on the use of the measure.

Comment: One commenter recommended that we adopt a minimum of 30 qualified FFS admissions per 12-month period to calculate a statistically valid SNFRM rate. The commenter further stated that

any SNFs with fewer events should be excluded from the measure's calculation.

Response: We will consider whether we should establish a minimum number of qualifying admissions for the SNFRM in future rulemaking. The SNFRM utilizes shrinkage estimates to address the possibility of undue variation for smaller facilities. This is a design feature common to many of our readmission measures, including those implemented in the aforementioned programs, to ensure statistically valid rates.

Comment: One commenter stated that we should only count readmissions that occur while the patient resides in the SNF, not after discharge. The commenter stated that measure readmissions within the 30-day window but after SNF discharge necessitates measurement of 30-day rehospitalization rates for other providers as well. Commenters also noted that PAMA does not specify that the SNF measure align with the hospital's 30-day window and the Act uses ''Skilled Nursing Facility Measure'' throughout, which some commenters read to mean SNF only, not SNF plus follow on care after discharge.

Response: We agree that readmission rates for other providers are necessary, and this is one reason we have taken steps to implement readmissions measures in multiple settings across a wide variety of relevant quality programs. We believe that excluding readmissions that occur after discharge creates a perverse incentive for facilities to prematurely discharge patients who represent the highest risk for readmission to avoid penalty. Given that this measure is the sole determinant of a VBP program for SNFs, we believe it is appropriate to include readmissions that occur post-discharge but within the 30-day window, aligning with other readmission measures implemented by CMS. The goal of this measure is to capture readmissions that are attributable to care provided by the SNF, even those that occur after discharge. We have already established a panel of readmission measures (such as those utilized for hospitals, ESRD care, IRFs, and LTCHs) that similarly seek to identify readmissions attributable to care received within the facility, even if the patient has been discharged. Those developed for ESRD facilities and Home Health agencies follow a 30-day window as well. We believe that the 30-day window is consistent with PAMA and that it is also consistent with the standard implemented in multiple settings. Absent a compelling reason to limit the measure to within stay, and given the potential for unintended consequences if such a measure were implemented as the sole determining factor of a VBP program, we believe remaining consistent with other programs is appropriate. We might consider a purely within-stay measure were it paired with a post-discharge measure, as this would allow us to avoid unintended consequences to patients, such as inappropriate early discharge from the SNF, but the statutory mandate does not allow us to implement additional measures in the SNF–VBP program.

Comment: One commenter requested that we clarify whether the SNFRM includes all hospitalizations billed to Medicare or if it is limited to hospitalizations of residents who are in a Part A stay in a SNF. The commenter suggested that a broader measure of readmissions, including Medicare claims for dually-eligible residents not in a Part A stay or for private-pay residents could be used.

Another commenter suggested that we explore merging FFS and Medicare Advantage data sets given the relative prevalence of MA patients in the SNF setting. The commenter also noted that the IMPACT Act does not separate Medicare beneficiaries by MA status. The commenter also recommended that facilities be allowed to complete and submit a combined Admission Assessment with the 5-day Assessment for Medicare Advantage beneficiaries to track readmission outcome data for all payer types in the facility.

Response: The index stays that are included in the proposed SNFRM are for those that have FFS Part A Medicare enrollment. We do not have claims data for managed care, private pay, or Medicaid residents who may be receiving skilled services. Thus, this measure only includes Medicare FFS patients.

For private-pay residents, we do not always have claims for the index hospital stay (the proximate stay at an acute-care hospital that precedes care with a SNF and defines the denominator), even if the related readmissions could be identified in Medicare data. In addition, we do not have reliable sources of data for Medicare Advantage patients. The most reliable data available for determining readmissions during a SNF stay are for Part A FFS beneficiaries.

We agree that as penetration of the Medicare Advantage market in the SNF setting increases, finding ways of including readmissions for these patients should be a priority. We will continue to explore ways to include these patients in future years, given the differences in data sources.

Comment: Another commenter also expressed concern that the SNFRM captures only Medicare FFS beneficiaries. The commenter noted that the SNF VBP Program's statute does not specifically restrict the measure to FFS beneficiaries, and urged us to find an all-payer measure. The Commenter further noted that the SNFRM does not capture hospital admissions that are classified as ''observation status,'' which are paid under Part B, and stated that the measure should be broadened to include residents not in a Medicare Part A stay.

Response: At present, we are not able to include all payers in the SNFRM, as the measure is dependent upon Medicare claims data to identify readmissions and risk-adjust for patient comorbidities. While an all-payer measure based on the MDS does exist, it has several characteristics that we believe are potentially problematic for use in a VBP program. The MDS-based measure excludes readmissions that occur after discharge from the SNF, which creates a perverse incentive for SNFs to discharge patients prematurely to avoid being penalized if they are considered a high risk for readmission. The MDS-based measure also does not exclude planned readmissions, which are not indications of poor quality. We do not believe observation stays are appropriate for inclusion in the readmission measure, because the statute requires a measure of readmissions, not of rehospitalizations, which could also include ED and outpatient visits, including observation stays. We have tested the inclusion of observation stays, and note that doing so would have little or no impact on facility assessment by the measure. In addition, evidence suggests that the number of observation stays of patients originating from a SNF is quite small in comparison to the total number of SNF stays (0.7 percent of all SNF stays), and very few readmissions occur after an observation stay. Including observation stays from the SNF hospital readmission measure will not make a meaningful difference in the SNF facility-level rate of hospital readmissions or in the relative ranking of SNF providers according to this measure.

Comment: One commenter requested that we clarify whether the SNFRM's condition list has been tested for the ICD–10 transition scheduled to be completed on October 1, 2015.

Response: We will monitor and test the measure performance and update the risk adjustment model with the transition to ICD–10. We are prepared

for the implementation of ICD–10 for this measure. Mappings of ICD–10 codes for the diagnoses and procedures have been prepared by the AHRQ for the CCS groups used in the risk-adjustment models. Similarly, mappings to the HCC groups have been done. These are used in the risk adjustment of the measure and the definition of planned readmissions. The effects of the change of codes will be system-wide and the models will be re-estimated when the necessary new data become available with the implementation of ICD–10.

Comment: One commenter suggested that we use SNFs' actual readmission rate rather than predicted actual. The commenter noted that the predicted actual rate mutes the differences in rates for small sample size (for example, a facility with an actual count of 0 readmissions could have a projected rate that is greater than 0).

Response: This measure and several other post-acute care measures were designed to align with the Hospital-Wide Readmission measure for all-cause readmissions, and these measures utilize a hierarchical modeling approach that relies on generating a predicted rate consistent with recommendations made in the 2011 Committee of Presidents of Statistical Societies commissioned paper Statistical Issues in Assessing Hospital Performance.[11] This decision was made based on the validity of calculating the standardized risk ratio (SRR), which is the predicted number of readmissions at the facility divided by the expected number of readmissions for the same patients if these patients had been treated at the average SNF. The predicted number of readmissions for each SNF is calculated as the sum of the predicted probability of readmission for each patient in the facility, including the SNF-specific (random) effect. The measure developer (RTI International) also designed a test to explore calibration over ranges of predicted probabilities by doing a comparison of the observed and predicted readmissions by decile (for a table of results, please refer to the SNFRM Technical Report, Section 3.3 Model Validation). These results indicate that the difference between the predicted number of readmissions and the observed number of readmissions in percentage points is minimal, less than one percentage point across deciles of expected rates of readmission, which suggests that the differences in rates will not be muted by using the predicted rate.

Comment: One commenter suggested that we increase the minimum denominator size to address small volume variation. The commenter noted many SNFs admit fewer than 50 Medicare FFS beneficiaries per year and some of these would be excluded if the proposed minimum denominator size of 25 stays is adopted. They also noted that for facilities with Ns smaller than 40, the confidence intervals of the readmission rate start to increase; for Ns smaller than 30, the confidence intervals increase rapidly. The commenter recommended that we should show both the impact that different minimum denominator sizes have on the number of SNFs excluded and the range of confidence intervals of the SNFs rehospitalization rates for Ns smaller than 50 to below 20. They also recommended that bootstrap analysis be conducted to test minimum denominator size to see how the confidence interval around small facilities increases as the denominator decreases as was done for NQF #2375.

Response: We did not propose a minimum denominator size of 25 stays, nor did we specify any minimum SNF size for inclusion. We will consider whether we should establish a minimum denominator for the SNFRM in future rulemaking along with the scoring methodology we are developing for the SNF VBP Program.

(3) Exclusions

Patients whose prior proximal hospitalization was for the medical treatment for cancer are excluded. Analyses of this population during measure development showed them to have a different trajectory of illness and mortality than other patient populations, which is consistent with findings in studies in other patient populations.[12]

SNF stays excluded from the measure are:

- SNF stays where the patient had one or more intervening post-acute care (PAC) admissions (inpatient rehabilitation facility (IRF), long-term care hospital (LTCH), or another SNF) which occurred either between the prior proximal hospital discharge and SNF admission (from which the patient was readmitted) or after the SNF discharge but before the readmission, within the 30-day risk window.
- SNF stays with a gap of greater than 1 day between discharge from the prior proximal hospitalization and the SNF admission.
- SNF stays in which the patient was discharged from the SNF against medical advice (AMA).
- SNF stays in which the principal diagnosis for the prior proximal hospitalization was for rehabilitation care; fitting of prostheses and for the adjustment of devices.
- SNF stays in which the prior proximal hospitalization was for pregnancy.
- SNF stays in which data were missing on any variable used in the SNFRM construction.

Readmissions within the 30-day risk window that are usually considered planned due to the nature of the procedures and principal diagnoses of the readmission are also excluded from the measure. In addition to the list of planned procedures is a list of diagnoses (provided in the SNFRM Technical Report), which, if found as the principal diagnosis on the readmission claim, would indicate that the usually planned procedure occurred during an unplanned acute readmission. In addition to the HWR Planned Readmission Algorithm, the SNFRM incorporates procedures that are considered planned in post-acute care settings as identified in consultation with TEPs. Full details on the planned readmissions criteria used, including the additional procedures considered planned for post-acute care may be found in the SNFRM Technical Report. Details regarding the TEP proceedings can be found in the SNFRM TEP Report.

A discussion of the general comments that we received on the SNFRM exclusions, and our responses to those comments, appears below.

Comment: One commenter suggested that we should not limit the SNFRM to a 30-day readmission window, and should hold SNFs accountable for all readmissions that occur while a beneficiary is in a SNF. The commenter also suggested that we adopt a SNF measure that holds SNFs accountable for readmissions 30 days after discharge from the SNF, which commenters stated would help ensure smooth care transitions.

Response: We agree with the commenter's concerns that SNFs should be accountable for longer-stay patients who are readmitted to an acute care hospital. The SNFRM is designed to assess failed transitions from acute care to the SNF, and is not intended to capture all hospitalizations that may

[11] The COPSS–CMS White Paper Committee: Arlene S. Ash, Ph.D.; Stephen E. Fienberg, Ph.D.; Thomas A. Louis, Ph.D.; Sharon-Lise T. Normand, Ph.D.; Therese A. Stukel, Ph.D., Jessica Utts, Ph.D. Available for download here: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/Statistical-Issues-in-Assessing-Hospital-Performance.pdf.*

[12] National Quality Forum. ''Patient Outcomes: All-Cause Readmissions Expedited Review 2011''. July 2012. pp. 12.

occur in a SNF population. Including all admissions beyond 30 days in the population would attenuate the association between the transitions of care at the proximate discharge from an acute care hospital to the readmission. Adding additional measures to account for readmissions post discharge from the SNF seems a reasonable suggestion, but we lack the statutory authority to include additional quality measures in the SNF VBP program.

Comment: One commenter expressed concern about the SNFRM's exclusion of patients admitted to SNFs from inpatient rehabilitation facilities and long-term care hospitals. The commenter agreed that these patients may be in a different phase of recovery than acute care hospital patients, but suggested that they should still be included in the measure with a separate risk adjustment method.

Response: We excluded patients who have intervening IRF or LTCH admissions before their first SNF admission. While developing the measure specifications, we found that these patients started their SNF admission later in the 30-day readmission window and received other additional types of services as compared with patients admitted directly to the SNF from the prior proximal hospitalization. Thus, they are clinically different, and their risk for readmission is different from the rest of SNF admissions. We report details on this exclusion in the SNFRM Technical Report.[13] SNF patients with intervening IRF/LTCH stays had the lowest rates of readmission (8.6 percent) as compared with those with no intervening IRF/LTCH stay.

Additionally, we found that those with intervening IRF/LTCH admissions had longer hospital lengths of stay and more prior proximal hospitalizations involving surgical procedures compared to those without an intervening stay. This observation supports the rationale that patients who had intervening IRF/LTCH stays are entering the SNF at a later stage of their recovery and are therefore at a different risk for readmission than patients who were admitted directly to the SNF from their prior proximal hospitalization. This issue also impacts a relatively small number of SNF stays; 6 percent have an intervening PAC stay (IRF, LTCH, or another SNF) or go home from their prior proximal hospitalization and are later admitted to a SNF within the 30-day readmission window.

Combined, these analyses provide justification for excluding SNF admissions with intervening IRF or LTCH admissions, or with multiple SNF stays, by showing these exclusions will not have a substantial effect on the SNFRM. Patients with multiple PAC stays after a prior proximal hospitalization are not systematically different from those with only one SNF stay with regard to comorbidities, but are very different with regard to readmission risk. Additionally, concerns about attribution, given the mix of providers these patients have received services from during the risk period, argues for the appropriateness of excluding these patients. Lastly, patients with multiple PAC stays do not cluster in a small group of facilities, so no facilities are disproportionately impacted by these exclusions.

Comment: One commenter strongly disagreed with the SNFRM's exclusion criteria where the patient had one or more intervening admissions to an IRF which occurred either prior to the proximal hospital discharge and SNF admission or after the SNF discharge but before the readmission. The commenter stated that the criteria would not take into account medically complex patients who may be readmitted to the hospital for issues treated as comorbidities. The commenter stated that admission to an IRF should be considered as a proximal hospitalization.

Response: With regard to considering an IRF stay as a proximal hospitalization, we would like to clarify that this measure was developed to harmonize with other hospital readmission measures which do not consider post-acute care settings, like IRFs, as proximal hospitalizations. We have previously adopted a hospital readmission measure for the IRF QRP and have adopted the NQF-endorsed version of the All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from an IRF (NQF #2502) for the IRF QRP. Although IRFs are licensed as hospitals, we include them in the PAC continuum of care and as such, have proposed NQF #2502 to account for readmissions following discharge from the IRF setting.

Comment: One commenter suggested that we exclude ventilator-dependent residents from the readmission measure when those patients' prior proximal hospitalization required being placed on a ventilator for the first time. The commenter noted that these patients require frequent rehospitalizations as part of the adjustment to ventilator dependency.

Response: This measure of all-cause unplanned hospital readmission measures was harmonized with measures adopted in other inpatient and post-acute care programs. Consistent with these other measures, we do not exclude these types of patients. Rather, the measure is designed to take into account a variety of patient-level risk factors through risk adjustment, including principal diagnoses or comorbidities that require use of mechanical ventilation.

Comment: One commenter supported our proposal to exclude from the measure those patients whose prior proximal hospitalization was for medical treatment of cancer, and encouraged us to examine whether other populations should be excluded from the measure as well.

Response: The rationale for excluding from the measure patients whose prior proximal hospitalization was for medical treatment of cancer is that these patients with these admissions have a very different mortality and readmission risk from the rest of the Medicare population, and outcomes for these admissions do not correlate well with outcomes for other patients, as determined in the development of the Hospital-Wide Readmission (HWR) measure (NQF #1789). Further detail and relevant analyses supporting this exclusion criterion are available in the SNFRM Technical Report, section 2.3.1. In the development of the HWR and SNFRM measures, we have not identified additional patient populations or medical conditions whose post-discharge trajectory of readmissions was not consistent with other patient groups such that they would require exclusion from the measure as well.

Comment: One commenter suggested that we include planned readmissions in the denominator but exclude them from the numerator of the SNFRM. The commenter noted that the way planned readmissions are counted is not clear in the rule. In one section, commenter noted, the rule stated that they are excluded; in another, it states that they are included in the denominator but excluded from the numerator.

Response: We would like to clarify that the measure includes planned readmissions in the denominator but excludes them from the numerator. This is consistent with how planned readmissions are treated in in the Hospital-Wide All-Cause Unplanned Readmission Measure (HWR), upon which this measure is based.

[13] Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNFRM-Technical-Report-3252015.pdf.*

(4) Eligible Readmissions

An eligible SNF admission is considered to be in the 30-day risk window from the date of discharge from the proximal acute hospitalization until: (1) The 30-day period ends; or (2) the patient is readmitted to an IPPS or CAH. If the readmission is unplanned, it is counted as a readmission in the numerator of the measure. If the readmission is planned, the readmission is not counted in the numerator of the measure. The occurrence of a planned readmission ends further tracking for readmissions in the 30-day period.

We did not receive any comments on the specific topic of eligible readmissions. However, we addressed comments on exclusions from the measure above.

(5) Risk Adjustment

Readmission rates are risk-adjusted for patient case-mix characteristics, independent of quality. The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health status variables on the probability of readmission. More specifically, the risk-adjustment model for SNFs accounts for demographic characteristics (age and sex), principal diagnosis during the prior proximal hospitalization, comorbidities based on the secondary medical diagnoses listed on the patient's prior proximal hospital claim and diagnoses from prior hospitalizations that occurred in the previous 365 days, length of stay during the patient's prior proximal hospitalization, length of stay in the ICU, body system specific surgical indicators, ESRD status, whether the patient was disabled, and the number of prior hospitalizations in the previous 365 days.

A discussion of the general comments that we received on the SNFRM risk adjustment, and our responses to those comments, appears below.

Comment: Some commenters urged us to adjust the proposed readmission measure for sociodemographic factors before the SNF VBP Program is implemented in FY 2019. Commenters stated that factors outside the control of the hospital, such as availability of primary care, mental health services, access to medications and appropriate food, may significantly influence the likelihood of a patient's health improving after hospital discharge and whether a readmission may be necessary. Commenters suggested that we consider using proxy data on sociodemographic status, such as census-derived data on income and education level, and claims data on the proportion of patients dually eligible for Medicare and Medicaid, to adjust the SNFRM.

One commenter stated that we should submit the SNFRM to NQF under its pilot program for socioeconomic risk adjustment evaluation. The commenter stated that many SNFs provide care to the most vulnerable residents of their communities and that those patients present greater challenges in maintaining optimal medical and functional outcomes, including greater risk for readmission.

Another commenter stated that the SNFRM, and any other measures used in the VBP program, should be appropriately risk adjusted for the population served. The commenter stated that there is significant variation in size, patient populations, and scope of service that are not fully accounted for by current risk adjustments. The commenter also stated that readmission predictors are more highly linked to functional needs and family/caregiver support resources, neither of which are included in risk adjustment.

Response: While we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, we continue to have concerns about holding providers to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on facilities' results on our measures.

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For 2 years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of socioeconomic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of these reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Comment: One commenter requested that residents identified as residing in a designated sub-acute unit within a SNF be considered under the ''other health status'' variable for risk adjustment.

Response: We undertake annual maintenance of our quality measures. We will consider this suggestion through this process. We thank the commenters for their contribution.

Comment: One commenter noted that certain SNFs specialize in serving certain patient populations that are associated with higher rates of hospitalization, and stated that our risk adjustment model should not inadvertently penalize SNFs that offer these programs.

Response: We believe that the risk adjustment model that we have proposed for the SNFRM will ensure that SNFs serving more complex patient populations will not be penalized inadvertently under the SNF VBP Program.

Comment: One commenter stated that we should consider adjusting the SNFRM using HCCs based on hospital and outpatient claims during the prior year rather than the number of prior hospital stays for a facility. The commenter suggested that HCCs are more likely to capture the full risk of a patient's comorbidities than secondary diagnoses coded during the immediately preceding hospital stay.

Response: To clarify, we note that this measure uses for risk adjustment the HCCs based on hospital claims from the prior year in addition to secondary diagnoses coded during the immediately preceding hospital stay. Consistent with other hospital readmission measures, this measure captures HCCs based only on inpatient claims and does not include outpatient claims.

(6) Measurement Period

The SNFRM utilizes 1 year of data to calculate the measure rate. Given that there are more than 2 million Medicare FFS SNF admissions per year in more than 15,000 SNFs, 1 year of data is sufficient to calculate this measure with a model in which the risk adjusters have sufficient sample size to have good precision. The relevant reliability testing may be found in the SNFRM Technical Report.

We sought public comments on the SNFRM's measurement period, and have responded to them in the ''FY 2019 Performance Period and Baseline Period Considerations'' section below.

(7) Stakeholder/MAP Input

Our measure development contractor convened a TEP which provided input on the technical specifications of this quality measure. The TEP was supportive of the design of this measure. We also solicited stakeholder feedback on the development of this measure through a public comment process from July 15th to 29th, 2013. In December 2014, the NQF endorsed the SNF 30-Day All-Cause Readmission Measure (NQF #2510).

We also considered input from the Measures Application Partnership (MAP) when selecting measures under the CMS SNF VBP Program. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890(a) of the Act. The MAP has noted the need for care transition measures in PAC/Long Term Care (LTC) performance measurement programs and stated that setting-specific admission and readmission measures under consideration would address this need.[14] We included the SNFRM on the December 1, 2014 List of Measures under Consideration (MUC List), and the MAP supported the measure. A spreadsheet of MAP's 2015 Final Recommendations is available at NQF's Web site at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711.*

We sought public comments on our proposal to adopt the SNF 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) for use in the SNF VBP Program, and our responses appear in subsections i. through vii. above, as well as in subsection viii. below.

(8) Feedback Reports to SNFs

Section 1888(g)(5) of the Act requires that beginning October 1, 2016, SNFs be provided quarterly confidential feedback reports on their performance on measures specified under sections 1888(g)(1) or (2) of the Act.

We intended to address this topic in future rulemaking. However, we requested public comment on the best means by which to communicate these reports to SNFs. For example, we could consider providing confidential, downloadable feedback reports to SNFs through a secure portal, such as QualityNet. We also invited comment on the level of detail that would be most helpful to SNFs in understanding their performance on the new quality measures. The comments we received on these topics, with their responses, appear below.

Comment: One commenter supported our suggested plan to provide SNFRM feedback reports to SNFs via a secure portal such as QualityNet. The commenter suggested that we provide full details on how their scores were determined, including data on readmitted beneficiaries and details on SNFs' rankings, so that facilities may validate their performance and perform quality improvement efforts.

Response: We will provide information to providers on facilities' scores on this measure. As discussed further below, we intend to consider what information should be included in SNFRM feedback reports in the future, and we will further consider the commenter's feedback when we develop our proposals on that topic. However, while we may provide information pertaining to a patient's readmission episode, we cannot interpret such determinations and readmission rationales, or provide post-discharge information. As part of their quality improvement and care coordination efforts, SNFs are encouraged to monitor hospital readmissions and follow up with patients post discharge. Therefore, although we will not be providing specific information at the patient level in the feedback reports, we believe that SNFs will monitor their overall hospital readmission rates and assess their performance.

Comment: One commenter noted that the quarterly feedback reports required under the Program will use claims data, but that these data may not be accurate if SNFs do not submit their claims timely. The commenter noted that SNFs have up to 12 months to submit claims, which may affect performance measurement.

Response: We intend to monitor SNFRM performance to ensure that unintended consequences related to the time facilities have to submit or resubmit claims do not result.

After consideration of the public comments that we have received, we are finalizing our proposal to specify the SNF 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) and to adopt the measure for the SNF VBP as the SNF all-cause, all-condition hospital readmission measure under section 1888(g)(1) of the Act as proposed.

d. Performance Standards

(1) Background

Section 1888(h)(3) of the Act requires the Secretary to establish performance standards for the SNF VBP Program. The performance standards must include levels of achievement and improvement, and must be established and announced not later than 60 days prior to the beginning of the performance period for the FY involved. To assist us in developing our proposals to establish performance standards for the SNF VBP program, we reviewed a number of innovative health care programs and demonstration projects, both public and private, to discover if any could serve as a prototype for the SNF VBP program. One methodology of important note that provides us an analogous framework for implementation of performance standards is the Performance Assessment Model, implemented for our Hospital VBP program. We also reviewed the Hospital Acquired Conditions Reduction Program, as well as the Hospital Readmissions Reduction Program and the End-Stage Renal Disease Quality Incentive Program (ESRD QIP).

We invited comment on several potential approaches for calculating performance standards under the SNF VBP Program. The comments we received on this topic, with their responses, appear below after discussion of these potential approaches.

(a) Hospital Value-Based Purchasing Program

Under the Hospital VBP Program, a hospital's Total Performance Score is determined by aggregating and weighting domain scores, which are calculated based on hospital performance on measures within each domain. The domain scores are then weighted to calculate a TPS that ranges between 0 and 100 points. At this time, we do not anticipate proposing to adopt quality measurement domains akin to other CMS quality programs under the SNF VBP Program due to fact that this program is based on only one measure.

To calculate HVBP measure scores, hospital performance on specified quality measures is compared to performance standards established by the Secretary. These performance standards include levels of achievement and improvement and enable us to award between 0 and 10 points to each hospital based on its performance on each measure during the performance period. An achievement threshold, generally defined as the median of all hospital performance on most measures during a specified baseline period, is the minimum level of performance required to receive achievement points. The benchmark, generally defined as the

[14] National Quality Forum. *Measure Applications Partnership Pre-Rulemaking Report: 2013 Recommendations of Measures Under Consideration by HHS: February 2013.* Available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=72738.*

mean of the top decile of all hospital performance on a measure during the baseline period, is the performance level required for receiving the maximum number of points on a given measure. The Program also establishes an improvement threshold for each measure, set at each individual hospital's performance on the measure during the baseline period, to award points for improvement over time.

We believe that the Hospital VBP Program's performance standards methodology is a well-understood methodology under which health care providers and suppliers can be rewarded both for providing high-quality care and for improving their performance over time. The statutory authority for the Hospital VBP Program is structured similarly to the statutory authority for the SNF VBP Program, and we are considering adoption of a similar methodology for establishing performance standards under the SNF VBP Program. We also seek to align our pay-for-performance and QRPs as much as possible. Specifically, we could consider adopting performance standards based on all SNF performance during the baseline period on the measure specified under section 1888(g)(1) or (2) of the Act in the form of the achievement threshold—median of all SNF performance during a baseline period—and the benchmark—mean of the top decile of all SNF performance during a baseline period. We could then consider awarding points along a continuum relative to those performance levels.

(b) Hospital-Acquired Conditions Reduction Program

We also considered whether we should adopt any components of the scoring methodology that we have finalized for the HAC Reduction Program under the SNF VBP Program. The HAC Reduction Program requires the Secretary to reduce eligible hospitals' Medicare payments to 99 percent of what would otherwise have been paid for discharges when hospitals rank in the worst performing quartile for risk-adjusted HAC quality measures. These quality measures comprise efforts to promote quality of care by reducing the number of HACs in the acute inpatient hospital setting.

We determine a hospital's Total HAC Score by first assigning each hospital a score of between 1 and 10 for each measure based on the hospital's relative performance ranking in 10 groups (or deciles) for that measure. Second, the measure score is used to calculate the domain score. We discuss other details of the HAC Reduction Program's scoring methodology in further detail in this section.

Although the HACRP statutory authority is not structured the same as the SNF VBP statutory authority, we view the HACRP's use of decile-based performance standards as one conceptual possibility for constructing performance standards under the SNF VBP Program. Specifically, we could consider setting performance standards based on SNFs' ranked performance on the measures specified under sections 1888(g)(1) or (2) of the Act during the performance period. We could divide SNFs' performance on the measures into deciles and award between 1 and 10 points to all SNFs within each decile. While this type of performance standards calculation would measure and reward achievement, we are concerned that it would not incorporate improvement, and we invited comment on the best means by which we could include improvement in this type of calculation.

(c) Hospital Readmissions Reduction Program (HRRP)

We also considered aspects of the Hospital Readmissions Reduction Program (HRRP) for adaptation under the SNF VBP Program. HRRP reduces Medicare payments to hospitals with a higher number of readmissions for applicable conditions over a specified time period.

Hospital readmissions are defined as Medicare patients who are readmitted to the same or another hospital within 30 days of a discharge from the same or another hospital, which includes short-term inpatient acute care hospitals. The initial hospital inpatient admission (the discharge from which starts the 30-day potential penalty clock) is termed the index admission. The hospital inpatient readmission (which can be used to determine application of a penalty if the readmission occurs within 30 days of the index inpatient admission stay) can be for any cause, that is, it does not have to be for the same cause as the index admission.

Using historical data, we determine whether eligible IPPS hospitals have readmission rates that are higher than expected, given the hospital's case mix, while accounting for the patient risk factors, including age, and chronic medical conditions identified from inpatient and outpatient claims for the 12 months prior to the hospitalization. A hospital's excess readmission ratio for each condition is a measure of a hospital's readmission performance compared to the national average for the hospital's set of patients with that applicable condition. If the hospital's actual readmission rate, based on the hospital's actual performance, for the year is greater than its CMS-expected readmission rate, the hospital incurs a penalty up to the maximum cap. If a hospital performs better than an average hospital that admitted similar patients, the hospital will not be subjected to a payment reduction. If a hospital performs worse than average (below a 1.000 score), the poorer performance triggers a payment reduction. For FY 2013, the reduction was capped at 1 percent, for FY 2014 at 2 percent, and at 3 percent for FY 2015 and for subsequent years.

We view the Hospital Readmissions Reduction Program as a potential model for the SNF VBP Program because that program does not weight scores based on domains. That is, under the HRRP, hospitals' risk-adjusted readmissions ratios form the basis for Medicare payment adjustments. Under SNF VBP (and as discussed further in this section), the Program's statute requires us to select only one measure to form the basis for the SNF Performance Score. We believe that this conceptual similarity stands distinct from certain other CMS quality programs that incorporate quality measurement domains and domain weighting into the scoring calculations. However, the HRRP sets an effective performance standard based on the average readmissions adjustment factor of 1.000. We invited comment on whether we should adopt a similar form of performance standard under the SNF VBP Program.

This performance standard could take the form of the median or mean performance on the specified quality measure during the performance period. However, we believe we would also need to consider more granular delineations in SNF scoring to ensure an appropriate distribution of value-based incentive payments under the Program, and we invited comment on what additional policies we should consider adopting in this topic area.

(d) End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The ESRD QIP is authorized by section 1881(h) of the Act. The program promotes patient health by providing a financial incentive for renal dialysis facilities to deliver high-quality care to their patients.

Section 1881(h)(3)(A)(i) of the Act requires the Secretary to develop a methodology for assessing the total performance of each provider and facility based on performance standards. For each clinical measure adopted under the ESRD QIP, we assess

performance on both achievement and improvement. For the achievement score, facility performance on a measure during a performance period is compared against national facility performance on that measure during a specified baseline period. To calculate the improvement score, we compare a facility's performance during the performance period to its performance during a specified baseline period. In determining a clinical measure score for each measure, we take the higher of the improvement or achievement score.

For each reporting measure, we assess performance based on whether the facility completed the reporting for that measure as specified. If a facility reports data according to the specifications we have adopted, then the facility earns the maximum number of points on the measure. If the facility partially reports data according to the specifications we have adopted, the hospital earns some points on the measure, but less than the maximum.

We believe that the ESRD QIP performance standards methodology is a well-understood methodology under which health care providers and suppliers can be rewarded both for providing high-quality care and for improving their performance over time. The scoring methodology rewards achievement and improvement, and is generally aligned with other pay-for-performance and QRPs. Like the Hospital VBP Program statutory language, the ESRD QIP statutory language is structured similar to the SNF VBP Program statutory language, and we are considering adoption of a similar methodology for calculating performance standards under the SNF VBP Program. Specifically, we could consider adopting performance standards based on all SNF performance during the baseline period on the measure specified under sections 1888(g)(1) or (2) of the Act in the forms of the achievement threshold—median of all SNF performance—and the benchmark—mean of the top decile of all SNF performance. We could then consider awarding points for those performance levels.

A discussion of the comments that we received on potential approaches to calculating performance standards, and our responses to those comments, appears below.

Comment: One commenter suggested that we reconsider using the ''higher of'' achievement and improvement requirement when determining the performance score and we should focus the SNF VBP Program on having all providers furnish high quality of care.

Response: We do not believe we have the authority to reconsider using the ''higher of'' achievement and improvement requirement given the statutory requirement in section 1888(h)(3)(B) of the Act, which requires us to adopt performance standards that include levels of achievement and improvement, and further directs us to use the higher of either improvement or achievement in calculating the SNF performance score under paragraph (4).

Comment: Commenters urged us to establish performance standards prior to the beginning of the performance period, as we do in the Hospital VBP Program. Commenters stated that this policy enables providers to understand in advance what level of performance they must reach under the Program.

Response: We intend to establish and announce performance standards in advance of the performance period in accordance with the requirement in section 1888(h)(3)(C) of the Act.

We will consider these comments further in future rulemaking.

(2) Measuring Improvement

We are considering several methodologies for improvement scoring under the SNF VBP Program, and we invited public comments on these options or others that we should consider as we develop our SNF VBP Program policies for future rulemaking.

Section 1888(h)(4)(B) of the Act specifically requires us to construct a ranking of SNF performance scores. While we view such a ranking system as fairly straightforward when based on achievement scoring—for example, ranking SNFs based on their performance on a measure during the performance period could be achieved by ordering SNF performance rates on the measure specified for the Program year—we are considering several approaches for including improvement in the SNF scoring methodology because we are limited to one measure for each SNF Program year. These approaches include:

- Improvement points, awarded using a similar methodology as the one we use to award improvement points in the Hospital VBP Program.
- Measure rate increases, in which a SNF's performance rate on a measure would be increased as a result of its improvement over time.
- Ranking increases, in which a SNF's ranking relative to other SNFs would be increased as a result of improvement.
- Performance score increases, in which a SNF's performance score would be increased as a result of improvement.

We discuss each of these options in further detail in the FY 2016 SNF PPS proposed rule (80 FR 22063 through 22064).

The comments we received on this topic, along with their responses, appear below.

Comment: Commenters stated that we should not adjust SNFs' measure rates directly to reward improvement, cautioning that making those types of adjustments could make valid comparisons of SNF performance more difficult.

Response: We thank the commenters for this feedback.

Comment: Some commenters did not believe that improvement measurement should apply to providers in the top quartile of SNFRM performance. Commenters supported recognizing improvement efforts, but believed that the top quartile should recognize top performers.

Response: We thank the commenters for this feedback, and we will take it into account as we develop our performance standards policy proposals in the future.

Comment: One commenter suggested that we not adopt an achievement threshold under the SNF VBP Program to ensure that all SNFs may qualify for points. The commenter also suggested that we place equal emphasis on improvement under the program, and noted that the Hospital VBP Program separately calculates achievement and improvement and awards the higher of the two to participating hospitals.

Response: We thank the commenter for this feedback, and we will take it into account as we develop our performance standards policy proposals in the future.

Comment: One commenter urged us not to set an absolute level of performance to which SNFs would have to aspire to receive points. The commenter stated that adopting performance standards in this manner would disincentivize improvement, as some SNFs would be unable to receive value-based incentive payments.

Response: We thank the commenter for this feedback, and will consider it in the future.

Comment: One commenter requested that we solicit public comments on performance standards, performance scoring, and the exchange function after releasing detailed analysis of the various options, as well as performance data on the SNFRM.

Response: We thank the commenter for this feedback. We intend to provide as much information as possible on our proposals for this Program in the future.

Comment: One commenter recommended that we award points to SNFs for achievement and improvement, but ensure that low-performing SNFs that improve are not ranked higher than high-performing SNFs.

Response: We thank the commenter for this feedback and will take it into account when developing our proposals in the future.

We will consider these comments further in future rulemaking.

e. FY 2019 Performance Period and Baseline Period Considerations

(1) Performance Period

We intended to specify a performance period for a payment year close to the payment year's start date. We strive to link performance furnished by SNFs as closely as possible to the payment year to ensure clear connections between quality measurement and value-based payment. We also strive to measure performance using a sufficiently reliable population of patients that broadly represent the total care provided by SNFs. As such, we anticipate that our annual performance period end date must provide sufficient time for SNFs to submit claims for the patients included in our measure population. In other programs, such as HRRP and the Hospital Inpatient Quality Reporting Program (HIQR), this time lag between care delivered to patients who are included in the readmission measures and application of a payment consequence linked to reporting or performance on those measures has historically been close to 1 year. We also recognize that other factors contribute to this time lag, including the processing time we need to calculate measure rates using multiple sources of claims needed for statistical modeling, time for providers to review their measure rates and included patients, and processing time we need to determine whether a payment adjustment needs to be made to a provider's reimbursement rate under the applicable PPS based on its reporting or performance on measures.

For the FY 2019 SNF VBP Program's performance period, we are also considering the necessary timeline we need to complete measure scoring to announce the net result of the Program's adjustments to Medicare payments not later than 60 days prior to the FY, in accordance with section 1888(h)(7) of the Act. We are also considering the number of SNF stays typically covered by Medicare each year. As discussed previously, Medicare typically covers more than 2 million Medicare Part A stays per year in more than 15,000 SNFs. Therefore, we believe that 1 year of SNFRM data is sufficient to ensure that the measure rates are statistically reliable.

We intended to propose a performance period for the FY 2019 SNF VBP Program in future rulemaking. We invited public comment on the most appropriate performance period length. The comments we received on this topic, with their responses, appear below.

Comment: Commenters supported a one-year performance period, and suggested that we also consider establishing a minimum annual case count which data from multiple years could be pooled to create more statistically-reliable measure scores.

Response: We thank the commenters for their support. We will consider whether we should establish a minimum annual case count for the SNFRM in future rulemaking.

We will consider these comments further in future rulemaking.

(2) Baseline Period

As described previously, in other Medicare quality programs such as the Hospital VBP Program and the ESRD Quality Incentive Program, we generally adopt a baseline period that occurs prior to the performance period for a FY to measure improvement and establish performance standards.

We view the SNF VBP Program as necessitating a similarly-adopted baseline period for each FY to measure improvement (as required by section 1888(h)(3)(B) of the Act) and to enable us to calculate performance standards that we must establish and announce prior to the performance period (as required by section 1888(h)(3)(A) of the Act). As with the Hospital VBP Program, we intend to adopt baseline periods that are as close as possible in duration as the performance period specified for a FY. However, we may occasionally need to adopt a baseline period that is shorter than the performance period to meet operational timelines. We also intended to adopt baseline periods that are seasonally aligned with the performance periods to avoid any effects on quality measurement that may result from tracking SNF performance during different times of the calendar year.

We stated our intent to propose a baseline period for purposes of calculating performance standards and measuring improvement in future rulemaking. We invited public comment on the most appropriate baseline period for the FY 2019 Program, including what considerations we should take into account when developing this policy for future rulemaking. The comments we received on this topic, with their responses, appear below.

Comment: Commenters supported our proposal to adopt a 12-month baseline period for purposes of quality measurement. Some commenters suggested that we test longer time periods, however, to see whether more time improves the measure's variation. Commenters further suggested that we align the baseline and performance periods under the SNF VBP Program to the calendar year.

Response: We thank the commenters for their support. We will consider testing longer time periods in the future.

We will consider these comments further in future rulemaking.

f. SNF Performance Scoring

(1) Considerations

As with our performance standards policy considerations described above, we considered how other Medicare quality programs score eligible facilities. Specifically, we considered how the Hospital VBP Program and the Hospital-Acquired Conditions Reduction Program score eligible hospitals. We discussed the Hospital Readmissions Reduction Program's scoring above in relation to performance standards.

(a) Hospital Value-Based Purchasing

A Hospital VBP domain score is calculated by combining the measure scores within that domain, weighting each measure equally. The domain score reflects the number of points the hospital has earned based on its performance on the measures within that domain for which it is eligible to receive a score. After summing the weighted domain scores, the TPS is translated using a linear exchange function into the percentage multiplier to be applied to each Medicare discharge claim submitted by the hospital during the applicable FY. (We discuss the Exchange Function in further detail below).

Unlike the Hospital VBP Program, the SNF VBP program focuses on a single readmission measure, one that will be replaced by a single resource use measure as soon as is practicable. As described above, we do not anticipate adopting quality measure domains akin to other CMS quality programs under the SNF VBP Program. We therefore invited comment on how, if at all, we should adapt the HVBP Program's scoring methodology to accommodate both the smaller number of measures and the ranking required under the SNF VBP Program. We responded to comments on this topic below.

(b) Hospital-Acquired Conditions Reduction Program

The Hospital-Acquired Conditions (HAC) Reduction Program scores measures that have been categorized into domains, in a manner that is similar to the HVBP Program's domain structure. For Domain 1, the points awarded to the single assigned measure yield the Domain 1 score, since Domain 1 only contains one measure. For Domain 2, the points awarded for the domain measures are averaged to yield a Domain 2 score. A hospital's Total HAC Score is determined by the sum of weighted Domain 1 and Domain 2 scores. Higher scores indicate worse performance relative to the performance of all other eligible hospitals. Hospitals with a Total HAC Score above the 75th percentile of the Total HAC Score distribution are subject to a payment reduction.

Unlike the Hospital VBP program, referenced above, there is no requirement in the HAC Reduction Program that measures or performance standards must incorporate improvement and achievement scores. As with the HVBP Program above, we invited public comments on the extent to which, if at all, we should adopt components of the HAC Reduction Program's scoring methodology for purposes of the SNF VBP Program. We specifically invited comments on whether we should set an absolute level of performance that must be reached to receive a positive SNF value-based incentive payment. We responded to comments on this topic below.

(c) Other Considerations

We stated our intention to consider several additional factors when developing the performance scoring methodology. We believe that it is important to ensure that the performance scoring methodology is straightforward and transparent to SNFs, patients, and other stakeholders. SNFs must be able to clearly understand performance scoring methods and performance expectations to maximize their quality improvement efforts. The public must understand the scoring methodology to make the best use of the publicly reported information when choosing a SNF. We also believe that scoring methodologies for all Medicare VBP programs should be aligned as appropriate given their specific statutory requirements. This alignment will facilitate the public's understanding of quality information disseminated in these programs and foster more informed consumer decision making about health care. We believe that differences in performance scores must reflect true differences in performance. To ensure that these beliefs are appropriately reflected in the SNF VBP Program, we stated our intention to assess the quantitative characteristics of the measures specified under sections 1888(g)(1) and (2) of the Act, including the current state of measure development, to ensure an appropriate distribution of value-based incentive payments as required by the SNF VBP statute.

We invited public comment on what other considerations we should take into account when developing our proposed scoring methodology for the SNF VBP Program in future rulemaking. The comments we received on this topic, as well as all other comments on considerations we should take into account when developing the SNF VBP Program's scoring methodology, along with their responses, appear below.

Comment: Some commenters agreed that adapting the Hospital VBP Program's scoring methodology is advantageous for the SNF VBP Program because it is well-understood and tested. Other commenters noted that we have substantial experience with this type of approach and stated that this approach provides the strongest incentive for all SNFs to improve their performance.

Response: We thank the commenters for their support and will take this feedback into account when developing our proposals in the future.

Comment: One commenter provided general suggestions for us as we develop the SNF VBP Program's scoring methodology, including the beliefs that the methodology should be easy to understand and that we should provide education to SNFs in the first years of the program. The commenter also expressed support for public reporting of SNF performance scores and quality measure performance, and suggested that we provide regular feedback to SNFs prior to publication.

Response: We thank the commenters for the feedback and support. We will take these recommendations into account in future rulemaking.

Comment: One commenter outlined several principles for our consideration while designing the SNF VBP Program, including aligning incentives, involving stakeholders, focusing on improving quality instead of cost-cutting, providing rewards that motivate change, implementing the program incrementally, rewarding both high levels of performance and substantial improvements, using measures developed in an open, consensus-based manner, including evidence-based measures, and designing the program to avoid perpetuating care disparities.

Response: We thank the commenter for the feedback and will take it into account when developing our proposals in the future.

Comment: One commenter urged us to continue engaging stakeholders in discussions on the SNF VBP Program's design, particularly given the commenter's opinion that the program is more characteristic of a penalty program than an incentive program.

Response: We disagree with the commenter's characterization of the Program as a ''penalty program.'' The SNF VBP Program is designed to reward SNFs based on their quality performance, whether accomplished through achievement or improvement over time.

Comment: One commenter urged us to consider the variations in the types and intensity of SNF-based care when developing performance standards and the ranking for the SNF VBP Program, stating that we should distinguish between primarily short-term, transitional care and medically complex, longer-term patients. The commenter suggested that we consider adopting a similar policy to the long-term care hospital interrupted stay policy for the SNF PPS to ensure that facilities are not provided with incentives to withhold medically necessarily care for fear of loss of significant revenue.

Response: The SNFRM, which was endorsed by the NQF, has been risk adjusted for case-mix to account for differences in patient populations. The goal of risk adjustment is to account for these differences so that providers who treat sicker or more vulnerable patient populations are not unnecessarily penalized. The current measure accounts for all of the factors proposed in the comment above, including the following: principal diagnosis from the Medicare claim corresponding to the prior proximal hospitalization as categorized by AHRQ's CCS groupings, length of stay during the patient's prior proximal hospitalization, length of stay in the ICU, ESRD status, whether the patient was disabled, the number of prior hospitalizations in the previous 365 days, system-specific surgical indicators, individual comorbidities as grouped by CMS's HCC or other comorbidity indices, and a variable counting the number of comorbidities if the patient had more than two HCCs. However, as discussed above, this measure does not currently adjust for beneficiaries that are dually eligible in Medicare and Medicaid. Based on the results of the NQF trial period for risk-

adjustment for socioeconomic status, as well as work being conducted on this issue by ASPE, the measure specifications may be revised to include additional risk adjusters in the future related to socioeconomic status or sociodemographics.

Comment: One commenter suggested that we conduct data analyses to determine whether different measures or scoring should be applied to hospital-based and freestanding SNFs.

Response: We thank the commenter for this feedback and will consider whether this type of adjustment is appropriate in the future.

Comment: One commenter suggested that we modify the ESRD QIP's scoring methodology for adoption under the SNF VBP Program. The commenter stated that the other models described in the proposed rule do not meet the Program's statutory requirements.

Response: We thank the commenter for this feedback. We intend to ensure that any proposed scoring methodology under the SNF VBP Program complies fully with applicable statutory requirements.

We will consider these comments further in future rulemaking.

(2) Notification Procedures

As described above, we stated our intention to address the topic of quarterly feedback reports to SNFs related to measures specified under sections 1888(g)(1) and (2) of the Act in future rulemaking. We also stated that we intend to address how to notify SNFs of the adjustments to their PPS payments based on their performance scores and ranking under the SNF VBP Program, in accordance with the requirement in section 1888(h)(7) of the Act, in future rulemaking.

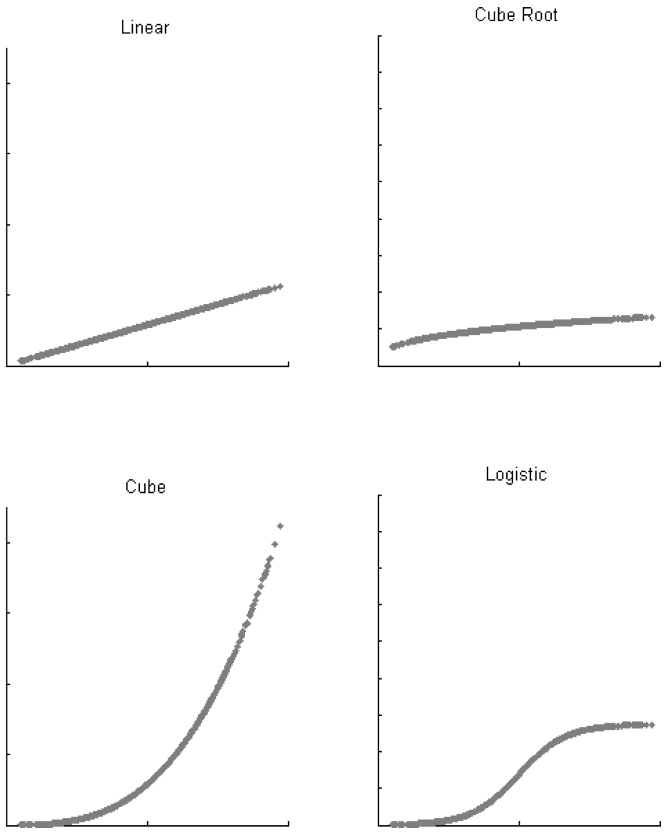
We invited public comment on the best means by which to so notify SNFs. We responded to comments on this topic below in the ''SNF-Specific Performance Information'' subsection.

(3) Exchange Function

As described above in reference to the Hospital VBP Program's scoring methodology, we use a linear exchange function to translate a hospital's Total Performance Score under that Program into the percentage multiplier to be applied to each Medicare discharge claim submitted by the hospital during the applicable FY. We refer readers to the Hospital Inpatient VBP Program Final Rule (76 FR 26531 through 26534) for detailed discussion of the Hospital VBP Program's Exchange Function, as well as responses to public comments on this issue.

We believe we could consider adopting a similar exchange function methodology to translate SNF performance scores into value-based incentive payments under the SNF VBP Program, and we invited comment on whether we should do so. However, as we did for the Hospital VBP Program, we believe we would need to consider the appropriate form and slope of the exchange function to determine how best to reward high performance and encourage SNFs to improve the quality of care provided to Medicare beneficiaries. As illustrated in figure 1, we could consider the following four mathematical exchange function options: Straight line (linear); concave curve (cube root function); convex curve (cube function); and S-shape (logistic function), and we seek comment on what form of the exchange function we should consider implementing if we adopt such a function under the SNF VBP Program.

Figure 1. Exchange Function Options.



We also invited comment on what considerations we should take into account when determining the appropriate form of the exchange function under the SNF VBP Program. We stated our intention to consider how such options would distribute the value-based incentive payments among SNFs, the potential differences between the value-based incentive payment amounts for SNFs that perform poorly and SNFs that perform very well, the different marginal incentives created by the different exchange function slopes, and the relative importance of having the exchange function be as simple and straightforward as possible. We requested public comments on what additional considerations, if any, we should take into account. The comments we received on this topic, with their responses, appear below.

Comment: One commenter expressed support for a linear exchange function under the SNF VBP Program, stating that such a function is easily understood by providers and may encourage practice pattern changes more easily than a more complex function. Commenters also noted that a linear exchange function gives equal importance to improvement for lower- and higher-performing SNFs, and gives all providers an equal opportunity to earn an incentive payment.

Response: We thank the commenter for the feedback on this topic. We will take these recommendations into account in future rulemaking.

Comment: One commenter suggested that we adopt a logistic exchange function and ensure that top-performing SNFs earn back more than 2 percent of their payments from the Program.

Response: We thank the commenter for the feedback on this topic. We will take these recommendations into account in future rulemaking.

We will consider these comments further in future rulemaking.

g. SNF Value-Based Incentive Payments

Sections 1888(h)(5) and (6) of the Act outline several requirements for value-based incentive payments under the SNF VBP Program, including the value-based incentive payment percentage that must be determined for each SNF and the funding available for value-based incentive payments.

We stated our intention to address this topic in future rulemaking. A discussion of the general comments that we received on the SNF Value-Based incentive payments, and our responses to those comments, appears below.

Comment: Commenters recommended that we distribute the maximum 70 percent of the funds withheld from participating SNF payments under the SNF VBP Program to ensure that the program offers payment for value instead of becoming a penalty program. Some commenters also suggested that the remaining 30 percent of funds withheld be used to fund SNF quality improvement initiatives. Other commenters requested that we explain how the remaining 30–50 percent of funds will be used.

Response: We thank the commenters for this feedback. As the commenters noted, section 1888(h)(5)(C)(ii)(III) of the Act requires that the total amount of value-based incentive payments under the SNF VBP Program for all SNFs in a fiscal year must be greater than or equal to 50 percent, but not greater than 70 percent, of the total amount of the reductions to the SNF PPS payments for that fiscal year, as estimated by the Secretary. We do not believe we have the authority to use the balance of funds that will remain after paying out value-based incentive payments to SNFs under the Program for other SNF quality improvement initiatives. We believe these funds are required to remain in the Medicare Trust Fund.

We will consider these comments further in future rulemaking.

h. SNF VBP Public Reporting

(1) SNF-Specific Performance Information

Section 1888(h)(9)(A) of the Act requires the Secretary to post information on the performance of individual SNFs under the SNF VBP Program on the *Nursing Home Compare* Web site or its successor. This information is to include the SNF performance score for the facility for the applicable FY and the SNF's ranking for the performance period for such FY.

We stated our intention to address this topic in future rulemaking. We invited public comment on how we should display this SNF-specific performance information, whether we should allow SNFs an opportunity to review and correct the SNF-specific performance information that we will post on *Nursing Home Compare*, and how such a review and correction process should operate. The comments we received on this topic, with their responses, appear below.

Comment: One commenter requested that SNFs have an opportunity to review and correct their performance information prior to its posting on *Nursing Home Compare*. Commenters requested that the information furnished to SNFs for this purpose should incorporate sufficient detail for SNFs to validate their performance and ranking. The commenters also stated that any public reporting should include explanations of the SNFRM's methodology, what the measure is intended to show, and any of its limitations.

Response: We thank the commenters for this feedback. We will take it into account as we develop our policies on posting SNF-specific information in the future.

Comment: One commenter supported our intention to distribute confidential feedback reports to SNFs via a secure portal. However, the commenter suggested that we use QIES rather than QualityNet, as the former is familiar to SNFs.

Response: We thank the commenter for this feedback, and will take it into account in the future.

Comment: Other commenters suggested that we use the existing mechanism, QIES, for providing SNFs feedback reports and access to their quality measures as to provide quarterly performance reports. The commenters noted that these reports should provide information on performance relative to others and ranking relative to the payment adjustment. Commenters requested that the reports include actual, non-adjusted measures, predicted actual, expected rate, standardized RR, risk adjusted rate, actual numerator, actual denominator, list of patients in numerator, improvement score, achievement score, performance score and performance rank.

Response: We thank the commenters for these suggestions. We will provide details on infrastructure decisions such as this in future rulemaking. We interpret the comment to indicate that it would be useful for providers to receive from CMS readmission-related information so that they can better understand why a given patient was readmitted and for care-related improvement purposes. We support the intent to seek information that will drive improved quality; however, as described above, while we may provide information pertaining to a patient's readmission episode, we cannot interpret such determinations and readmission rationales, or provide post-discharge information. As part of their quality improvement and care coordination efforts, SNFs are encouraged to monitor hospital readmissions and follow up. Therefore, although this measure will not provide specific information at the patient level, we believe that SNFs will be able to monitor their overall hospital readmission rates and assess their performance.

Comment: Commenters requested that we make claims available to providers and others to calculate the SNFRM measure on an ongoing basis (for example quarterly) such as we are doing by providing claims data to the Bundled Payments for Care Improvement (BPCI) initiative participants. Commenters also recommended that we make available Part A claims on a much more frequent basis (for example, quarterly) so that organizations, vendors, and other stakeholders can calculate the rehospitalization rates for SNF patients and provide additional analyses and profiling that can help SNFs with their quality improvement efforts such as what is currently done with MDS data and quality measures.

Response: We thank the commenters for these suggestions. We will address data availability in future rulemaking.

We will consider these comments further in future rulemaking.

(2) Aggregate Performance Information

Section 1888(h)(9)(B) of the Act requires the Secretary to post aggregate information on the SNF VBP Program on the *Nursing Home Compare* Web site, or a successor Web site, to include the range of SNF performance scores and the number of SNFs that received value-based incentive payments and the range and total amount of such value-based incentive payments.

We stated our intention to address this topic in future rulemaking. We invited public comment on the most appropriate form for posting this aggregate information to make such information easily understandable for the public. The comments we received on this topic, with their responses, appear below.

Comment: One commenter suggested that we combine aggregate performance information with individual rehospitalization performance scores and rankings when posting SNFs' performance information on *Nursing Home Compare*. The commenter stated that the ranking and SNF performance score alone will be confusing because they will combine achievement and improvement.

Response: We thank the commenter for this feedback, and will take it into account in the future rulemaking.

2. Advancing Health Information Exchange

HHS has a number of initiatives designed to encourage and support the adoption of health information technology and to promote nationwide health information exchange (HIE) to improve health care. As discussed in the August 2013 Statement ''Principles and Strategies for Accelerating Health Information Exchange'' (available at *http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf*), HHS believes that all individuals, their families, their healthcare and social service providers, and payers should have consistent and timely access to health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the individual's care. Health information technology (IT) that facilitates the secure, efficient and effective sharing and use of health-related information when and where it is needed is an important tool for settings across the continuum of care, including SNFs and NFs. While these facilities are not eligible for the Medicare and Medicaid EHR Incentive Programs, effective adoption and use of health information exchange and health IT tools will be essential as these settings seek to improve quality and lower costs through initiatives such as VBP.

The Office of the National Coordinator for Health Information Technology (ONC) has released a document entitled ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0 (draft Roadmap) (available at *http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf*) which describes barriers to interoperability across the current health IT landscape, the desired future state that the industry believes will be necessary to enable a learning health system, and a suggested path for moving from the current state to the desired future state. In the near term, the draft Roadmap focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. The draft Roadmap's goals also align with the IMPACT Act of 2014 which requires assessment data to be standardized and interoperable to allow for exchange of the data. Moreover, the vision described in the draft Roadmap significantly expands the types of electronic health information, information sources and information users well beyond clinical information derived from electronic health records (EHRs). This shared strategy is intended to reflect important actions that both public and private sector stakeholders can take to enable nationwide interoperability of electronic health IT such as: (1) Establishing a coordinated governance framework and process for nationwide health IT interoperability; (2) improving technical standards and implementation guidance for sharing and using a common clinical data set; (3) enhancing incentives for sharing electronic health information according to common technical standards, starting with a common clinical data set; and (4) clarifying privacy and security requirements that enable interoperability.

In addition, ONC has released the draft version of the 2015 Interoperability Standards Advisory (available at *http://www.healthit.gov/standards-advisory*), which provides a list of the best available standards and implementation specifications to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these ''best available standards'' into account as they implement HIE across the continuum of care, including care settings such as behavioral health, long-term and post-acute care, and home and community-based service providers.

We encourage stakeholders to utilize HIE and certified health IT to effectively and efficiently help providers improve internal care delivery practices, support management of care across the continuum, enable the reporting of electronically specified clinical quality measures (eCQMs), and improve efficiencies and reduce unnecessary costs. As adoption of certified health IT increases and interoperability standards continue to mature, HHS will seek to reinforce standards through relevant policies and programs.

The comments we received on this topic, with their responses, appear below.

Comment: All of the comments received on this topic supported the overall agency goal to accelerate HIE within SNFs, and among the post-acute care providers generally. One commenter asked CMS to keep in mind that certain types of clinicians, such as physical therapists, operate in different provider settings. Another commenter urged CMS to consider the potential impact of HIE regulations and policies on innovation and business practices. Finally, one commenter urged CMS to provide the same type of incentives and considerations to post-acute care providers as they do in other areas with regard to accelerating HIE.

Response: We appreciate the broad support for this initiative and the helpful suggestions provided by the commenters. We will share these comments with the appropriate CMS staff and other governmental agencies to ensure they are taken into account as we

continue to encourage adoption of health information technology.

3. SNF Quality Reporting Program (QRP)

a. Background and Statutory Authority

We seek to promote higher quality and more efficient health care for Medicare beneficiaries, and our efforts are furthered by QRPs coupled with public reporting of that information. Such QRPs already exist for various settings such as the Hospital Inpatient Quality Reporting (HIQR) Program, the Hospital Outpatient Quality Reporting (HOQR) Program, the Physician Quality Reporting System, the Long-Term Care Hospital (LTCH) QRP, the Inpatient Rehabilitation Facility (IRF) QRP, the Home Health Quality Reporting Program (HHQRP), and the Hospice Quality Reporting Program (HQRP). We have also implemented QRPs for home health agencies (HHAs) that are based on conditions of participation, and an ESRD QIP and a Hospital Value-Based Purchasing (HVBP) Program that link payment to performance.

SNFs are providers that must meet conditions of participation for Medicare to receive Medicare payments. Some SNFs are also certified under Medicaid as nursing facilities (NFs), and these types of long-term care facilities furnish services to both Medicare beneficiaries and Medicaid enrollees. SNFs provide short-term skilled nursing services, including but not limited to rehabilitative therapy, physical therapy, occupational therapy, and speech-language pathology services. Such services are provided to beneficiaries who are recovering from surgical procedures, such as hip and knee replacements, or from medical conditions, such as stroke and pneumonia. SNF services are provided when needed to maintain or improve a beneficiary's current condition, or to prevent a condition from worsening. The care provided in a SNF (as a free-standing facility or part of a hospital), is aimed at enabling the beneficiary to maintain or improve his/her health and to function independently. SNF care is a benefit under Medicare Part A and such care is covered for up to 100 days in a benefit period if all coverage requirements are met.[15] In 2014, 2.6 million covered Medicare Part A stays occurred within 15,421 SNFs.

Section 1888(e)(6)(B)(i)(II) of the Act requires that each SNF submit, for FYs beginning on or after the specified application date (as defined in section 1899B(a)(2)(E) of the Act), data on quality measures specified under section 1899B(c)(1) of the Act and data on resource use and other measures specified under section 1899B(d)(1) of the Act in a manner and within the timeframes specified by the Secretary. In addition, section 1888(e)(6)(B)(i)(III) of the Act requires, for FYs beginning on or after October 1, 2018, that each SNF submit standardized patient assessment data required under section 1899B(b)(1) of the Act in a manner and within the timeframes specified by the Secretary. Section 1888(e)(6)(A)(i) of the Act requires that, for FYs beginning with FY 2018, if a SNF does not submit data, as applicable, on quality and resource use and other measures in accordance with section 1888(e)(6)(B)(i)(II) of the Act and on standardized patient assessment in accordance with section 1888(e)(6)(B)(i)(III) of the Act for such FY, the Secretary reduce the market basket percentage described in section 1888(e)(5)(B)(ii) of the Act by 2 percentage points.

The IMPACT Act adds section 1899B to the Act that imposes new data reporting requirements for certain PAC providers, including SNFs. Sections 1899B(c)(1) and 1899B(d)(1) of the Act collectively require that the Secretary specify quality measures and resource use and other measures with respect to certain domains not later than the specified application date in section 1899B(a)(2)(E) of the Act that applies to each measure domain and PAC provider setting. The IMPACT Act also amends section 1886(e)(6) of the Act, to require the Secretary to reduce the PPS payments to a SNF that does not submit the data required in a form and manner, and at a time, specified by the Secretary. Section 1886(e)(6)(A)(i) of the Act would require the Secretary in a FY beginning with FY 2018 to reduce by 2 percentage points the market basket percentage increase as adjusted by the productivity adjustment for SNFs that do not submit the required data.

Under the SNF QRP, we proposed that the general timeline and sequencing of measure implementation would occur as follows: (1) Specification of measures; (2) proposal and finalization of measures through notice-and-comment rulemaking; (3) SNF submission of data on the adopted measures; analysis and processing of the submitted data; (4) notification to SNFs regarding their quality reporting compliance with respect to a particular FY; (5) review of any reconsideration requests; and (6) imposition of a payment reduction in a particular FY for failure to satisfactorily submit data with respect to that FY. We also proposed that any payment reductions that are taken for a FY for the QRP would begin approximately 1 year after the end of the data submission period for that FY and approximately 2 years after we first adopt the measure.

This timeline, which is similar in the other QRPs, reflects operational and other practical constraints, including the time needed to specify and adopt valid and reliable measures, collect the data, and determine whether a SNF has complied with our quality reporting requirements. It also takes into consideration our desire to give SNFs enough notice of new data reporting obligations so that they are prepared to start reporting the data in a timely fashion. Therefore, we stated our intention to follow the same timing and sequence of events for measures specified under section 1899B(c)(1) and (d)(1) of the Act that we currently follow for the other QRPs. We stated our intention to specify each of these measures no later than the specified application dates set forth in section 1899B(a)(2)(E) of the Act and proposed to adopt them consistent with the requirements in the Act and Administrative Procedure Act. To the extent that we finalize to adopt a measure for the SNF QRP that satisfies an IMPACT Act measure domain, we stated our intention to require SNFs to report data on the measure for the FY that begins 2 years after the specified application date for that measure. Likewise, we stated our intention to require SNFs to begin reporting any other data specifically required under the IMPACT Act for the FY that begins 2 years after we adopt requirements that would govern the submission of that data.

We received multiple public comments pertaining to the general timeline and plan for implementation of the IMPACT Act, sequencing of measure implementation, standardization of PAC assessment tools, and timing of payment consequences for the failure to comply with reporting requirements. The following is a summary of the comments received on this topic and our responses.

Comment: We received several comments regarding the timing of the development of the IMPACT Act measures, the development of associated data elements, data collection and reporting. One commenter noted the considerable time constraints under which the Secretary is required to implement the provisions of the IMPACT Act. Several commenters requested that CMS communicate estimated implementation timelines for all data collection and reporting

[15] Section 1812(a)(2) and (b)(2) of the Act; 42 CFR 409.61; *http://www.medicare.gov/Pubs/pdf/10153.pdf.*

requirements. One commenter requested that CMS provide more detailed information in the rule regarding multiple topics, including the replacement of existing data elements in the PAC assessment tools with a suggested common assessment tool, endorsement of quality measures, and the sequence and timeline of events for measure implementation.

Response: We appreciate the public's feedback regarding the timing issues related to IMPACT Act implementation. We recognize the need for transparency as we move forward to implement the provisions of the IMPACT Act and we intend to continue to engage stakeholders and ensure that our approach to implementation and timing is communicated in an open and informative manner. We will use the rulemaking process to communicate timelines for implementation, including timelines for the replacement of items in PAC assessment tools, timelines for implementation of new or revised quality measures and timelines for public reporting. We will also provide information through pre-rulemaking activities surrounding the development of quality measures, which includes public input as part of our process. Additionally, we intend to engage stakeholders and experts in developing the assessment instrument modifications necessary to meet data standardization requirements of the IMPACT Act.

We will also continue to provide information about measures at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html*.

Comment: We received several comments requesting the development of a comprehensive overall plan for implementation across all settings covered by the IMPACT Act. Commenters stated that a comprehensive implementation plan would give PAC providers an opportunity to plan for the potential impacts on their operations, and enable all stakeholders to understand CMS's approach to implementing the IMPACT Act across care settings. One commenter requested that CMS plans be communicated as soon as possible and that CMS develop setting-specific communications to facilitate understanding of the IMPACT Act requirements.

Response: We appreciate the request for a comprehensive plan to allow PAC providers to plan for implementation of the IMPACT Act, as well as the need for stakeholder input, the development of reliable, accurate measures, clarity on the level of standardization of items and measures, and avoidance of unnecessary burden on PAC providers. Our intent has been to comply with these principles in the implementation and rollout of QRPs in the various care settings, and we will continue to adhere to these principles as the agency moves forward with implementing IMPACT Act requirements.

In addition, in implementing the IMPACT Act requirements, we will follow the strategy for identifying cross-cutting measures, timelines for data collection and timelines for reporting as outlined in the IMPACT Act. As described more fully above, the IMPACT Act requires CMS to specify measures that relate to at least five stated quality domains and three stated resource use and other measure domains. The IMPACT Act also outlines timelines for data collection and timelines for reporting. In addition, we must follow all processes in place for adoption of measures including the MAP and the notice and comment rulemaking process. In our selection and specification of measures, we employ a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act. This process is based on a private-public partnership, and it occurs via the MAP. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890 of the Act, to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B). The NQF must convene these stakeholders and provide us with the stakeholders' input on the selection of such measures. We, in turn, must take this input into consideration in selecting such measures. In addition, the Secretary must make available to the public by December 1 of each year a list of such measures that the Secretary is considering under Title XVIII of the Act. Additionally, proposed measures and specifications are to be announced through the Notice of Proposed Rulemaking (NPRM) process in which proposed rules are published in the **Federal Register** and are available for public view and comment.

Comment: We received several comments about the level of standardization of data collection instruments across PAC settings as required by the IMPACT Act. Commenters noted the importance of standardized resident assessment data for cross-setting comparisons of patient outcomes. Some commenters recognized the need to have as much standardization of measures and data collection across PAC settings as possible, while recognizing that some variations among settings may be necessary. Those commenters cautioned that complete standardization of PAC data may not be possible and urged CMS to consider standardization around topics or domains but allowing different settings to use assessment instruments that were most appropriate for the patient populations assessed. One commenter requested that the specific items added to achieve standardization to the Minimum Data Set (MDS) for NFs, the Outcome and Assessment Information Set (OASIS) for home healthcare, the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF PAI), and Long-Term Care Hospitals Continuity Assessment Record and Evaluation data set (LTCH–CARE) be published for comments.

Response: We agree that standardization is important for data comparability and outcome analysis. The IMPACT Act requires the modification of the assessment instruments to include standardized data for multiple purposes including quality reporting, interoperability and data comparison, and we will work to ensure that items pertaining to measures required under the IMPACT Act that are used in assessment instruments are standardized. We agree that there may be instances where such data is not necessary or applicable to all four of the post-acute settings' assessment instruments, but is used in more than one assessment instrument. In that circumstance, we work to ensure that such data is standardized.

With regard to the commenter's suggestion that a common assessment tool be developed for PAC settings, we wish to clarify that while the IMPACT Act requires the modification of PAC assessment instruments to revise or replace certain existing patient assessment data with standardized patient assessment data as soon as practicable, it does not require a single data collection tool. We intend to modify the existing PAC assessment instruments as soon as practicable to ensure the collection of standardized data. While we agree that it is possible that within the PAC assessment instruments certain sections could incorporate a standardized assessment data collection tool, for example, the Brief Interview for Mental Status (BIMS), we have not yet concluded that this kind of modification of the PAC assessment instruments is necessary.

All proposed and finalized changes to the PAC instruments are, and will

continue to be, published on the applicable CMS Web sites. As previously mentioned, it is our intention to develop such standardization through clinical and expert input as well as stakeholder and public engagement where we would receive input.

Comment: We received many comments about the burden on PAC providers of meeting new requirements imposed as a result of the implementation of the IMPACT Act. Commenters requested that CMS consider minimizing the burden for PAC providers when possible and avoid duplication in data collection.

Response: We appreciate the importance of avoiding undue burden and will continue to evaluate and consider any burden the IMPACT Act and the SNF QRP places on SNFs. In implementing the IMPACT Act thus far, we have taken into consideration the new burden that our requirements place on PAC providers, and we believe that standardizing patient assessment data will allow for the exchange of data among PAC providers in order to facilitate care coordination and improve patient outcomes.

Comment: We received one comment requesting that, in the future, cross-setting measures and assessment data changes related to the IMPACT Act be addressed in one stand-alone notice and rule that applies to all four post-acute care settings.

Response: We will take this suggestion under consideration.

Comment: One commenter expressed support for the reduction of a SNF's annual update by 2 percentage points for failure to report the required quality data. Additionally, this commenter recommends that imposition of the financial penalty should be published on a public reporting Web site.

Response: We thank the commenter for its support of the SNF QRP reduction as mandated by the IMPACT Act, and the suggestion to publicize payment consequences imposed upon SNFs for failure to satisfactorily report quality data. We will take this under consideration.

Final Decision: After consideration of the public comments received, we are finalizing the adoption of general timeline and sequencing of measure implementation and that any payment reductions that are taken with respect to a FY would begin approximately 1 year after the end of the data submission period for that FY and approximately 2 years after we first adopt the measure as proposed for the SNF QRP.

As provided at section 1888(e)(6)(A)(ii) of the Act, depending on the market basket percentage for a particular year, the 2 percentage point reduction under section 1888(e)(6)(A)(i) of the Act may result in this percentage, after application of the productivity adjustment under section 1888(e)(5)(B)(ii) of the Act, being less than 0.0 percent for a FY and may result in payment rates under the SNF PPS being less than payment rates for the preceding FY. In addition, as set forth at section 1888(e)(6)(A)(iii) of the Act, any reduction based on failure to comply with the SNF QRP reporting requirements applies only to the particular FY involved, and any such reduction must not be taken into account in computing the SNF PPS payment rates for subsequent FYs.

For purposes of meeting the reporting requirements under the SNF QRP, section 1888(e)(6)(B)(ii) of the Act states that SNFs or other facilities described in section 1888(e)(7)(B) of the Act (other than a CAH) may submit the resident assessment data required under section 1819(b)(3) of the Act using the standard instrument designated by the state under section 1819(e)(5) of the Act. Currently, the resident assessment instrument is titled the MDS 3.0. To the extent data required for submission under subclause (II) or (III) of section 1888(e)(6)(B)(i) of the Act duplicates other data required to be submitted under clause (i)(I), section 1888(e)(6)(B)(iii) provides that the submission of data under subclause (II) or (III) is to be in lieu of the submission of such data under clause (I), unless the Secretary makes a determination that such duplication is necessary to avoid delay in the implementation of section 1899B of the Act taking into account the different specified application dates under section 1899B(a)(2)(E) of the Act.

In addition to requiring a QRP for SNFs under new section 1888(e)(6), the IMPACT Act requires feedback to SNFs and public reporting of their performance. More specifically, section 1899B(f)(1) of the Act requires the Secretary to provide confidential feedback reports to SNFs on their performance on the quality measures and resource use and other measures specified under that section. The Secretary must make such confidential feedback reports available to SNFs beginning 1 year after the specified application date that applies to the measures in that section and, to the extent feasible, no less frequently than on a quarterly basis, except in the case of measures reported on an annual basis, as to which the confidential feedback reports may be made available annually.

Section 1899B(g)(1) of the Act requires the Secretary to provide for the public reporting of SNF performance on the quality measures specified under section 1899B(c)(1) of the Act and the resource use and other measures specified under section 1899B(d)(1) of the Act by establishing procedures for making the performance data available to the public. Such procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, that SNFs have the opportunity to review and submit corrections to the data and other information before it is made public as required by section 1899B(g)(2) of the Act. Section 1899B(g)(3) of the Act requires that the data and information is made publicly available beginning no later than 2 years after the specified application date applicable to such a measure and SNFs. Finally, section 1899B(g)(4)(B) of the Act requires that such procedures must provide that the data and information described in section 1899B(g)(1) of the Act for quality and resource use measures be made publicly available consistent with sections 1819(i) and 1919(i) of the Act.

b. General Considerations Used for Selection of Quality Measures for the SNF QRP

We strive to promote high quality and efficiency in the delivery of health care to the beneficiaries we serve. Performance improvement leading to the highest quality health care requires continuous evaluation to identify and address performance gaps and reduce the unintended consequences that may arise in treating a large, vulnerable, and aging population. QRPs, coupled with public reporting of quality information, are critical to the advancement of health care quality improvement efforts.

Valid, reliable, relevant quality measures are fundamental to the effectiveness of our QRPs. Therefore, selection of quality measures is a priority for CMS in all of its QRPs.

We proposed to adopt for the SNF QRP three measures that we are specifying under section 1899(B)(c)(1) of the Act for purposes of meeting the following three domains: (1) Functional status, cognitive function, and changes in function and cognitive function; (2) skin integrity and changes in skin integrity; and (3) incidence of major falls. These measures align with the CMS Quality Strategy,[16] which

[16] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

incorporates the three broad aims of the National Quality Strategy: [17]

- *Better Care:* Improve the overall quality of care by making healthcare more patient-centered, reliable, accessible, and safe.
- *Healthy People, Healthy Communities:* Improve the health of the U.S. population by supporting proven interventions to address behavioral, social, and environmental determinants of health in addition to delivering higher-quality care.
- *Affordable Care:* Reduce the cost of quality healthcare for individuals, families, employers, and government.

In deciding to propose these measures, we also took into account national priorities, including those established by the National Priorities Partnership (*http://www.qualityforum.org/Setting_Priorities/NPP/National_Priorities_Partnership.aspx*), and the HHS Strategic Plan (*http://www.hhs.gov/secretary/about/priorities/priorities.html*).

These measures also incorporate common standards and definitions that can be used across post-acute care settings to allow for the exchange of data among post-acute care providers, to provide access to longitudinal information for such providers to facilitate coordinated and improved outcomes, and to enable comparison of such assessment data across all such providers as required by section 1899B(a) of the Act.

We received comments on the topic of the General Considerations Used for Selection of Quality Measures for the SNF QRP. The following is a summary of the comments received and our responses.

Comment: One commenter expressed support for the goals and principles outlined to improve quality and help guide the selection and specification of measures in the SNF QRP.

Response: We appreciate the support.

Comment: While we received some comments expressing appreciation for opportunities for stakeholder feedback regarding implementation of the IMPACT Act, we also received several comments regarding the need for more opportunities for stakeholder input into various aspects of the measure development process. Commenters requested opportunities to provide early and ongoing input into measure development. One commenter requested opportunities for input prior to the development of proposed measure specifications. Commenters requested that CMS hold meetings with PAC providers on a frequent and regular basis to provide feedback on implementation and resolve any perceived inconsistencies in the proposed rule.

Response: We appreciate the commenter's feedback. It is our intent to move forward with IMPACT Act implementation in a manner in which the measure development process continues to be transparent, and includes input and collaboration from experts, the PAC provider community, and the public at large. It is of the utmost importance to CMS to continue to engage stakeholders, including patients and their families, throughout the measure development lifecycle through their participation in our measure development public comment periods; the pre-rulemaking process; participation in the TEPs provided by our measure development contractors, as well as open door forums and other opportunities. We have already provided multiple opportunities for stakeholder input, which include the following activities: our measure development contractor(s) convened a TEP that included stakeholder experts on February 3, 2015; we convened two separate listening sessions on February 10th and March 24, 2015; we heard stakeholder input during the February 9th 2015 ad hoc MAP meeting provided for the sole purpose of reviewing the measures adopted in response to the IMPACT Act. Additionally, we implemented a public mail box for the submission of comments in January 2015, *PACQualityInitiative@cms.hhs.gov*, which is listed on our post-acute care quality initiatives Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html*, and we held a Special Open Door Forum to seek input on the measures on February 25, 2015. The slides from the Special Open Door Forum are available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html*.

Comment: One commenter expressed concern at the brief time between the passage of the IMPACT Act and the development of the proposed rule because it did not allow for extensive coordination with the professional community. While the commenter appreciated the opportunity to participate in the IMPACT Act listening session, the commenter viewed the proposed rule for the SNF QRP as hasty and reactive, contrary to the deliberate and measured process that was recommended by stakeholders and sought by CMS through the collaborative listening session.

Response: We appreciate the public's interest in active participation in the measure development process. As noted in the proposed rule, the timeline and sequence of events proposed for the SNF QRP, which is generally followed in other quality reporting programs, requires that we give providers sufficient time after adoption of measures and before reporting obligations begin to enable them to prepare to report the data. We intend to propose measures consistent with the sequence we follow in other quality reporting programs. As noted above, we engaged in multiple activities to solicit stakeholder input including TEPs, listening sessions, ad hoc MAP meetings, Special Open Door Forums and a public email address. As described above, we also initiated an Ad Hoc MAP process to obtain input on the measures that we are finalizing in this final rule.

On February 5th, 2015, we made publicly available a list of Measures Under Consideration (called the ''List of Ad Hoc Measures Under Consideration for the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014'') (MUC list) as part of an Ad Hoc MAP convened by the NQF. The MAP Post-Acute Care/Long-Term Care Workgroup convened on February 9, 2015 to ''review the measures technical properties as they are adapted for use in new settings and whether the new settings impact the measures' adherence to the NQF Scientific Acceptability criterion.'' [18] The NQF published the MUC list on our behalf for public comment from February 11, 2015 through February 19, 2015 on its Web site. The MAP Coordinating Committee convened on February 27, 2015 to discuss the public comments received, and those public comments are listed here *http://public.qualityforum.org/MAP/MAP%20Coordinating%20Committee/MAP_CC%20Feb%2027_Discussion_Guide.html#agenda*.

The MAP issued a pre-rulemaking report on March 6, 2015. This Pre-Rulemaking Report is available for download at *http://www.qualityforum.org/Project_Pages/MAP_Post-Acute_CareLong-Term_Care_Workgroup.aspx*. The MAP's input for

[17] *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.*

[18] . Ad-hoc Review: Expansion of Settings . (n.d.). Retrieved March 5, 2015, from *http://www.qualityforum.org/Projects/a-b/Ad_Hoc_Reviews/CMS/Ad_Hoc_Reviews-CMS.aspx.*

each of the proposed measures is discussed in this section.

Section 1899B(j) of the Act requires that we allow for stakeholder input as part of the pre-rulemaking process. Therefore, we sought stakeholder input on the measures we proposed to adopt in this final rule as follows: We implemented a public mail box for the submission of comments in January 2015, *PACQualityInitiative@cms.hhs.gov* which is located on our post-acute care quality initiatives Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html;* we convened a TEP that included stakeholder experts and patient representatives on February 3, 2015; and we sought public input during the February 2015 ad hoc MAP process. In addition, we held a National Stakeholder Special Open Door Forum on February 25, 2015 for the purpose of seeking input on these measures. Lastly, we held two separate listening sessions on February 10 and March 24, 2015, respectively. These sessions sought feedback from providers regarding best practices for collecting quality data with respect to the IMPACT Act requirements.

Comment: Multiple commenters expressed concern that the MAP process was not implemented properly and had concerns about when MAP Workgroup rosters are open for public comment, the inclusion of additional measures during the MAP, and other items such as MAP composition. Commenters also expressed concern that the open door forums and listening sessions designed to meet public input requirements did not include sufficient public discussion of the proposed quality measures. One commenter stated that there is confusion among NQF and MAP members over whether they can review all related NQF-endorsed measures or are restricted to reviewing only measures preferred by CMS and requested that CMS issue them written guidance. In addition, the commenter urged CMS to change the MAP public comment process.

Response: With regard to the commenters' concerns pertaining to the processes associated with the MAP such as when MAP Workgroup rosters are open for public comment, the inclusion of additional measures during the MAP, and other items such as MAP composition, we note that the operations of the MAP are directed by the NQF, and not by CMS. Further, while the MAP provides input on measures selected by the Secretary, the pre rulemaking provisions of the Act do not restrict the MAP from reviewing or recommending alternative measures and methodologies to those proposed by the Secretary. Therefore, we refer readers to the MAP Web site at *http://www.qualityforum.org/map/*. Additionally, we intend to provide the commenters' input to the NQF.

We also, as part of our measure development process for the proposed measures, sought public input at the February 2015 Special Open Door Forum, during which we provided information pertaining to the IMPACT Act and the measures that were listed as Measures Under Consideration for the IMPACT Act of 2014 for review by the MAP. We also advised that interested parties could submit feedback and questions on the measures and other topics, via our mailbox, *PACQualityInitiative@cms.hhs.gov*. We also sought feedback from subject matter experts who responded to an open call to participate in the numerous TEPs held by our measure development contractor for all measures considered for adoption into the SNF QRP prior to rulemaking.

c. Policy for Retaining SNF QRP Measures for Future Payment Determinations

For the SNF QRP, for the purpose of streamlining the rulemaking process, we proposed that when we adopt a measure for the SNF QRP for a payment determination, this measure would be automatically retained in the SNF QRP for all subsequent payment determinations unless we propose to remove, suspend, or replace the measure.

Section 1899B(h)(1) of the Act provides that the Secretary may remove, suspend or add a quality measure or resource use or other measure specified under section 1899B(c)(1) or (d)(1) of the Act so long as the Secretary publishes a justification for the action in the **Federal Register** with a notice and comment period. Consistent with the policies of other QRPs including the HIQR Program, the HOQR Program, LTCH QRP, and the IRF QRP, we proposed that quality measures would be considered for removal if: (1) Measure performance among SNFs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made in which case the measure may be removed or suspended; (2) performance or improvement on a measure does not result in better resident outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) a more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available; (5) a measure that is more proximal in time to desired resident outcomes for the particular topic is available; (6) a measure that is more strongly associated with desired resident outcomes for the particular topic is available; or (7) collection or public reporting of a measure leads to negative unintended consequences other than resident harm.

We also noted that under section 1899B(h)(2) of the Act, in the case of a quality measure or resource use or other measure for which there is a reason to believe that the continued collection raises possible safety concerns or would cause other unintended consequences, the Secretary may promptly suspend or remove the measure and publish the justification for the suspension or removal in the **Federal Register** during the next rulemaking cycle.

For any measure that meets this criterion (that is, a measure that raises safety concerns), we will take immediate action to remove the measure from SNF QRP, and, in addition to publishing a justification in the next rulemaking cycle, will immediately notify SNFs and the public through the usual communication channels, including listening session, memos, email notification, and web postings.

We invited public comment on this proposed policy for Retaining SNF QRP Measures for Future Payment Determinations. The following is a summary of the comments received and our responses.

Comment: One commenter supported several of the criteria for possible removal of a measure but opposed or recommended changes to other criteria. The commenter recommended changes to deleting criteria to remove measures that have high performance, remove or clarify phrases associated with the term ''clinical practice,'' and also incorporating language to clarify how to add measures rather than remove them.

Response: We interpret the comment to mean that CMS should maintain measures that have high performance. We required reporting on measures with high performance rates in the past. We will continue to perform a case-by-case analysis through program monitoring to evaluate the importance of measure continuation vs. measure suppression or removal. Additionally, we will evaluate the application of language and phrases associated with the term clinical practice as necessary. We believe that we have addressed the approach we take in measure selection and proposal for adoption in our preamble, and when we present our measures under consideration. Generally, we apply an

approach that involves alignment with the National Quality Strategy, and the CMS Quality Strategy, with an effort to address gaps in quality and priority areas for achieving high quality care. We note that the proposed criteria for consideration for removal of measures in the SNF QRP are consistent with the policies of other QRPs in the Medicare Program, including the HIQR Program, the HOQR Program, LTCH QRP, and the IRF QRP.

After consideration of the public comments received, we are finalizing the adoption of the policy for retaining SNF QRP Measures for Future Payment Determinations as proposed.

d. Process for Adoption of Changes to SNF QRP Program Measures

Section 1899B(e)(2) required that quality measures under the IMPACT Act selected for the SNF QRP must be endorsed by the NQF unless they meet the criteria for exception in section 1899B(e)(2)(B) of the Act. The NQF is a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other healthcare stakeholder organizations. The NQF was established to standardize healthcare quality measurement and reporting through its consensus development process (*http://www.qualityforum.org/About_NQF/Mission_and_Vision.aspx*). The NQF undertakes review of: (a) New quality measures and national consensus standards for measuring and publicly reporting on performance; (b) regular maintenance processes for endorsed quality measures; (c) measures with time-limited endorsement for consideration of full endorsement; and (d) ad hoc review of endorsed quality measures, practices, consensus standards, or events with adequate justification to substantiate the review (*http://www.qualityforum.org/Measuring_Performance/Ad_Hoc_Reviews/Ad_Hoc_Review.aspx*).

The NQF solicits information from measure stewards for annual reviews and 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 TEP 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.

The NQF regularly maintains its endorsed measures through annual and triennial reviews, which may result in the NQF making updates to the measures. We believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates made by the NQF into the measure specifications as we have adopted for the Hospital IQR Program so that these measures remain up-to-date. We also recognize that some changes the NQF might make to its endorsed measures are substantive in nature and might not be appropriate for adoption using a subregulatory process.

Therefore, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505), we finalized a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the Hospital IQR Program. For what constitutes substantive versus nonsubstantive changes, we expect to make this determination on a case-by-case basis. Examples of nonsubstantive changes to measures might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and exclusions for a measure (such as the addition of a hospice exclusion to the 30-day mortality measures). We believe that nonsubstantive changes may include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based.

Therefore, we proposed to use rulemaking to adopt substantive updates made to measures as we have for the Hospital IQR Program. 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 (for example, changes in acceptable timing of medication, procedure/process, or test administration). Another example of a substantive change would be where the NQF has extended its endorsement of a previously endorsed measure to a new setting, such as extending a measure from the inpatient setting to hospice. These policies regarding what is considered substantive versus nonsubstantive would apply to all measures in the SNF QRP. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process.

We believe this policy adequately balances our need to incorporate updates to the SNF QRP measures in the most expeditious manner possible while preserving the public's ability to comment on updates that so fundamentally change an endorsed measure that it is no longer the same measure that we originally adopted.

We invited public comment on our Proposed Process for the Adoption of Changes to SNF QRP Program Measures. The following is a summary of the comments received and our responses.

Comment: One commenter suggested that CMS more clearly define the subregulatory process criteria for determining what constitutes a non-substantive change and recommended that CMS not wait until rulemaking to make changes that are considered substantive and have progressed through the NQF process.

Response: We believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates made by the NQF into the measure specifications so that the measures remain up-to-date. For example, we could use the CMS Web site as a place to announce changes. As noted in the proposed rule, the subregulatory process proposed is the same process as we have adopted for the Hospital IQR Program and which has been used successfully in that program. We believe that the criteria for what constitutes a non-substantive change could vary widely and is best described by examples, as we have done in the proposed rule. As noted, what constitutes a substantive versus nonsubstantive changes is determined on a case-by-case basis.

Final Decision: After consideration of the public comments, we are finalizing the adoption of the Process for Adoption of Changes to SNF QRP Program Measures.

New Quality Measures for FY 2018 and Subsequent Payment Determinations

For the FY 2018 SNF QRP and subsequent years, we proposed to adopt three cross-setting quality measures to meet the requirements of the IMPACT Act. These measures address the following domains: (1) Skin integrity and changes in skin integrity; (2) incidence of major falls; and (3) functional status, cognitive function, and changes in function and cognitive function, which are all required measure domains under section 1899B(c)(1) of the Act. The proposed quality measure addressing skin integrity and changes in skin integrity is the NQF-endorsed measure, Percent of Residents or Patients with Pressure

Ulcers That Are New or Worsened (Short Stay) (NQF #0678) (*http://www.qualityforum.org/QPS/0678*). The proposed quality measure addressing the incidence of major falls is an application of the NQF-endorsed Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) (*http://www.qualityforum.org/QPS/0674*). Finally, the proposed quality measure addressing functional status, cognitive function, and changes in function and cognitive function is an application of the Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015) (*http://www.qualityforum.org/QPS/2631*).

The proposed quality measures addressing the domains of incidence of major falls and functional status, cognitive function, and changes in function and cognitive function, are not currently NQF-endorsed for the SNF population. We reviewed the NQF's endorsed measures and were unable to identify any NQF-endorsed cross-setting quality measures that focused on these domains. We are also unaware of any other cross-setting quality measures that have been endorsed or adopted by another consensus organization.

Section 1899B(e)(2) of the Act requires we use a NQF-endorsed measure unless the measure meets the exception. In the case of a specified area or medical topic determined by the Secretary for which a feasible and practical measure has not been NQF endorsed, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to a measure that has been endorsed or adopted by a consensus organization identified by the Secretary.

We received several general comments pertaining to the topic of our use of measures that are not endorsed or are not endorsed for use in the SNF resident population, as well as processes related to our adoption of such measures, their reliability and processes pertaining to the NQF endorsement process as well as the MAP review process. The following is a summary of the comments received and our responses.

Comment: We received several comments about the reliability and accuracy of the proposed measures. We also received several comments supporting and encouraging the use of NQF endorsed measures and commenters expressed concerns that not all of the measures proposed for the FY 2018 payment determination were NQF endorsed. One commenter expressed concern that the statute's exemption allowing the use of measures that are not NQF endorsed provided that ''due consideration'' is given to endorsed measures is not well defined. One commenter urged CMS to use only measures that have been NQF endorsed as cross-setting measures and another commenter expressed that all measures should be reviewed by the MAP and a technical expert panel (TEP). Additionally, one commenter believed that all measures should be NQF endorsed before they are specified and if the measure is not endorsed, CMS should specify the criteria justifying the exception to endorsement. In addition, one commenter suggested that the NQF endorsement process does not take into account the expertise necessary for rehabilitation services and post-acute care services.

Response: We intend to consider and propose appropriate measures that meet the requirements of the IMPACT Act measure domains and that have been endorsed or adopted by a consensus organization, whenever possible. However, when this is not feasible because there is no NQF-endorsed measure that meets all the requirements for a specified IMPACT Act measure domain, we intend to rely on the exception authority given to the Secretary in section 1899B(e)(2)(B) of the Act. This statutory exception, allows the Secretary to specify a measure for the SNF QRP setting that is not NQF-endorsed where, as here, we have not been able to identify other measures on the topic that are endorsed or adopted by a consensus organization. With respect to the proposed measures for the SNF QRP, we sought MAP review, as well as expert opinion, on the validity and reliability of those measures. We disagree with the commenter who expressed concerns pertaining to the expertise applied in the panels overseeing the NQF endorsement proceedings; however, we intend to provide this feedback to the NQF.

(1) Quality Measure Addressing the Domain of Skin Integrity and Changes in Skin Integrity: Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678)

We proposed to adopt for the SNF QRP, beginning with the FY 2018 payment determination, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) measure as a cross-setting quality measure that satisfies the skin integrity and changes in skin integrity domain. This measure assesses the percentage of short-stay residents or patients in SNFs, IRFs, and LTCHs with Stage 2 through 4 pressure ulcers that are new or worsened since admission.

Pressure ulcers are a serious medical condition that result in pain, decreased quality of life, and increased mortality in aging populations.[19] [20] [21] [22] Pressure ulcers typically are the result of prolonged periods of uninterrupted pressure on the skin, soft tissue, muscle, and bone.[23] [24] [25] Older adults in SNFs are prone to a wide range of medical conditions that increase their risk of developing pressure ulcers. These medical conditions include impaired mobility or sensation, malnutrition or under-nutrition, obesity, stroke, diabetes, dementia, cognitive impairments, circulatory diseases, dehydration, the use of wheelchairs, medical devices, and a history of pressure ulcers or a pressure ulcer at admission.[26] [27] [28] [29] [30] [31] [32] [33] [34] [35] [36]

[19] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' Nurs N Z 19(10): 20–24.

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[23] Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. Ann Int Med. 2001;135 (8 Part 2), 744–51.

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[26] Agency for Healthcare Research and Quality (AHRQ). Agency news and notes: pressure ulcers are increasing among hospital patients. January 2009. Available from *http://www.ahrq.gov/research/jan09/0109RA22.htm.=*

[27] Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. Ann Int Med. 2001;135 (8 Part 2), 744–51.

[28] Cai, S., et al. (2013). ''Obesity and pressure ulcers among nursing home residents.'' Med Care 51(6): 478–486.

[29] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' Nurs N Z 19(10): 20–24.

[30] Hurd D, Moore T, Radley D, Williams C. Pressure ulcer prevalence and incidence across post-acute care settings. Home Health Quality Measures & Data Analysis Project, Report of Findings, prepared for CMS/OCSQ, Baltimore, MD, under Contract No. 500–2005–000181 TO 0002. 2010.

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Continued

Section 1899B(a)(1)(B) of the IMPACT Act requires that the data submitted on quality measures under section 1899B(c)(1) of the Act be standardized and interoperable across PAC settings, and section 1899B(c)(2)(A) of the Act requires that the measures be reported through the use of a PAC assessment instrument. These requirements are in line with the NQF Steering Committee report, which stated that ''to understand the impact of pressure ulcers across settings, quality measures addressing prevention, incidence, and prevalence of pressure ulcers must be harmonized and aligned.'' [37] This measure has been implemented in nursing homes for resident population with stays of less than 100 days under CMS's Nursing Home Quality Initiative. We also adopted the measure for use in the LTCH QRP (76 FR 51753 through 51756) beginning with the FY 2014 payment determination, and for use in the IRF QRP (76 FR 47876 through 47878) beginning with the FY 2014 payment determination. We have not, to date, adopted the measure for the home health setting. More information on the NQF endorsed quality measure the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), is available at *http://www.qualityforum.org/QPS/0678*.

A TEP convened by our measure development contractor provided input on the technical specifications of the quality measure, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), including the feasibility of implementing the measure across PAC settings. The TEP supported the measure's implementation across PAC settings and was also supportive of our efforts to standardize the measure for cross-setting development. The MAP also supported the use of the quality measure the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) in the SNF QRP as a cross-setting quality measure.

We proposed that the data for this quality measure would be collected using the MDS 3.0, currently submitted by SNFs through the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) system. We believe that this data collection method will minimize the reporting burden on SNFs because SNFs are already required to submit MDS data for multiple purposes, such as for payment purposes. For more information on SNF submission using the QIES ASAP system, readers are referred to *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30TechnicalInformation.html.*

The data items that we proposed to calculate the quality measure, the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) include: M0800A (Worsening in Pressure Ulcer Status Since Prior Assessment (OBRA or scheduled PPS assessment) or Last Admission/Entry or Reentry, Stage 2), M0800B (Worsening in Pressure Ulcer Status Since Prior Assessment (OBRA or scheduled PPS assessment) or Last Admission/Entry or Reentry, Stage 3), and M0800C (Worsening in Pressure Ulcer Status Since Prior Assessment (OBRA or scheduled PPS assessment) or Last Admission/Entry or Reentry, Stage 4). This measure would be calculated at two points in time, at admission and discharge (see Form, Manner, and Timing of Quality Data Submission). The specifications and data items for the quality measure, the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) are available in the MDS 3.0 Quality Measures User's Manual available on our Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html.*

We invited public comments on our proposal to adopt the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) for the SNF QRP for the FY 2018 payment determination and subsequent years. The following is a summary of the comments received and our responses.

Comment: We received many comments in support of our proposal to implement the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened quality measure (Short Stay) (NQF #0678) to fulfill the requirements of the IMPACT Act. Commenters believed that measuring skin integrity and changes in skin integrity is important in the post-acute care setting and appreciated that the pressure ulcer measure is NQF-endorsed and is already collected for the Nursing Home Quality Initiative using the MDS 3.0 data.

Response: We thank the commenters for their support of the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) to fulfill the requirements of the IMPACT Act. We agree that skin integrity and changes in skin integrity are high priority issues for PAC settings.

Comment: One commenter supported our proposal to use the MDS 3.0 as the source of data collection for this measure and to have SNFs submit the data via the QIES ASAP system.

Response: We thank the commenter for its support of the use of the MDS 3.0 and the QIES ASAP system for data collection and reporting of the pressure ulcer measure. The ongoing use of the MDS 3.0 and the QIES ASAP system will minimize burden for SNFs.

Comment: Several commenters were supportive of the intent of this measure but provided recommendations regarding risk adjustment of the pressure ulcer measure. Commenters highlighted the importance of risk adjusting all quality measures and expressed concern that the measure may not be risk adjusted appropriately for the diverse populations across PAC settings. The commenters encouraged CMS to engage in ongoing evaluation of the risk adjustment methodology used for this measure to ensure that the methodology is appropriate for standard cross-setting risk adjustment, as the current risk adjustment methodology is based on data collection tools specific to each PAC setting. Commenters recommended that CMS add several different risk factors to the risk adjustment model including: primary diagnosis; impairments; demographics; co-existing conditions/comorbidities; decreased sensory awareness; and patients or residents at the end of life. Commenters also encouraged CMS to ensure that the measure is fully tested prior to implementation in the QRPs.

One commenter was concerned that the measure is limited to only high risk

Available from *http://www.amda.com/publications/caring/march2003/policies.cfm*.

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[33] National Pressure Ulcer Advisory Panel (NPUAP) Board of Directors; Cuddigan J, Berlowitz DR, Ayello EA (Eds). Pressure ulcers in America: prevalence, incidence, and implications for the future. An executive summary of the National Pressure Ulcer Advisory Panel Monograph. Adv Skin Wound Care. 2001;14(4):208–15.

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[35] Reddy, M. (2011). ''Pressure ulcers.'' Clin Evid (Online) 2011.

[36] Teno, J. M., et al. (2012). ''Feeding tubes and the prevention or healing of pressure ulcers.'' Arch Intern Med 172(9): 697–701.

[37] National Quality Forum. National voluntary consensus standards for developing a framework for measuring quality for prevention and management of pressure ulcers. April 2008. Available from *http://www.qualityforum.org/Projects/Pressure_Ulcers.aspx*

patients or residents, and that the denominator size is decreased by excluding individuals who are low risk. The commenter indicated that pressure ulcers do develop in low risk individuals and that this exclusion will impact each PAC setting differently because the prevalence of low risk individuals varies across settings. The commenter recommended that CMS use a logistic regression model for risk adjustment to allow for an increase in the measure sample size by including all admissions, take into consideration low volume providers, and capture the development of pressure ulcers in low risk individuals. The commenter suggested that a patient or resident's risk is not dichotomous (for example, high risk vs. low risk) and recommended that CMS grade risk using an ordinal scale related to an increasing number and severity of risk factors. The commenter also expressed that the populations and types of risk for pressure ulcers varies significantly across PAC settings, and that using a logistic regression model would be a more robust way to include a wide range of risk factors to better reflect the population across PAC settings. The commenter noted that the TEP that evaluated this cross-setting pressure ulcer measure also recommended that CMS consider expanding the risk adjustment model and discussed excluding or risk adjusting for hospice patients and those at the end of life.

Response: We thank the commenters for their support of the intent of this measure and for their recommendations regarding risk adjustment for this measure. Section 1899B(c)(3)(B) of the Act states that quality measures shall be risk adjusted, as determined appropriate by the Secretary. In regards to the commenter who recommended we risk adjust using a logistic regression model and incorporate low risk patients into the measure, we believe that this commenter may have submitted comments regarding the wrong quality measure. Their comments apply to the quality measure Percent of High Risk Residents with Pressure Ulcers (Long Stay) (NQF #0679), which is not the measure that we proposed for the SNF QRP. The proposed measure is the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (NQF #0678). This measure is currently risk adjusted using a logistic regression model and includes low risk residents. In the model, patients or residents are categorized as either high or low risk based on four risk factors: (1) Functional limitation; (2) bowel incontinence; (3) diabetes or peripheral vascular disease/peripheral arterial disease; and (4) low body mass index (BMI). An expected score is calculated for each patient or resident using that patient or resident's risk level on the four risk factors described above. The patient/resident-level expected scores are then averaged to calculate the facility-level expected score, which is compared to the facility-level observed score to calculate the adjusted score for each facility. Additional detail regarding risk adjustment for this measure is available in the measure specifications, available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html.*

When developing the risk adjustment model for this measure, we reviewed the literature, conducted analyses to test additional risk factors, convened TEPs to seek stakeholder input, and obtained clinical guidance from subject matter experts and other stakeholders to identify additional risk factors. We have determined that risk adjustment is appropriate for this measure. Therefore, we have developed and implemented the risk adjustment model using the risk factors described above. Nonetheless, we will continue to analyze this measure as more data is collected and will consider changing the risk adjustment model, expanding the risk stratifications, and testing the inclusion of other risk factors as additional risk adjustors for future iterations of the measure. We will also take into consideration the TEP discussion and the commenter's feedback regarding the exclusion or risk adjustment for hospice patients and those at the end of life. As we transition to standardized data collection across PAC settings to meet the mandate of the IMPACT Act, we intend to continue our ongoing measure development and refinement activities to inform the ongoing evaluation of risk adjustment models and methodology. This continued refinement of the risk adjustment models will ensure that the measure remains valid and reliable to inform quality improvement within and across each PAC setting, and to fulfill the public reporting goals of QRPs, including the SNF QRP.

Comment: One commenter requested that CMS consider risk adjusting the quality measure for sociodemographic status, to better reflect the realities that affect the care of special populations and the need for coordination with hospitals within a geographic region. The commenter suggested that some beneficiaries in certain populations are more complex, and therefore, their skin integrity may be compromised.

Response: While we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, we continue to have concerns about holding providers to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on facilities' results on our measures.

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For 2 years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of socioeconomic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of these reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Comment: One commenter expressed concerns that although the MAP supports the cross-setting use of this measure, it is only NQF endorsed for the SNF setting and suggested that CMS delay implementing the cross-setting measure until it is NQF endorsed across all PAC settings. The commenter also pointed out that the specifications available on the NQF Web site are dated October 2013.

Response: Although the proposed pressure ulcer measure was originally developed for the SNF/nursing home resident population, it has been re-specified for the LTCH and IRF settings, underwent review for expansion to the LTCH and IRF settings by the NQF Consensus Standards Approval

Committee (CSAC) on July 11, 2012 [38] and was subsequently ratified by the NQF Board of Directors for expansion to the LTCH and IRF settings on August 1, 2012.[39] As reflected on the NQF Web site the endorsed settings for this measure include Post-Acute/Long Term Care Facility: Inpatient Rehabilitation Facility, Post Acute/Long Term Care Facility: Long Term Acute Care Hospital, Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility.[40] NQF endorsement of this measure indicates that NQF supports the use of this measure in the LTCH and IRF settings, as well as in the SNF setting. As one commenter indicated, this measure was fully supported by the MAP for cross-setting use at its meeting of February 9, 2015. With regard to the measure specifications posted on the NQF Web site, the most up-to-date version of the measure specifications were posted for stakeholder review at the time of the proposed rule on the CMS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/Skilled-Nursing-Facility-Quality-Reporting-Program-Quality-Measure-Specifications-for-FY-2016-Notice-of-Proposed-Rule-Making-report.pdf*. The specifications currently posted on the NQF Web site are computationally equivalent and have the same measure components as those posted on the CMS Web site at the time of the proposed rule. However, we provided more detail in the specifications posted with the proposed rule, in an effort to more clearly explain aspects of the measure that were not as clear in the NQF specifications. Additionally, we clarified language to make phrasing more parallel across settings, and updated item numbers and labels to match the 2016 data sets (MDS 3.0, LTCH CARE Data Sets, and IRF–PAI). We are working closely with NQF to make updates and ensure that the most current language and clearest version of the specifications are available on the NQF Web site.

Comment: A few commenters expressed concern regarding the reliability and validity of this measure across different PAC settings. The commenters were concerned that the reliability and validity testing for this measure was only conducted in the SNF setting.

Response: Although this measure was originally developed for the SNF setting, the NQF expanded its endorsement of the measure to the IRF and LTCH settings as a cross setting quality measure in 2012, and the expanded measure was finalized in the FY 2014 IRF PPS final rule (78 FR 47911 through 47912) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863). As part of quality measure maintenance for this quality measure, we and our measure contractor will continue to perform reliability and validity testing. Early data analyses have shown that data continues to be valid and reliable.

We appreciate the commenters' concern that the SNF, LTCH, and IRF populations are not identical and that some differences may exist in the reliability and validity of the measure across settings. We are working towards standardizing data across PAC settings as mandated in the IMPACT Act. As such, we continue to conduct measure development and testing to explore the best way to standardize quality measures, while ensuring reliability and validity for the measures to appropriately account for the unique differences in populations across PAC settings.

Comment: Several commenters were concerned that the pressure ulcer measure is not standardized across PAC settings. The commenters stated that although the measure appears meets the goals and the intent of the IMPACT Act, it does not use a single data assessment tool.

One commenter specifically mentioned the frequency of assessments, highlighting the fact that the LTCH and IRF versions of the measure are calculated using two assessment time-points (admission and discharge), while the SNF version uses multiple assessment time-points. The commenter expressed concern that the higher frequency of assessments for the MDS could potentially result in higher rates of pressure ulcer counts for SNFs. Another commenter voiced particular concerns regarding differences in the look-back periods, for the items used on the IRF, SNF, and LTCH assessments (MDS=7-day assessment period, IRF=3-day assessment period, LTCH = 3-day assessment period) and suggested that this would result in different rates of detection of new or worsened ulcers. Commenters encouraged CMS to address all of these discrepancies, and suggested that we should switch to using only an admission and discharge assessment in the SNF version of the measure.

Response: We appreciate the commenters' review of the measure specifications across the post-acute care settings. We wish to clarify that while the IMPACT Act requires the modification of PAC assessment instruments to revise or replace certain existing patient assessment data with standardized patient assessment data as soon as practicable, it does not require a single data collection tool. We intend to modify the existing PAC assessment instruments as soon as practicable to ensure the collection of standardized data. While we agree that it is possible that within the PAC assessment instruments certain sections could incorporate a standardized assessment data collection tool, for example, the Brief Interview for Mental Status (BIMS), we have not yet concluded that this kind of modification of the PAC assessment instruments is necessary.

As to the concern that the pressure ulcer measure calculation is based on more frequent assessments in the SNF setting than in the LTCH and IRF settings, we wish to clarify that result of the measure calculation for all three PAC providers is the same. For all three PAC providers, the measure calculation ultimately shows the difference between the number of pressure ulcers present on admission and the number of new or worsened pressure ulcers present on discharge. While SNF measure calculation arrives at that number differently than does the measure calculation in the IRF and LTCH settings, ultimately all three settings report the same result—as noted, the difference between the number of pressure ulcers present on admission and the new or worsened pressure ulcers at discharge. To explain, in IRFs and LTCHs, pressure ulcer assessment data is obtained only at two points in time—on admission and on discharge. Therefore, the calculation of the measure includes all new or worsened pressure ulcers since admission. In contrast, in SNFs pressure ulcer assessment data is obtained on admission, at intervals during the stay (referred to as ''interim assessments''), and at discharge. Each interim assessment and the discharge assessment only look back to whether there were new or worsened pressure ulcers since the last interim assessment. The sum of number of new or worsened pressure ulcers identified at each interim assessment and at the time of discharge yields the total number of new or worsened pressure ulcers that

[38] Nation Quality Forum, Consensus Standardbreds Approval Committee. Meeting Minutes, July 11, 2012. 479–489.

[39] National Quality Forum. NQF Removes Time-Limited Endorsement for 13 Measures; Measures Now Have Endorsed Status. August 1, 2012. Available; *http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Removes_Time-Limited_Endorsement_for_13_Measures;_Measures_Now_Have_Endorsed_Status.aspx.*

[40] National Quality Forum. Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay). Available: *http://www.qualityforum.org/QPS/0678.*

occurred during the stay and that were present on discharge. In other words, the collection of pressure ulcer data in LTCHs and IRFs is cumulative, whereas in SNFs, data collection is sequential. In both cases the calculation reaches the same result—the total number of new or worsened pressured ulcers between admission and discharge. Thus, this is the same result of the measure calculation for SNFs as is obtained for IRFs and LTCHs. With respect to the commenter's concern that the use of interim assessment periods on the MDS will result in a higher frequency of pressure ulcers for SNF residents, we clarify that pressure ulcers found during interim assessments that heal before discharge are not included in the measure calculation.

In regards to the commenter's concern about different look-back periods, we acknowledge that although the LTCH CARE Data Set and IRF–PAI allow up to the third day starting on the day of admission as the assessment period and the MDS allows for an assessment period of admission up to day 7, we note that the training manuals for SNFs, LTCHs and IRFs provide specific and equivalent-coding instructions related to the items used to calculate this measure (found in Section M—skin conditions for all three assessments). These instructions ensure that the assessment of skin integrity occurs at the initiation of patients' or residents' PAC stays regardless of setting. All three manuals direct providers to complete the skin assessment for pressure ulcers present on admission as close to admission as possible, ensuring a harmonized approach to the timing of the initial skin assessment. Regardless of differences in the allowed assessment periods, providers across PAC settings should adhere to best clinical practices, established standards of care, and the instructions in their respective training manuals, to ensure that skin integrity information is collected as close to admission as possible. Although the manual instructions are harmonized to ensure assessment at the beginning of the stay, based on the commenter's feedback, we will take into consideration the incorporation of uniform assessment periods for this section of the assessments.

Comment: Commenters expressed concerns about the pressure ulcer measure not being standardized across PAC settings, specifically noting differences in the payers that are required to report patient or resident data for this measure resulting in differences in the denominators for each setting. Commenters also expressed concern with the exclusion of Medicare Advantage beneficiaries from the numerator and denominator for this measure. One commenter noted that measures based on only Medicare FFS beneficiaries may be incomplete, because according to some estimates, only about half of SNF residents are covered by Medicare FFS.

In a related comment, a commenter expressed concern regarding differences in the populations across quality measures in the SNF QRP. The commenters stated that the falls measure (NQF #0674) and function measure (NQF #2631) include only Medicare FFS residents, while the pressure ulcer measure (NQF #0678) includes all short-stay NH residents. The commenter mentioned that this inconsistency could result in confusion for providers because of the varying denominators across measures.

Response: We appreciate the commenters' comments pertaining to the differences in the pressure ulcer quality measure denominators by payer type across the IRF, SNF and LTCH settings. Additionally, we appreciate the commenters' suggested expansion of the population used to calculate all measures to include payer sources beyond Medicare PPS Part A and agree that quality measures that include all persons treated in a facility are better able to capture the health outcomes of that facility's patients or residents, and that quality reporting on all patients or residents is a worthy goal. Although we currently collect data only on the SNF and the IRF Medicare populations, we believe that quality care is best assessed through the collection of patient data regardless of payer source and we agree that consistency in the data would reduce confusion in data interpretation and enable a more comprehensive evaluation of quality. We appreciate the commenter's concerns and although we had not proposed all payer data collection through this current rulemaking, we will take into consideration the expansion of the SNF QRP to include all payer sources through future rulemaking.

Comment: One commenter asked CMS to clarify how the addition of the proposed SNF PPS Part A Discharge Assessment will impact the measure specifications for the numerator and denominator of the pressure ulcer measure. The commenter noted that CMS proposed modifying the MDS discharge assessment to collect information for Part A FFS Medicare beneficiaries who continue in the SNF after ending their Part A stay, but did not clarify how this change will be implemented in the proposed pressure ulcer measure. The commenter is concerned that if the new MDS discharge assessment is not modified to add the pressure ulcer measure assessment items, the measure will exclude individuals who are admitted but not discharged from the SNF during their PAC stay, which will limit CMS's ability to provide meaningful information to provider and consumers. Finally the commenter expressed concern regarding the increase in burden that will be required to complete this assessment, and encouraged CMS to only include the minimum information necessary to calculate the quality measures.

Response: We proposed that the SNF PPS Part A Discharge Assessment would include the pressure ulcer data elements for the quality measure, the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short stay) (NQF #0678), in order to capture complete pressure ulcer information for Medicare beneficiaries who continue in the SNF after the end of a Part A stay (–all information between admission and discharge or end of a Part A stay). For more information on the Part A PPS Discharge assessment, we direct readers to the specifications posted on the SNF QRP Measures and Technical Information Web site, at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

Comment: Many commenters expressed concern with the accuracy of data used to calculate the pressure ulcer measure. One commenter was specifically concerned that CMS excludes residents or patients for whom missing data precludes calculation of the measure from the measure calculations. The commenter expressed that this exclusion may lead to miscoding because if a facility recognizes that a resident is declining, it can simply omit some data for that resident, ensuring that the resident is excluded from the measure. The commenter referenced several different media reports that highlight the seriousness of gaming of MDS 3.0 data. One commenter noted a recent survey that identified deficiencies in reporting by a small sample of SNFs.

Response: As discussed below, we are finalizing our proposal that beginning with the FY 2018 payment determination, any SNF that does not meet the requirement that 80 percent of all MDS assessments submitted contain 100 percent of all data items necessary to calculate the SNF QRP measures would be subject to a reduction of 2

percentage points to its FY 2018 market basket percentage. This requirement will provide an incentive to SNFs to submit complete MDS 3.0 assessments. Analysis of 2014 MDS 3.0 data submitted for the NHQI indicates that for each of the three items used to calculate the pressure ulcer measure (M0800A, M0800B, and M0800C), missing data for calculating measures were approximately 0.1 percent across all target assessments in a given quarter. Less than 0.1 percent of residents were excluded due to missing all three items needed to calculate the measure, suggesting that missing data is not a serious concern. Further, we intend to align with other QRPs and propose through future rulemaking a data validation process that will further ensure that data reported for the SNF QRP is accurate and complete.

Comment: One commenter asked CMS to clarify whether the pressure ulcer measure proposed for the SNF QRP can be reported using the current MDS 3.0 pressure ulcer items, or if new items would be required for this measure. The commenter asked if SNFs would be required to submit different data for the SNF QRP and the Nursing Home Quality Initiative.

Response: The proposed pressure ulcer measure is the same measure that nursing homes have been reporting for short stay residents through CMS's Nursing Home Quality Initiative since 2010. The items used to calculate the measure are the same in the SNF QRP and the Nursing Home Quality Initiative. SNFs will only be required to submit data for this measure once to fulfill the requirements of both programs.

Comment: One commenter was concerned that the MDS 3.0 data does not adequately capture multiple pressure ulcers and presence at admission for each wound. The commenter was concerned that this could result in confusion for SNFs as they may lose track of which ulcers were present on admission and which are new or worsened, resulting in inaccurate counts in the quality measure.

Response: The MDS 3.0 does not require SNF providers to provide individual tracking information for each pressure ulcer. However, we note that the MDS does not replace standard clinical practice. We expect that all SNFs are conducting comprehensive skin assessments throughout the stay and documenting all of the necessary information to fully prevent and manage pressure ulcers for all residents. As such SNFs are able to utilize the data they collect as part of standard clinical practice to track and manage pressure ulcers, in order to complete the MDS 3.0 items related to the improvement and worsening of pressure ulcers during the resident's Part A covered stay in the facility.

Comment: One commenter did not support the proposed measure, the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678). The commenter was concerned that the measure timeframe is too short to properly capture pressure ulcer improvement, disadvantaging facilities that serve more frail populations. The commenter indicated that capturing a healed pressure ulcer is particularly difficult as SNFs have a very limited amount of time from admission to the end of a short-stay episode to heal a pressure ulcer.

Response: We would like to clarify that the proposed quality measure assesses the percent of residents or patients with Stage 2–4 pressure ulcers that are *new* or *worsened* since the prior assessment, and does not focus on capturing the improvement of pressure ulcers. This measure specifies that if a pressure ulcer is present on admission and worsened during the stay, it would be included in the numerator. Further, if the pressure ulcer is present on admission, and did not worsen during the stay, it would not be included in the numerator. We agree with the commenter that the timeframe is often too short to heal pressure ulcers amongst the frail and elderly population; therefore the measure does not capture information about healed pressure ulcers. Rather, the intent of the measure is to hold providers accountable for preventing the worsening of or onset of new pressure ulcers.

Comment: One commenter expressed concern that SNFs with a sub-acute unit will be at risk for reporting higher percentages of residents or patients with pressure ulcers than SNFs that do not have a designated sub-acute unit under the proposed measure.

Response: We agree that some SNF residents are at higher risk for developing new or worsened pressure ulcers. However, pressure ulcers are severe, life threatening, and high-cost adverse events, and many SNF residents may have medically complex conditions that put them at high risk for the development or worsening of pressure ulcers. Given their impact on mortality, morbidity, and quality of life, we believe that SNFs should be responsible for preventing and managing pressure ulcers among both high and low risk residents or patients and that facilities with certain types of patients should not be exempt from reporting new or worsened pressure ulcers. In effort to account for the added challenges that facilities with more high risk residents may face, the proposed quality measure is risk adjusted for four risk factors: (1) Functional limitation, (2) bowel incontinence, (3) diabetes or peripheral vascular disease/peripheral arterial disease, and (4) low body mass index (BMI).

Comment: Many commenters encouraged CMS to align measures where possible with existing CMS initiatives, across settings, and payments types.

Response: We strive to harmonize and align quality measures across initiatives, settings, and payment types whenever possible and will continue to do so as we develop and implement quality measures under the IMPACT Act.

Final Decision: Having carefully considered the comments we received on the quality measure, the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), we are finalizing the adoption of this measure for use in the SNF QRP.

As part of our ongoing measure development efforts, we are considering a future update to the numerator of the quality measure, the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678). This update would require PAC providers to report the development of unstageable pressure ulcers, including suspected deep tissue injuries (sDTIs). Under this potential change we are considering, the numerator of the quality measure would be updated to include unstageable pressure ulcers, including sDTIs that are new/developed in the facility, as well as Stage 1 or 2 pressure ulcers that become unstageable due to slough or eschar (indicating progression to a stage 3 or 4 pressure ulcer) after admission. SNFs are already required to complete the unstageable pressure ulcer items on the MDS 3.0. As such, this update would require a change in the way the measure is calculated but would not increase the data collection burden for SNFs.

A TEP convened by our measure development contractor strongly recommended that CMS update the specifications for the measure to include these pressure ulcers in the numerator, although it acknowledged that unstageable pressure ulcers and sDTIs cannot and should not be assigned a numeric stage. The TEP also recommended that a Stage 1 or 2 pressure ulcer that becomes unstageable due to slough or eschar should be

considered worsened because the presence of slough or eschar indicates a full thickness (equivalent to Stage 3 or 4) wound.[41] [42] These recommendations were supported by technical and clinical advisors and the National Pressure Ulcer Advisory Panel.[43] Additionally, exploratory data analysis conducted by our measure development contractor suggests that the addition of unstageable pressure ulcers, including sDTIs, will increase the observed incidence of new or worsened pressure ulcers at the facility level and may improve the ability of the quality measure to discriminate between poor- and high-performing facilities.

We invited public comments to inform our consideration of the inclusion of unstageable pressure ulcers, including sDTIs in the numerator of the quality measure, the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) as part of our future measure development efforts. The following is a summary of the comments received and our responses.

Comment: One commenter supported our proposal to include unstageable pressure ulcers and suspected deep tissue injuries in the numerator of the proposed quality measure as an area for future measure development. The commenter agreed that these cases should be included in the measure population.

Response: As noted, the recommendation addresses an important clinical concern, and may improve the ability of the quality measure to discriminate between poor and high-performing facilities. As we consider the possibility of adding unstageable pressure ulcers and suspected deep tissue injuries to the numerator, we will carefully consider all comments received from stakeholders.

Comment: Several commenters were supportive of our proposal to include unstageable pressure ulcers (we interpret their comment as referring to unstageable pressure ulcers due to slough or eschar and due to non-removable dressing/device) in the numerator of the quality measure as an area for future measure development, but expressed reservations about the possible future inclusion of suspected deep tissue injuries (sDTIs) in the numerator of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) quality measure. Commenters cited information from the National Pressure Ulcer Advisory Council suggesting that sDTIs can take between 72 hours and seven days to become visible, indicating that there is no reliable and consistent way to determine whether an sDTI at admission is facility acquired or not. Commenters also mentioned confusion surrounding pressure ulcers that are unavoidable or times when prevention is not possible. Finally, multiple commenters stated that the time frame during which sDTIs become visible varies and there is potential for miscoding, both of which may make this an unreliable quality measure.

One commenter requested more information about how this change would be incorporated into the measure specifications. The commenter also requested more information regarding the impact this change would have on the reliability and validity of the measure, as well as how it may impact the risk adjustment methodology. Finally the commenter encouraged CMS to submit any proposed changes through NQF review and specify all details in future rule making. Commenters also encouraged CMS to update the coding instructions for the RAI manual if this change is made, apply this change across all PAC settings, and gather additional stakeholder and expert input on this change prior to implementation.

Response: We appreciate the recommendations regarding the approach to future implementation. We will continue to conduct analyses and solicit input before making any final decisions regarding this possible change to the measure specifications. We intend to continue monitoring the literature, conduct reliability and validity testing, seek input from subject matter experts and stakeholders, and participate in ongoing refinement activities to inform this measure before proposing to adopt any changes. Should we move forward with the addition of unstageable and sDTIs to the measure numerator, we intend to submit any changes through NQF, provide information that will allow providers to accurately interpret and complete quality reporting items, ensure that the MDS 3.0 Resident Assessment Instrument Manual and training materials provide accurate and up-to-date coding instructions for all items, and seek public comment on future measure concepts or revisions.

In regard to the commenters' concerns regarding sDTIs, we believe that it is important to do a thorough admission assessment on each resident or patient who is admitted to a SNF, including a thorough skin assessment documenting the presence of any pressure ulcers of any kind—including sDTIs. When considering the addition of sDTIs to the measure numerator, we convened cross-setting TEPs in June and November 2013, and obtained input from clinicians, experts, and other stakeholders. While we agree that ongoing research is needed, sDTIs are a serious medical condition and given their potential impact on mortality, morbidity, and quality of life, it may be detrimental to the quality of care to exclude them from future quality measures. We thank the commenters for their feedback and we will take into account the recommendations regarding the challenges in determining whether an sDTI at admission is facility acquired or not, the difficulty in coding sDTIs, and the confusion surrounding pressure ulcers that are unavoidable or times when prevention is not possible.

Comment: One commenter did not support the addition of unstageable pressure ulcers in the numerator of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) quality measure. The commenter was concerned that the measure timeframe is too short to properly capture pressure ulcer improvement, disadvantaging facilities that serve more frail populations. The commenter indicated that capturing a healed unstageable pressure ulcer is particularly difficult as SNFs have a very limited amount of time from admission to the end of a short-stay episode to heal a pressure ulcer.

Response: We will take all stakeholder feedback into account as we consider the possibility of including unstageable pressure ulcers, including

[41] Schwartz, M., Nguyen, K.H., Swinson Evans, T.M., Ignaczak, M.K., Thaker, S., and Bernard, S.L.: Development of a Cross-Setting Quality Measure for Pressure Ulcers: OY2 Information Gathering, Final Report. Centers for Medicare & Medicaid Services, November 2013. Available: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Quality-Measure-for-Pressure-Ulcers-Information-Gathering-Final-Report.pdf.*

[42] Schwartz, M., Ignaczak, M.K., Swinson Evans, T.M., Thaker, S., and Smith, L.: The Development of a Cross-Setting Pressure Ulcer Quality Measure: Summary Report on November 15, 2013, Technical Expert Panel Follow-Up Webinar. Centers for Medicare & Medicaid Services, January 2014. Available: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Pressure-Ulcer-Quality-Measure-Summary-Report-on-November-15-2013-Technical-Expert-Pa.pdf.*

[43] Schwartz, M., Nguyen, K.H., Swinson Evans, T.M., Ignaczak, M.K., Thaker, S., and Bernard, S.L.: Development of a Cross-Setting Quality Measure for Pressure Ulcers: OY2 Information Gathering, Final Report. Centers for Medicare & Medicaid Services, November 2013. Available: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Quality-Measure-for-Pressure-Ulcers-Information-Gathering-Final-Report.pdf.*

sDTIs in the numerator of the quality measure in the future.

(2) Quality Measure Addressing the Domain of the Incidence of Major Falls: An Application of the Measure Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674)

We proposed to adopt beginning with the FY 2018 SNF QRP, an application to the SNF setting of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure that satisfies the incidence of major falls domain. This outcome measure reports the percentage of residents who have experienced falls with major injury during episodes ending in a 3-month period. This measure was developed by CMS and is NQF-endorsed for long-stay residents of NFs.

Research indicates that fall-related injuries are the most common cause of accidental death in people aged 65 and older, responsible for approximately 41 percent of accidental deaths annually.[44] Rates increase to 70 percent of accidental deaths among individuals aged 75 and older.[45] In addition to death, falls can lead to fracture, soft tissue or head injury, fear of falling, anxiety, and depression.[46] Research also indicates that approximately 75 percent of nursing facility residents fall at least once a year. This is twice the rate of their counterparts in the community.[47] Further, it is estimated that 10 percent to 25 percent of nursing facility resident falls result in fractures and/or hospitalization.[48]

Falls also represent a significant cost burden to the entire health care system, with injurious falls accounting for 6 percent of medical expenses among those age 65 and older.[49] In one study, Sorensen et al. estimated the costs associated with falls of varying severity among nursing home residents.[50] Their work suggests that acute care costs incurred for falls among nursing home residents range from $979 for a typical case with a simple fracture to $14,716 for a typical case with multiple injuries. A similar study of hospitalizations of nursing home residents due to serious fall-related injuries (intracranial bleed, hip fracture, other fracture) found an average cost of $23,723.[51] Among the SNF population, the average 6-month cost of a resident with a hip fracture was estimated at $11,719 in 1996 U.S. dollars.[52]

According to Morse, 78 percent of falls are anticipated physiologic falls, which are falls among individuals who scored high on a risk assessment scale, meaning their risk could have been identified in advance of the fall.[53] To date, studies have identified a number of risk factors for falls.[54 55 56 57 58 59 60 61 62] The identification of such risk factors suggests the potential for health care facilities to reduce and prevent the incidence of falls. The Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) quality measure is NQF-endorsed and has been successfully implemented in the Nursing Home Quality Initiative for nursing facility long-stay residents since 2011. In addition, the quality measure is currently publicly reported on CMS's Nursing Home Compare Web site at *http://www.medicare.gov/nursinghomecompare/search.html*. Further, an application of the quality measure was adopted for use in the LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290), we revised the data collection period for this measure with data collection to begin starting April 1, 2016.

Although the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) is not currently endorsed for the SNF setting, we reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed cross-setting quality measures for that setting that are focused on falls with major injury. We are aware of one NQF-endorsed measure, Falls with Injury (NQF #0202), which is a measure designed for adult acute inpatient and rehabilitation patients capturing ''all documented patient falls with an injury level of minor or greater on eligible unit types in a calendar quarter, reported as injury falls per 100 days.'' [63] NQF #0202 is not appropriate to meet the IMPACT Act domain as it includes minor injury in the numerator definition. Additionally, including all falls could result in providers limiting the freedom of activity for individuals at higher risk for falls. We are unaware of any other cross-setting quality measures for falls with major injury that have been endorsed or adopted by another consensus organization for the SNF setting. Therefore, we proposed to adopt this measure under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act.

A TEP convened by our measure development contractor provided input on the technical specifications of an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), including the feasibility of implementing the measure across PAC settings. The TEP was supportive of the implementation of this measure across PAC settings and was also supportive of our efforts to standardize this measure for cross-

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[58] Currie LM. Fall and injury prevention. Annu Rev Nurs Res. 2006; 24:39–74.

[59] Ellis AA, Trent RB. Do the risks and consequences of hospitalized fall injuries among older adults in California vary by type of fall? J Gerontol A Biol Sci Med Sci. Nov 2001; 56(11):M686–692.

[60] Chen XL, Liu YH, Chan DK, Shen Q, Van Nguyen H. Chin Med J (Engl). Characteristics associated with falls among the elderly within aged care wards in a tertiary hospital: a retrospective. 2010 Jul; 123(13):1668–72.

[61] Frisina PG, Guellnitz R, Alverzo J. A time series analysis of falls and injury in the inpatient rehabilitation setting. Rehabil Nurs. 2010 JulAug; 35(4):141–6, 166.

[62] Lee JE, Stokic DS. Risk factors for falls during inpatient rehabilitant Am J Phys Med Rehabil. 2008 May; 87(5):341–50; quiz 351, 422.

[63] American Nurses Association (2014, April 9). Falls with injury. Retrieved from *http://www.qualityforum.org/QPS/0202*.

setting development. The MAP conditionally supported the use of an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) in the SNF QRP as a cross-setting quality measure. More information about the MAP's recommendations for this measure is available in the report entitled MAP Off-Cycle Deliberations 2015: Measures under Consideration to Implement Provisions of the IMPACT Act are available at *http://www.qualityforum.org/Project_Pages/MAP_Post-Acute_CareLong-Term_Care_Workgroup.aspx*.

More information on the NQF-endorsed quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) is available at *http://www.qualityforum.org/QPS/0674*.

We proposed that data for this quality measure would be collected using the MDS 3.0, currently submitted by SNFs through the QIES ASAP system for the reason noted previously.

The data items that we will use to calculate this proposed quality measure include: J1800 (Any Falls Since Admission/Entry (OBRA or Scheduled PPS) or Reentry or Prior Assessment, whichever is more recent); and J1900 (Number of Falls Since Admission/Entry (OBRA or Scheduled PPS) or Reentry or Prior Assessment, whichever is more recent). This measure will be calculated at the time of discharge (see Proposed Form, Manner, and Timing of Quality Data Submission). The specifications for an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) for the SNF population are available on our SNF QRP measures and technical Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

We referred readers to the Form, Manner, and Timing of Quality Data Submission section of the FY 2016 SNF PPS proposed rule (79 FR 22076 through 22077) for more information on the proposed data collection and submission timeline for this proposed quality measure.

We invited public comments on our proposal to adopt an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) for the SNF QRP beginning with the FY 2018 payment determination. The comments we received on this topic, with their responses, appear below.

Comment: Several commenters supported our proposal to implement an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) to fulfill the requirements of the IMPACT Act.

Response: We thank the commenters for their support.

Comment: One commenter supported measuring falls in SNFs, but stated a preference for measuring falls ''with or without injury'' and ''assisted or non-assisted'' and tracking by preventable falls (resident-related or environment- and other-related) and non-preventable (resident conditions like fainting).

Response: The proposed application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) assesses falls with major injuries, satisfying the domain in section 1899B(c)(1)(D) of the Act, the Incidence of Major Falls. We believe this domain mandates a quality measure related to falls with major injury. We agree that a provider's tracking of falls is important for the purpose of ensuring resident safety. The information suggested by the commenter for collection is already included in the MDS 3.0 enabling SNFs to track all falls, regardless of injury by including items indicating the number of falls with and without injury. The data elements used to track all falls, including major injury, J1800, J1900 A, B and C, are collected to ensure the reliability of the data. We note that Measure #0674 has been NQF-endorsed based on the manner in which it is calculated now, and its inter-rater reliability is based on the data collection of J1900 A, B and C. The measure has been tested, validated, and endorsed as it is currently collected, and to maintain our current accuracy, we have proposed to maintain those methods.

Comment: Several comments supported the addition of the proposed quality measure to the SNF QRP, but urged that the measure be risk adjusted, expressing concerns that public reporting of falls with injury rates across settings would be inappropriate without taking into account differences in resident acuity and other characteristics, such as cognition and socioeconomic status. One commenter stated that falls occur for various reasons, some of them unavoidable, and therefore, fall rates may not be suitable for quality comparison suggesting that it would be improper to use the measure in pay-for performance models. Another commenter suggested that falls with major injuries ''are a never event'' (that is, events or medical errors that should never transpire, such as falls that happen in a health care setting that result in patient death or serious injury[).[64] Another commenter cited American and British Geriatrics Society guidelines, which find no clear evidence on falls prevention. Some commenters pointed out that the TEP convened in 2015 recommended risk adjustment for cognitive impairment, which several commenters also supported, and one commenter asked whether the TEP was presented the current specifications of the cross-setting falls measure. One commenter provided support for risk adjustment by pointing out that the references cited in the proposed rule indicate that risks for falls vary by resident characteristics, that the State Operations Manual (SOM) for SNFs provides guidance for evaluating residents for risk for falls, and that documentation for not risk adjusting the measure was not provided in the proposed rule. The same commenter pointed to the PAC Payment Reform Demonstration (PAC PRD), in which the commenter stated that the research indicated that the risk of falls with injury differs across post-acute settings. Several commenters also stated that risk adjustment is required by the IMPACT Act, and that the MAP suggested that the measure should be risk adjusted.

Response: We appreciate the commenters' suggestions that the proposed application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) should be risk adjusted. The application of risk adjustment, as stated by the IMPACT Act, is ''as determined appropriate by the Secretary'' under section 1899B(c)(3)(B) of the Act.

While we acknowledge that resident characteristics that elevate risk for falls with major injury vary across the SNF population, a TEP convened in 2009 by the measurement development contractor concluded that risk adjustment of this quality measure concept was inappropriate because it is each facility's responsibility to take steps to reduce the rate of injurious falls, especially since such events are considered to be ''never events.'' We note that the PAC PRD did not analyze falls with major injury, as falls with major injury was not an assessment item that was tested. However, as the commenter pointed out, the prevalence

[64] National Quality Forum (NQF), *Serious Reportable Events In Healthcare—2011 Update: A Consensus Report,* Washington, DC: NQF; 2011.

of a history of falls prior to the PAC admission did vary across post-acute settings (as assessed by Item B7 from the CARE tool: ''History of Falls. Has the patient had two or more falls in the past year or any fall with injury in the past year? ''). Nonetheless, we believe that as part of best clinical practice, SNFs should assess residents for falls risk and take steps to prevent future falls with major injury.

The numerator, denominator, and exclusions definitions provided to the TEP in 2015 are virtually identical to the specifications we proposed to adopt for this measure, and did not include risk adjustment. Two out of 11 members of the 2015 TEP supported risk adjustment of the falls measure for cognitive impairment, but it was not the majority position. For more information on the 2015 TEP, please visit *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/SUMMARY-OF-FEEDBACK-FROM-THE-TECHNICAL-EXPERT-PANEL-TEP-REGARDING-CROSS-SETTING-MEASURES-ALIGNED-WITH-THE-IMPACT-ACT-OF-2014-Report.pdf.*

We believe factors that increase the risk of falling, such as cognitive impairment, should be included by facilities in their risk assessment to support proper care planning. As cited in the proposed rule, research suggests that 78 percent of falls are anticipated falls, occurring in individuals who could have been identified as at-risk for a fall using a risk-assessment scale. Risk adjusting for falls with major injury could unintentionally lead to insufficient risk prevention by the provider. As required by the Deficit Reduction Act of 2007, the Hospital Acquired Conditions-Present On Admission (HAC–POA) Indicator Reporting provision requires a quality adjustment in the Medicare Severity-Diagnosis Related Groups (MS–DRG) payments for certain HACs, which include falls and trauma, and these payment reductions are not risk adjusted. Furthermore, we note that the State Operations Manual (SOM) provides guidance for SNFs to assess resident risk for falls with the intent to aid providers in prevention of falls. The need for risk assessment, based on varying risk factors among residents, does not remove the obligation of providers to minimize that risk.

With regard to the MAP recommendation to risk adjust this measure cited by the commenter, the MAP feedback regarding risk adjustment for this quality measure applied to the home health setting, not to the SNF setting. We also refer readers to a more recent Cochrane review of 60 randomized controlled trials, which found that within care facilities, multifactorial interventions have the potential to reduce rates of falls and risk of falls.[65]

Comment: One commenter requested that CMS consider risk adjusting the proposed application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) for sociodemographic status, to better reflect the realities that affect the care of special populations and the need for coordination with hospitals within a geographic region. The commenter suggested that some beneficiaries in certain populations are more complex and therefore, their risk for falls resulting in major injuries may increase.

Response: While we appreciate these comments and the importance of the role that sociodemographic status plays in the care of patients, we continue to have concerns about holding providers to different standards for the outcomes of their patients of low sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on facilities' results on our measures.

NQF is currently undertaking a two-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate for each measure. For two-years, NQF will conduct a trial of a temporary policy change that will allow inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will determine whether to make this policy change permanent. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the ASPE is conducting research to examine the impact of socioeconomic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of these reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Comment: One commenter believed that collecting data on falls would be burdensome for residents who are on the unit for only part of a day. Another commenter recommended shortening the discharge assessment to only include necessary information to decrease the data collection burden.

Response: We appreciate the commenter's position that tracking falls for residents who are on the unit for only part of a day could be burdensome. However, given that facilities are responsible for residents' safety regardless of location within the facility or duration of time spent in various units, if a resident experiences an injurious fall, no matter their location in the facility, that fall will need to be tracked and reported. Moreover, data on falls are already collected in the MDS, so the additional burden associated with this measure is minimal. We note that the SNF PPS Part A Discharge assessment is limited to just the items necessary to calculate the three SNF QRP measures proposed in this rule to minimize any additional burden.

Comment: Several commenters supported the measure's addition to the SNF QRP, but expressed concerns about the measure not having been adequately tested in the short-stay or SNF population. Additionally, several commenters expressed concerns regarding the lack of NQF endorsement for an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) as a cross-setting measure for SNF, IRF and LTCH QRPs. Other commenters mentioned that the MAP conditionally supported this measure pending NQF endorsement.

Response: We thank the commenters for their support of the measure and suggested changes to the measure. We also appreciate the commenters' concerns pertaining the adequacy of the measure's testing for use in the short-stay or SNF population, which we interpret to mean adequacy regarding the reliability and validity of the proposed application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) and the items used to calculate the measure in the SNF setting.

This proposed measure is a cross-setting measure that we believe satisfies the measure required under section 1899B(c)(1)(D) of the Act domain, Incidence of Major Falls. For the reasons

[65] Cameron ID, Gillespie LD, Robertson MC, Murray GR, Hill KD, Cumming RG, Kerse N. Interventions for preventing falls in older people in care facilities and hospitals. *Cochrane Database of Systematic Reviews* 2012, Issue 12. Art. No.: CD005465. DOI: 10.1002/14651858.CD005465.pub3.

provided previously, we proposed this measure under the exception authority provided in section 1899B(e)(2)(B) of the Act, which allows CMS to apply a measure to the SNF setting that is not NQF-endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization.

With regard to the adequacy of the measure's testing for use in the short-stay or SNF population, the item-level testing during the development of the MDS 3.0 showed near-perfect inter-rater reliability for the MDS item (J1900C) used to identify falls with major injury; therefore, we disagree with the commenter's suggestion as to the strength of the item-level testing.[66] The NQF measure evaluation criteria do not require measure level reliability if item reliability is high.[67] However, we believe that, given the overlap in the populations and item-level testing results, the application of this measure for SNF residents will be reliable. That said, we intend to continue to test the measure once data collection begins as part of ongoing maintenance of the measure. We also note that a TEP convened in 2009 supported measuring falls with major injury in PAC settings regardless of the length of stay of the resident. The TEP also concurred that facilities need to take responsibility to not only prevent falls but to ensure that if they do occur, protections are in place so that the fall does not result in injury.

Comment: One commenter urged CMS to provide clarification in the final rule about the use of current falls MDS 3.0 data items under the SNF QRP. Others requested clarification on the measure specifications, stating that the specifications for how this measure will be constructed using admission and discharge assessments are unclear. Two commenters requested clarification about whether the numerator includes falls with and without injury. Another commenter asked if OBRA assessments are considered in the look-back scan and whether both long-stay and short-stay residents are included in the measure. One commenter requested that CMS clarify how the addition of the MDS discharge assessment will affect the measure specifications for the numerator and denominator of the falls measure. The commenter noted that CMS proposes modifying the MDS discharge assessment to collect information for Part A FFS Medicare beneficiaries who continue in the SNF after ending their SNF Part A covered stay, but does not clarify how this change will be implemented in the proposed falls measure. That commenter was concerned that if this new MDS discharge assessment is not included, the measure will exclude individuals who are admitted but not discharged from the SNF during their PAC stay and limit CMS' ability to provide meaningful information to both PAC providers and consumers.

Response: To clarify, the proposed quality measure will be calculated for the purposes of the SNF QRP on residents receiving services under a SNF Part A covered stay. To further clarify, although this measure is based on the data collection of two items, the numerator and denominator only use one item: the number of falls with major injury. The assessment instrument includes an item about whether any fall took place (J1800) as a gateway item. If there were any falls, the assessor then completes the next set of items (J1900) indicating the number of falls by injury status. Facilities must report the data associated with all these items in order to avoid issues with missing data and as a way to ensure accurate data collection, but only the data on falls with major injury are used in calculating the measure.

We also want to clarify that the items used to calculate the measure are already included on the existing MDS 3.0 item sets, for example, both OBRA and PPS assessments. The necessary falls items will also be added to the proposed SNF PPS Part A Discharge assessment to ensure the capture of falls with major injury at the end of the SNF Part A covered stay for residents who continue in the SNF after ending their SNF Part A covered stay.

Other than the proposed SNF PPS Part A Discharge assessment, the implementation of the proposed application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) does not represent new data collection for SNFs. SNFs have been submitting data for these items as part of the Nursing Home Quality Initiative since October 2010.

We note that specifications for the application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) for the SNF population are available on our SNF QRP measures and technical Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*. The specifications include information on how the SNF PPS Part A Discharge will be used in the measure, and specify that the measure will apply to both long- and short-stay Medicare FFS beneficiaries as long as they have had a SNF PPS Part A covered stay.

Comment: Several commenters expressed concerns about the falls measure not being standardized across PAC settings. One commenter stated that the measure should have the same wording, timeframe, and item set across all PAC settings, and that the denominator and exclusions should be the same; they also specifically noted differences in the payers that are required to report data for this measure. Two commenters objected to the exclusion of Medicare Advantage beneficiaries from the numerator and denominator for this measure. One commenter noted that measures based on only Medicare FFS beneficiaries may be incomplete, since, according to some estimates, only about half of SNF residents are covered by Medicare FFS.

Another commenter asked about the extent to which the time horizon (that is, the time period during which the measure will be calculated) will differ across settings, and another suggested that the exclusions listed in the specifications were different in different settings. One comment mistakenly asserted that the item used in the equivalent IRF specifications asks about the occurrence of two or more falls in the past year and whether a patient had major surgery, in contrast to the SNF specifications for the measure. Another commenter expressed concern regarding differences in the populations across quality measures in the SNF QRP. The commenters mentioned that the falls measure (NQF #0674) and function measure (NQF #2631) include only Medicare FFS residents, while the pressure ulcer measure (NQF #0678) includes all short-stay SNF residents. The commenter mentioned that this inconsistency could result in confusion for providers because of the varying denominators across measures.

Response: CMS appreciates the commenters' comments pertaining to the differences in the quality measure denominators by payer type across the IRF, SNF and LTCH settings. As previously stated, we believe that

[66] Saliba D. and Buchanan J. (2008). Development and Validation of a Revised Nursing Home Assessment Tool: MDS 3.0. Contract No. 500–00–0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from *http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf; http://www.geronet.med.ucla.edu/centers/borun/Appendix_A-G.pdf.*

[67] NQF. Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement. April 2015. Available online at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=79434.*

quality care is best represented through the inclusion of all patient data regardless of payer source. We agree that consistency in the data would reduce confusion in data interpretation and enable a more comprehensive evaluation of quality and although we had not proposed all payer data collection through this current rulemaking, we will take into consideration the expansion of the SNF QRP to include all payer sources through future rulemaking.

We appreciate the comment pertaining to consistent data collection across the reporting programs. We believe that quality measures that include all residents in a facility are better able to capture the health outcomes of that facility's residents, and thus, including all residents in quality reporting is important. Regarding expansion of the population used to calculate this measure to include payer sources beyond Medicare Part A, we agree with the commenter's position and intend to take this under consideration through future measure development and rulemaking.

We wish to clarify that this falls measure is not currently used for the short-stay nursing home population as part of Nursing Home Compare and that this measure will be calculated using only Medicare Part A data collected by the SNF.

With regard to the use of standardized items for this measure, until now, the post-acute assessment instruments have not included standardized items for falls with major injury. Although the quality measure, an Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), and the data collection items used to calculate this measure are harmonized across settings and assessment instruments, we believe that there are constraints in current data collection (that is, use of only admission and discharge assessments in IRFs and LTCHs vs. admission/re-entry, interim, and discharge assessments in SNFs.). For the purposes of measure calculation, we are able to compensate for this data collection approach to ensure a uniform application of the measure where currently practicable for providers and feasible for the measure so that we have harmonized the measure's calculation across all PAC settings. Although we believe that we have applied the measure consistently across the programs, to enable efficiencies in the measure's calculation, we intend to address any outstanding standardization issues through future rulemaking.

We would like to clarify that the occurrence of two or more falls in the past year and major surgery prior to admission are risk-adjusters for the function outcomes measures proposed in the FY 2016 IRF PPS proposed rule and are not related to the cross-setting falls measure, and therefore, are not included in SNF QRP version of the falls measure. We also wish to clarify that as proposed, the application of this measure for the SNF QRP will include a look-back from the time of discharge from the SNF Part A covered stay to the time of admission, so that the measure's calculation and time frame used will be consistent with the other QRPs. We note that the assessment at discharge is an actual discharge from the facility or a discharge from the SNF Part A covered stay with a transition in place. We also disagree that the exclusions listed in the measure specification for each setting are not standardized. Specifically, all three settings only exclude cases due to missing data.

Comment: One commenter supported this measure, but expressed concerns about the accuracy of the data on which the fall measure is calculated, noting that a recent survey identified deficiencies in reporting by a small sample of SNFs. One commenter expressed concerns regarding the fact that CMS excludes residents for whom missing data precludes calculation of the measure from the measure calculations. The commenter expressed concerns that this exclusion may encourage gaming, because if a facility recognizes that a resident is declining, it can simply omit some data for that resident, ensuring that the resident is excluded from the measure calculation. The commenter referenced several different media reports, which highlight the seriousness of gaming of MDS 3.0 data.

Response: We have proposed and are finalizing a threshold for reporting of actual resident data for determinations. We also intend to carefully monitor rates of missing data across all facilities. Specifically, we have proposed and are now finalizing that for FY 2018 SNF QRP, any SNF that does not meet the requirement that 80 percent of all MDS assessments submitted contain 100 percent of all data items necessary to calculate the SNF QRP measures would be subject to a reduction of 2 percentage points to its FY 2018 market basket percentage. We hope this requirement will provide incentives to providers to submit complete MDS 3.0 assessments. Further, we intend to align with other QRPs and propose through future rulemaking to implement a data validation program. Historically, rates of missing data for the items used to calculated for the NHQI falls measure in nursing homes have averaged less than 0.01 percent across all target assessments in a given quarter (for example, the rate of missing data in Q3 2014 was 0.004 percent), suggesting that missing data is minimal. Further, we intend to align with other QRPs and propose through future rulemaking a process and program surrounding data validation.

Comment: One commenter expressed concerns about providers being penalized for resident-centered care practices, such as allowing frail residents to ambulate without help.

Response: We fully support resident-centered care and enabling all residents to make informed decisions about their care. However, providers are responsible for resident safety, and falls with major injury are considered ''never events.'' Thus, providers must balance the desire to allow residents full autonomy with the need to care for their well-being, including appropriate care planning and taking steps to reduce injurious falls.

Having carefully considered the comments we received on the application of the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) measure, we are finalizing the adoption of this measure for use in the SNF QRP.

(3) Quality Measure Addressing the Domain of Functional Status, Cognitive Function, and Changes in Function and Cognitive Function: Application of Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; Endorsed on July 23, 2015)

We proposed to adopt, beginning with the FY 2018 SNF QRP, an application of the quality measure Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015) as a cross-setting quality measure that satisfies the functional status, cognitive function, and changes in functional status and cognitive function domain. This quality measure reports the percent of patients or residents with both an admission and a discharge functional assessment and an activity (self-care or mobility) goal that addresses function. The new self-care and mobility items are included in a new section of the MDS titled, Section GG.

The National Committee on Vital and Health Statistics' Subcommittee on

Health,[68] noted that ''[i]nformation on functional status is becoming increasingly essential for fostering healthy people and a healthy population. Achieving optimal health and well-being for Americans requires an understanding across the life span of the effects of people's health conditions on their ability to do basic activities and participate in life situations in other words, their functional status.'' This is supported by research showing that patient and resident functioning is associated with important outcomes such as discharge destination and length of stay in inpatient settings,[69] as well as the risk of nursing home placement and hospitalization of older adults living in the community.[70]

The majority of individuals who receive PAC services, including care provided by SNFs, HHAs, IRFs, and LTCHs, have functional limitations and many of these individuals are at risk for further decline in function due to limited mobility and ambulation.[71] The patient and resident populations treated by SNFs, HHAs, IRFs, and LTCHs vary in terms of their functional abilities at the time of the PAC admission and their goals of care. For IRF patients and many SNF residents, treatment goals may include fostering the person's ability to manage his or her daily activities so that he or she can complete self-care and/or mobility activities as independently as possible, and if feasible, return to a safe, active, and productive life in a community-based setting. For home health patients, achieving independence within the home environment and promoting community mobility may be the goal of care. For other home care patients, the goal of care may be to slow the rate of functional decline in order to allow the person to remain at home and avoid institutionalization.[72] Lastly, in addition to having complex medical care needs for an extended period of time, LTCH patients often have limitations in functioning because of the nature of their conditions, as well as deconditioning due to prolonged bed rest and treatment requirements (for example, ventilator use). The clinical practice guideline *Assessment of Physical Function*[73] recommends that clinicians document functional status at baseline and over time to validate capacity, decline, or progress. Therefore, assessment of functional status at admission and discharge and establishing a functional goal for discharge as part of the care plan is an important aspect of patient or resident care in all of these PAC settings.

Given the variation in patient or resident populations across the PAC settings, the functional activities that are typically assessed by clinicians for each type of PAC provider may vary. For example, rolling left and right in bed is an example of a functional activity that may be most relevant for low-functioning patients or residents who are chronically critically ill. However, certain functional activities such as eating, oral hygiene, lying to sitting on the side of the bed, toilet transfers, and walking or wheelchair mobility are important activities for patients or residents in each PAC setting.

Although, functional assessment data are currently collected by all four PAC providers and in NFs, this data collection has employed different assessment instruments, scales, and item definitions. The data cover similar topics, but are not standardized across PAC settings. The different sets of functional assessment items coupled with different rating scales makes communication about patient and resident functioning challenging when patients and residents transition from one type of setting to another. Collection of standardized functional assessment data across SNFs, HHAs, IRFs, and LTCHs using common data items would establish a common language for patient and resident functioning, which may facilitate communication and care coordination as patients and residents transition from one type of provider to another. The collection of standardized functional status data may also help improve patient and resident functioning during an episode of care by ensuring that basic daily activities are assessed for all PAC residents at the start and end of care and that at least one functional goal is established.

The functional assessment items included in the proposed functional status quality measure were originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration version of the Continuity Assessment Record and Evaluation (CARE) Item Set, which was designed to standardize the assessment of a person's status, including functional status, across acute and post-acute settings (SNFs, HHAs, IRFs, and LTCHs). The functional status items on the CARE Item Set are daily activities that clinicians typically assess at the time of admission and/or discharge in order to determine patient's or resident's needs, evaluate patient or resident progress, and prepare patients, residents, and their families for a transition to home or to another setting.

The development of the CARE Item Set and a description and rationale for each item is described in a report entitled ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set: Volume 1 of 3.''[74] Reliability and validity testing were conducted as part of CMS's Post-Acute Care Payment Reform Demonstration, and we concluded that the functional status items have acceptable reliability and validity. A description of the testing methodology and results are available in several reports, including the report entitled ''The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability Testing: Volume 2 of 3''[75] and the report entitled ''The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3.''[76] These reports are available on our Post-Acute Care Quality Initiatives Web page at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html*.

The functional status quality measure we proposed to adopt beginning with the FY 2018 SNF QRP is a process quality measure that is an application of the quality measure, Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015). This quality

[68] Subcommittee on Health National Committee on Vital and Health Statistics, ''Classifying and Reporting Functional Status'' (2001).

[69] Reistetter TA, Graham JE, Granger CV, Deutsch A, Ottenbacher KJ. Utility of Functional Status for Classifying Community Versus Institutional Discharges after Inpatient Rehabilitation for Stroke. *Archives of Physical Medicine and Rehabilitation,* 2010; 91:345–350.

[70] Miller EA, Weissert WG. Predicting Elderly People's Risk for Nursing Home Placement, Hospitalization, Functional Impairment, and Mortality: A Synthesis. Medical Care Research and Review, 57; 3: 259–297.

[71] Kortebein P, Ferrando A, Lombebeida J, Wolfe R, Evans WJ. Effect of 10 days of bed rest on skeletal muscle in health adults. JAMA; 297(16):1772–4.

[72] Ellenbecker CH, Samia L, Cushman MJ, Alster K. Patient safety and quality in home health care. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Vol 1.

[73] Kresevic DM. Assessment of physical function. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89–103.

[74] Barbara Gage et al., ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set'' (RTI International, 2012).

[75] Ibid.

[76] Ibid.

measure reports the percent of patients or residents with both an admission and a discharge functional assessment and a treatment goal that addresses function.

This process measure requires the collection of admission and discharge functional status data by clinicians using standardized clinical assessment items, or data elements, which assess specific functional activities, that is, self-care and mobility activities. The self-care and mobility function activities are coded using a 6-level rating scale that indicates the resident's level of independence with the activity at both admission and discharge. A higher score indicates more independence.

For this quality measure, there must be documentation at the time of admission that at least one activity (function) goal is recorded for at least one of the standardized self-care or mobility function items using the 6-level rating scale. This indicates that an activity goal(s) has been established. Following an initial assessment, the clinical best practice would be to ensure that the resident's care plan reflected and included a plan to achieve such an activity goal(s). At the time of discharge, function is reassessed using the same 6-level rating scale, enabling the ability to evaluate success in achieving the resident's activity performance goals.

To the extent that a resident has an unplanned discharge, for example, for the purpose of being admitted to an acute care facility, the collection of discharge functional status data might not be feasible. Therefore, for patients or residents with unplanned discharges, admission functional status data and at least one treatment goal must be reported, but discharge functional status data are not required to be reported.

A TEP convened by the measure development contractor for CMS provided input on the technical specifications of this quality measure, including the feasibility of implementing the measure across PAC settings. The TEP was supportive of the implementation of this measure across PAC settings and was also supportive of our efforts to standardize this measure for cross-setting use. Additionally, the MAP conditionally supported the use of an application of the Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015) for use in the SNF QRP as a cross-setting measure. The MAP noted that this functional status measure addresses an IMPACT Act domain and a MAP PAC/LTC core concept. The MAP conditionally supported this measure pending NQF-endorsement and resolution of concerns about the use of two different functional status scales for quality reporting and payment purposes. Finally, the MAP reiterated its support for adding measures addressing function, noting the group's special interest in this PAC/LTC core concept. More information about the MAP's recommendations for this measure is available in the report entitled MAP Off-Cycle Deliberations 2015: Measures under Considerations to Implement Provisions of the IMPACT Act, is available at *http://www.qualityforum.org/Project_Pages/MAP_Post-Acute_CareLong-Term_Care_Workgroup.aspx*.

The proposed measure is derived from the Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function quality measure, and we submitted the proposed measure to NQF for endorsement. The specifications are available for review at the SNF QRP measures and technical Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

We reviewed the NQF's endorsed measures and were unable to identify any NQF-endorsed cross-setting quality measures focused on assessment of function for PAC patients and residents. We are also unaware of any other cross-setting quality measures for functional assessment that have been endorsed or adopted by another consensus organization. Therefore, we proposed to adopt this function measure for use in the SNF QRP for the FY 2018 payment determination and subsequent years under the Secretary's authority under section 1899B(e)(2)(B) of the Act to select non-NQF-endorsed measures as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization.

We proposed that data for the proposed quality measure would be collected through the MDS 3.0, which SNFs currently submit through the QIES ASAP system. We refer readers to section V.C.7 of this final rule for more information on the proposed data collection and submission timeline for this proposed quality measure. The calculation algorithm of the proposed measure is described in the FY 2016 SNF PPS proposed rule (80 FR 22075).

For purposes of assessment data collection, we proposed to add new functional status items to the MDS 3.0. The items would assess specific self-care and mobility activities, and would be based on functional items included in the Post-Acute Care Payment Reform Demonstration version of the CARE Item Set. The items have been developed and tested for reliability and validity in SNFs, HHAs, IRFs, and LTCHs. More information pertaining to item testing is available on our Post-Acute Care Quality Initiatives Web page at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html*.

The proposed function items that we will add to the MDS for purposes of the calculation of this proposed quality measure do not duplicate existing items currently collected in that assessment instrument for other purposes. The currently used MDS function items evaluate a resident's most dependent episode that occurs three or more times, whereas the proposed functional items would evaluate an individual's usual performance at the time of admission and at the time of discharge. Additionally, there are several key differences between the existing and new proposed function items that may result in variation in the resident assessment results including: (1) The data collection and associated data collection instructions; (2) the rating scales used to score a resident's level of independence; and (3) the item definitions. A description of these differences is provided with the measure specifications on our SNF QRP measures and technical Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

Because of the differences between the current function assessment items (Section G of the MDS 3.0) and the proposed function assessment items that we would collect for purposes of calculating the proposed measure, we would require that SNFs submit data on both sets of items. Data collection for the new proposed function items do not substitute for the data collection under the current Section G.

We invited public comments on our proposal to adopt beginning with the FY 2018 SNF QRP an application of the quality measure Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015). The following is a summary of the comments received and our responses.

Comment: MedPAC did not support the adoption of the function process measure in the SNF QRP, and urged CMS to adopt outcomes measures focused on changes in resident physical and cognitive functioning while under a provider's care.

Response: We appreciate MedPAC's preference for moving toward the use of functional outcome measures in order to assess the resident's physical and cognitive functioning under a provider's care. We believe that the use of this process measure at this time will give us the data we need to develop a more robust outcome-based quality measure on this topic in the future. The proposed function quality measure, an Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), has attributes to enable outcomes-based evaluation by the provider. Such attributes include the assessment of functional status at two points in time, admission and discharge, enabling the provider to identify, in real time, changes, improvement or decline, as well as maintenance. Additionally, the proposed quality measure requires that the provider indicate at least one functional goal associated with a functional activity, and the provider can calculate the percent of patients who meet goals. Such real time use enables providers to engage in person-centered goal setting and the ability to use the data for quality improvement efforts. In particular, we are currently developing functional outcome measures, including self-care and mobility quality measures, for use in the SNF setting. These outcome function quality measures are intentionally being designed to use the same standardized functional assessment items that are included in the proposed function process measure, which will result in a limited additional reporting burden for SNFs.

Comment: One commenter supported the concept of measuring function and monitoring the percentage of residents with completed functional assessments. The commenter was pleased that the quality measure, an Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631, endorsed on July 23, 2015), was proposed for multiple PAC settings in accordance with the IMPACT Act. The commenter, as well as several other commenters, noted that the proposed quality measure is an application of the LTCH quality measure, and that fewer functional assessment items are in the proposed measure when compared to the LTCH process quality measure, the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631, endorsed on July 23, 2015. For example, one commenter noted that the Confusion Assessment Method (CAM©) items and the Bladder Continence items are not included in the proposed application of the quality measure.

Response: The proposed functional status process quality measure is specified as a cross setting quality measure and is standardized across multiple settings. However, to clarify which specific function items are included in each function measure for each QRP, we added a table to the document entitled, SNF QRP: Specifications of Quality Measures Adopted in the FY 2016 Final Rule, which identifies which functional assessment items are used in the cross-setting process measure as well as the setting-specific IRF and LTCH outcome quality measures. The document is available at*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

We believe that standardization of assessment items across the spectrum of post-acute care is an important goal. In this cross-setting process quality measure, there is a common core subset of function items that will allow tracking of residents' functional status across settings. We recognize that there are some differences in residents' clinical characteristics, including medical acuity, across the LTCH, SNF and IRF settings, and that certain functional items may be more relevant for certain patients/residents. Decisions regarding item selection for each quality measure were based on our review of the literature, input from a TEP convened by our measure contractor, our experiences and review of data in each setting from the PAC PRD, and public comments.

Comment: Several commenters questioned why CARE function items on the proposed IRF–PAI, MDS 3.0 and LTCH CARE Data Set are not the same set of items and believed the measure, an Application of The Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631; endorsed on July 23, 2015), meant that the items should be the same set of items.

Response: A core set of mobility and self-care items are proposed for IRFs, SNFs, and LTCHs, and are nested in the proposed section GG of the IRF–PAI, MDS 3.0 and LTCH CARE Data Set. Additional function items are included on the IRF–PAI and LTCH CARE Data Set due to the adoption of additional outcome-based quality measures in those specific settings. Therefore, a core set of items in the proposed section GG are standardized to one another by item and through the use of the standardized 6-level rating scale. We will work to harmonize the assessment instructions that better guide the coding of the assessment(s) as we believe that this will lead to accurate and reliable data, allowing us to compare the data within each setting.

Comment: Several commenters noted that the proposed function measure is a process measure and does not capture functional outcomes. One commenter did not believe that the measure would provide incentives to improve quality of care given that CMS will not determine if goals are achieved. The commenters expressed their preference for outcome measures. One commenter preferred an outcome measure, because they noted concerns about residents at risk for decline in function. Two commenters noted that functional outcome measures were under review at NQF, and two of these quality measures were developed for the SNF setting. Some of these commenters added that function outcome measures were proposed for IRFs, but no functional outcomes measures were proposed for LTCHs or SNFs. One commenter believed that CMS had a ''few'' years to implement the SNF QRP and, thus, has time to develop outcome measures. One commenter also noted that the name of the measure, which refers to Long-Term Care Hospital patients, is misleading. Several commenters expressed concern that the proposed function process measure does not meet the requirements of the IMPACT Act because measures must be outcome-based. One commenter stated that the proposed measure did not satisfy the specified IMPACT Act domain as the measure is not able to report on changes in function, and one other commenter claimed that the measure does not satisfy the reporting of data on functional status. Finally, a commenter stated that the measure does not have an appropriate numerator, denominator, or exclusions; lacks NQF endorsement; fails to be based on a common standardized assessment tool; and lacks evidence that associates the measure with improved outcomes. One

commenter claims that because the specifications for the proposed measure are inconsistent with the measure specifications posted by NQF for the measure that is under endorsement review, CMS failed to meet the requirements under the IMPACT Act to provide measure specifications to the public, and further asserted that one is not able to determine the specifications that are associated with the proposed measure, which is an application of the NQF version of the measure.

Response: We agree that the use of outcome measures is important and, as discussed above, we are currently developing functional outcome measures for the SNF setting. We appreciate the commenters concern about monitoring for decline in function and will take that into consideration as we develop the SNF outcome measures. With regard to the LTCH QRP, we adopted the quality measure Long-Term Care Hospital Functional Outcome Measure: Change in Mobility Among Patients Requiring Ventilator Support (NQF #2632; endorsed on July 23, 2015) in the FY 2015 Final Rule and data collection for this outcome measure begins in LTCHs on April 1, 2016.

The words ''Long-Term Care Hospital Patients'' are included in the title of the quality measure because it is an application to the SNF setting of the existing quality measure, Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF 2631; endorsed on July 23, 2015), which is a Long-Term Care Hospital quality measure.

We believe that the proposed function measure meets the requirements of the IMPACT Act. The statute requires, among other things, the submission of data on the quality measures specified in at least the domains identified in the Act, but does not require a particular type of measure (for example, outcome or process) for each measure domain. Further, as discussed in this section, the measure has attributes within the assessment and data collection that enables outcomes-based evaluation by the provider.

We also disagree with the comment that we failed to provide the specifications to the proposed measure. The proposed function process quality measure is *an application* of the measure, the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015). The now NQF-endorsed quality measure was proposed and finalized in the IPPS/LTCH PPS final rule (FR 79 50291 through 50298) for adoption in the LTCH QRP. An application of this measure was proposed in the FY 2016 SNF QRP proposed rule, and similarly it was proposed in the FY 2016 IPPS/LTCH PPS proposed rule and the FY 2016 IRF PPS proposed rule. We proposed the cross-setting version, an application of the LTCH QRP quality measure, based on guidance from multiple TEPs convened by our measure contractor, RTI International. The specifications for this quality measure, as well as all other proposed measures for the SNF, LTCH, and IRF QRPs were posted on the CMS Web site with the posting of the proposed rules to enable public comment. For the SNF QRP, please see the specifications at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*. These specifications were posted at the time we issued the proposed rule.

As discussed in the proposed rule under section V.C.5.c., prior to our consideration to propose this measure's use in the SNF QRP, we reviewed the NQF's endorsed measures and were unable to identify any NQF-endorsed, cross-setting or standardized quality measures focused on assessment of function for PAC patients/residents. We were also unaware of any other cross setting quality measures for functional assessment that have been endorsed or adopted by another consensus organization. Therefore, we proposed a modified version of the quality measure, the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), with such modifications to allow for its cross-setting application in the SNF QRP for the FY 2018 payment determination and subsequent years under the Secretary's authority to select a non-NQF-endorsed measure. Since the cross-setting measure is not identical to the measure recommended for NQF-endorsement, it is considered an application of the measure.

Comment: One commenter suggested that CMS conduct additional testing of the CARE function items with specific patient/resident subpopulations. The commenter also suggested research studies that compare CARE items with other instruments across diverse PAC populations. They suggested this data be used to improve the CARE items or replace them with other items to address any potential floor or ceiling effects. This commenter also suggested studies that compare models of care for subpopulations so as to elicit best practices related to complex conditions.

Response: We agree that adoption of the proposed quality measure, an application to of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF 2631; endorsed on July 23, 2015), would offer many opportunities to examine best practices for caring for SNF residents. Examining the data for any floor and ceiling effects in special populations is also a very worthy research idea. With regard to examining the CARE data against other functional assessment instrument data, as part of the PAC PRD analyses, we compared data from the existing items (that is, MDS, OASIS, and the FIM® instrument) with data from the analogous CARE items. More specifically, we ran cross tabulations of MDS function scores and CARE scores for the patients/residents in the PAC PRD to compare scores. A full description of the analyses and the results are provided in the report, The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set and Current Assessment Comparisons Volume 3 of 3, and the report is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html*. Finally, we agree that ongoing reliability and validity testing is critical for all items used to calculate quality measures.

Comment: One commenter recommended revising the definition of the item ''eating'' as it is a combination of multiple elements of self-feeding, swallowing ability, and diet texture modification.

Response: The item ''eating'' is classified as an activity, and is only scored when a resident eats by mouth. The ''eating'' score may reflect assistance needed due to various impairments such as hand/arm weakness or coordination issues or swallowing limitations. If a resident does not eat by mouth and relies on an alternative means of getting nutrition, ''eating'' is scored as ''activity not attempted.''

Comment: One commenter noted that proposed quality measures, such as the proposed function quality measure, should reflect several attributes, including low reporting burden, comprehensibility for beneficiaries, a

high level of significance to patients/residents, and data that is routinely captured.

Response: We believe that this proposed quality measure will have a high level of significance to residents and providers because it assesses resident functional status and goals, and that the measure will not impose a new, significant reporting burden on SNFs because many already assess these items as part of their standard care practices. Additionally, the NQF Person- and Family-Centered Care panel, which included several patient and patient advocates, indicated by preliminary vote that the measure meets the moderate level of evidence for ''Use and Usability.'' ''Use and Usability'' refers to whether the measure is meaningful, understandable, and useful for the intended audiences for public reporting and quality improvement. These preliminary results and the description of, ''Use and Usability'' are described in the report entitled, Phase 2 Draft Report for Voting, which is available on the Person-and Family-Centered Project Web site at *http://www.qualityforum.org/projects/person_family_centered_care/*. Among the panel, two members voted that the measure met the criteria at a high level, 12 indicated it met the moderate level of evidence, and three indicated it was low. With regard to the importance of the measure to residents, and their families, the measure reviewed by the Person-and Family-Centered Care panel did meet the importance criteria with the majority of panel members finding moderate level for evidence, performance gap and high-priority. These preliminary results and the description of ''Importance'' are described in the Report entitled, Phase 2 Draft Report for Voting, which is available on the Person-and Family-Centered Project Web site at *http://www.qualityforum.org/projects/person_family_centered_care/*.

Comment: Several commenters indicated they support quality measures focused on function, but did not support the proposed cross-setting functional status measure for the SNF QRP. Several commenters noted their lack of support was due to burden related to reporting functional status information using two distinct but similar standards and scales, using different time frames. One commenter noted that section G and section GG have different measurement metrics, with section GG providing a more granular look at the components of section G. They noted that collection of function data using different and conflicting items presents significant operational challenges and would undermine the accuracy of data collection. The commenters suggested that the adoption of the measure would also increase provider confusion because SNFs would need to be familiar with and apply different rules, definitions, and metrics when completing resident assessments. Commenters also suggested that the functional status measure increases the reporting burden on SNFs but will also lead to inaccurate coding of resident function for both measurement and payment. In addition, they noted providers would be required to spend significant time and resources providing training and oversight to ensure that each data set is completed accurately and at the right time in the resident's stay. Commenters also suggested that record keeping and reporting will be complicated, as electronic medical records will need to be updated to accommodate dual processes for recording similar clinical information leading to greater cost to providers and a decrease in the quality and accuracy of the data collected. Several commenters noted the significance of adequate training stressing the importance of appropriate coding of the new items used to calculate the proposed measures and one commenter specifically asked for clarification on which health care professional would be responsible for performing the assessment while another asked that the Minimum Data Set (MDS) Resident Assessment Instrument (RAI) Manual be provided with the necessary coding and assessment instructions for the provider's reference in a timely manner. One commenter suggested transparency with regard to how CMS will implement the new quality measures and stated that training for all providers, including instructions for the revised MDS RAI Manual, would be needed. The commenter suggested open door forums and training webinars for providers. One commenter specifically asked for clarification on which health care professional would be responsible for performing the assessment.

One commenter asked for clarification about the rationale for the short assessment period for section GG. In addition, a commenter noted that the coding of section GG, with the current look-back, will make coding of section G more complex and asked that a streamlined coding construct that is less complex be adopted. One commenter suggested that CMS develop a crosswalk to adapt the current items to create the standardization. One commenter suggested that CMS revise the MDS items to reduce burden and confusion from the duplication of data, variation in item definitions, and the variation in the rating scales. One commenter encouraged CMS to remove items from the existing data sets where possible. One commenter encouraged CMS to keep the transition period, during which both section G and section GG would be collected, short, which would allow for better cross-setting comparisons and better quality measures, and which is more in line with the intent of the IMPACT Act. Another commenter cautioned CMS about removing MDS items that are used for payment, particularly as section G has become a ''payment tool for Medicaid.'' Finally, a commenter suggested that CMS reach out to vendors to assure validity, timeliness, and accuracy when MDS changes occur.

Response: We appreciate the commenter's concerns related to the new requirements that SNFs will have to satisfy to report the proposed function measure. We agree with the importance of thorough and comprehensive training and we intend to provide such training in the near future for all updates to the MDS and assessment requirements. We also recognize that SNFs might need to conduct training to ensure that their staffs understand how to properly fill out both section G and section GG. We also intend to provide comprehensive training as we do each time the assessment items change.

In addition to the manual and training sessions, we will provide training materials through the CMS webinars, open door forums, and help desk support. We welcome ongoing input from stakeholders on key implementation and training considerations, which can be submitted via email: *PACQualityInitiative@cms.hhs.gov*.

We believe that the 6-level scale and additional items in section GG will allow us to better distinguish change at the highest and lowest levels of functioning by documenting minimal change from no change at the low end of the scale.[77] This is important for measuring progress in some of the most complex cases treated in PAC. The items in section GG were developed with input from the clinical therapy communities to better measure the change in function, regardless of the severity of the individual's functional limitations.

[77] Barbara Gage et al., ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set'' (RTI International, 2012).

To reduce the potential burden associated with collecting additional items, we have included several mechanisms in the section GG to reduce the number of items that apply to any one resident. First, in section GG, there are gateway questions pertaining to walking and wheelchair mobility that allow the clinician to skip items that ask if the resident does not walk or does not use a wheelchair, respectively. For example, in section GG, there is an item that asks whether or not the resident walks. If the resident does not walk, three items in section GG related to walking ability are skipped. Second, section GG items will only be collected at admission and discharge. The gateway questions and skip patterns mean that only a subset of section GG items are needed for most residents. However, by including all of them in the form, the standardized versions are available when appropriate for an individual resident. With regard to the assessment time frames, for the MDS items located in section G, the assessment time frames take into consideration all episodes of the activity that occur over a 24-hour period during each day of the 7-day assessment period, as a resident's ADL self-performance and the support required may vary from day to day, shift to shift, or within shifts. As stated in the CMS MDS 3.0 Resident Assessment Instrument manual, ''the responsibility of the person completing the assessment, therefore, is to capture the total picture of the resident's ADL self-performance over the 7-day period, 24 hours a day (that is, not only how the evaluating clinician sees the resident, but how the resident performs on other shifts as well)'' (CMS, 2014, ch. 3, p. G–4). The CARE function items in the proposed functional quality measures, to be nested in the proposed Section GG, have a shorter assessment time frame (3 calendar days), which is standardized across the PAC settings, based on the need for data reflecting the resident's status at the time of admission and discharge. For admission, the CARE function items are to reflect the status of the person as the person is admitted to the SNF; in other words, self-care and mobility limitations present at the time of admission. We recognize that when residents are first admitted to a SNF, clinicians often determine the resident's clinical status based on several observations and often after a period of time in which the resident adjusts to the new environment. We also recognize that several clinicians from different disciplines are observing the resident's status and this may not occur on the day of admission. Further, we are aware that residents who receive rehabilitation services may have improvement in function soon after admission to the SNF as therapy services may be provided on the day of admission or the next day. If the admission assessment is not completed early in the stay, the admission score may reflect improvement already achieved by the resident due to treatment provided. In other words, functional improvement would not be reflected in function scores if the admission assessment is conducted after therapy has started and impacted the resident's status or before therapy ends. Therefore, clinicians report resident's admission functional assessment for the CARE items based on 3 calendar days. This assessment time frame has been used in IRFs successfully and balances the need for data reflecting the resident's status at the time of admission and the interest in documenting changes in function between admission and discharge.

Finally, we thank the commenters for their comments pertaining to electronic medical records (EMRs). While we applaud the use of EMRs, CMS does not require that providers use EMRs to populate assessment data. It should be noted that with each assessment release, we provide free software to our providers that allows for the completion and submission of any required assessment data. The use of a vendor to design software that extracts data from a provider's EMR to populate CMS quality assessments, is a business decision that is made solely by the provider. We only require that assessment data be submitted via the QIES ASAP system in a specific compatible format. Providers can choose to use our free software, or the data submission specifications we provide that allow providers and their vendors to develop their own software, while ensuring compatibility with the QIES ASAP system.

Comment: Several commenters noted that the items included in the Section GG of the MDS differ from those tested during the PAC PRD and represented a limited set of items from the original CARE Tool. One of these commenter suggested that the contributions of occupational therapy may not be measureable with the limited set of items. Another commenter suggested that the assessment time frame differed from that used in the PAC PRD.

Response: The PAC PRD tested a range of items, some of which were duplicative, to identify the best performing items in each domain. Select items were removed from the item set where testing results and clinician feedback suggested the need for fewer items to be included in a particular scale. We also received feedback on the items tested in the PAC PRD from a cross-setting TEP convened by our measure development contractor, RTI International. Other changes from the original PAC–PRD items included incorporating instructional detail from the manual and training materials directly into the data collection form and updating skip patterns to minimize burden. We agree that the contribution of occupational therapy as well as other clinical disciplines, should be reflected in all item and measure development. During the PAC–PRD, clinicians from many different disciplines collected CARE data, including occupational therapists (OTs). In addition, the items in section GG were developed with the input from clinicians would be performing the assessments, including OTs.

With regard to the assessment time frame for the CARE function items, we instructed clinicians to use a 2-day time frame if the patients/residents were admitted before 12 p.m. (noon) or 3 calendar days if the patients/residents were admitted after 12 p.m. Our exit interviews revealed that most patients/residents were admitted to the SNF after 12 p.m. and that clinicians used 3 calendar days. Therefore, we have used the assessment time frame that most clinicians used during the PAC–PRD.

Comment: One commenter expressed concern about the reliability testing results for licensed nurses in the PAC PRD, given that licensed nurses play a large role in documenting function.

Response: The reliability results mentioned by this commenter were only one of several reliability analyses conducted to support the development of this measure as part of the PAC PRD. The results of licensed nurses reflect the small sample. In addition to the inter-rater reliability study mentioned by these commenters, we also examined: (1) Inter-rater reliability of the CARE items using videotaped case studies, which included 550 assessments from 28 providers; and (2) internal consistency of the function data, which included more than 2,749 SNF residents. Overall, these results indicate moderate to substantial agreement on these items. The report describing these additional analyses and an interpretation of the Kappa statistics results is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/The-Development-and-Testing-of-the-*

Continuity-Assessment-Record-and-Evaluation-CARE-Item-Set-Final-Reporton-Reliability-Testing-Volume-2-of-3.pdf.

Therefore, given the overall findings of these reliability analyses, we believe that the proposed function measure is sufficiently reliable for the SNF QRP.

Comment: One commenter was concerned that no data was provided clearly linking improved outcomes to this process measure.

Response: We believe that there is evidence that this is a best practice based on several clinical practice guidelines. The NQF requirement for endorsing process measures is that the process should be evidence-based, such as processes that are recommended in clinical practice guidelines. As part of the NQF process, CMS submitted several such clinical practice guidelines [78] [79] [80] to support this measure, and referenced another cross-cutting clinical practice guideline in the proposed rule. The clinical practice guideline Assessment of Physical Function [81] recommends that clinicians should document functional status at baseline and over time to validate capacity, decline, or progress. Therefore, assessment of functional status at admission and discharge and establishing a functional goal for discharge as part of the care plan (that is, treatment plan) is an important aspect of patient/resident care for all of these PAC providers.

Comment: Several commenters suggested that CMS develop a plan to revise the existing MDS function items to be more consistent with the data collected in the other PAC settings, noting this would lay the groundwork for a measure that is more ''standardized'' and ''interoperable'' across post-acute care settings. Some commenters noted that this transition would require considerable analysis to ensure there are not negative unintended consequences for SNF reimbursement, and testing in SNF facilities to ensure the revised instrument collects accurate, reliable and meaningful data.

Response: We have proposed to add a core set of CARE function items to the MDS for SNFs, the IRF–PAI for IRFs and the LTCH CARE Data Set. These standardized data will enable interoperability across these PAC settings. As noted above, the proposed IRF–PAI and proposed LTCH CARE Data Set include additional CARE function items, because those QRPs include additional functional outcome measures, and these measures require collection of more than just the core items included in the function process measure. The development of the entire original set of CARE function items, including the definitions for each activity, were selected based on a review of all existing items used by LTCHs, IRFs, SNFs and HHAs, a review of the literature, and input from stakeholders such as clinicians and researchers.

Comment: One commenter noted that the proposed function measure includes reporting of a goal as a way to document that residents have a care plan that addresses function, and that this reporting of function goals was not part of the original PAC PRD. The commenter further noted that reporting of only one goal was not ideal, because many residents have goals for multiple functional activities and the number of standardized functional assessment items is limited compared to the full set of function items tested as part of the PAC PRD. Finally, the commenter indicated that treatment goals may be to improve function, and therefore, are restorative in nature, while therapy may be necessary so to ensure the maintenance of a PAC resident's function.

Response: The proposed function measure requires a minimum of one (1) goal per resident stay; however, clinicians can report goals for each self-care and mobility item included in the proposed section GG of the MDS. We believe that assessing resident function goals should be part of clinical care and builds upon the conditions of participation (CoPs) for SNF providers. The IMPACT Act also specifically mentions goals of care as an important aspect of the use of standardized assessment data, quality measures, and resource use to inform discharge planning and incorporate resident preference. We agree that for many PAC patients/residents, the goal of therapy is to improve function and we also recognize that for some residents, delaying decline may be the goal. We believe that individual, person-centered goals exist in relation to individual preferences and needs. We will provide instructions pertaining to the reporting of goals in a training manual and in training sessions in order to better clarify that goals set at admission may be focused on improvement of function or maintenance of function.

Comment: Several commenters were concerned that the measure, an Application of the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631;endorsed on July 23, 2015) was not NQF endorsed. Some of these commenters noted that it was under review at NQF for the LTCH setting and not for the SNF setting.

Response: We agree that the NQF endorsement process is an important part of measure development. We have proposed an application of the quality measure, the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function. This quality measure is now NQF endorsed. We have a rigorous process of construct testing and measure selection, guided by the TEPs, public comments from stakeholders, and recommendations by the PAC/LTC MAPs.

Comment: One commenter recognized the burden of changing assessment items, but noted the utilization of standardized assessment items is expected to improve transitions. The commenter indicated that proposal was an action of good intent toward the statutory standardization of assessment.

Response: We thank the commenter for their comment and support for the inclusion of the standardized (that is, CARE) functional assessment items. We agree that standardized assessment across PAC settings has the potential to improve care.

Comment: One commenter noted that one reason for standardized assessment items ''would be to establish a common language for patient and resident functioning, which may facilitate communication and care coordination as patients and residents transition from one type of provider to another,'' and asked CMS to provide data on the number or percent of patients/residents that transition from one type of provider to another. The commenter further requested information about why the

[78] Kresevic DM. Assessment of physical function. In: Boltz M., Capezuti E., Fulmer T., Zwicker D., editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89–103. Retrieved from *http://www.guideline.gov/content.aspx?id=43918*.

[79] Centre for Clinical Practice at NICE (UK). (2009). Rehabilitation after critical illness (NICE Clinical Guidelines No. 83). Retrieved from *http://www.nice.org.uk/guidance/CG83*.

[80] Balas M.C., Casey C.M., Happ M.B. Comprehensive assessment and management of the critically ill. In: Boltz M., Capezuti E., Fulmer T., Zwicker D., editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 600–27. Retrieved from *http://www.guideline.gov/content.aspx?id=43919*.

[81] Kresevic DM. Assessment of physical function. In: Boltz M., Capezuti E., Fulmer T., Zwicker D., editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89–103. Retrieved from *http://www.guideline.gov/content.aspx?id=43918*.

current measures fail to provide clinicians with the information needed.

Response: Several studies have documented patient/resident transition patterns following discharge from the hospital and continuing for 30, 60, or 90 days.[82] [83] [84] While the exact proportions discharging to each type of care vary slightly across the years, the proportion of acute hospital admissions being discharged to PAC has grown from 35 percent in 2006 to 43 percent in more recent years (MedPAC, 2014). Among those discharged to PAC, the majority are discharged to SNF or HHA, and a much smaller proportion are discharged to IRFs and LTCHs. Further examination shows that among each of the four PAC admissions, many individuals continue to transition to subsequent sites of care. Common discharge patterns from the IRF, for example, include over 75 percent of cases continuing into HHA or outpatient therapy services. SNF cases are commonly discharged home with either outpatient therapy or home health services. One report outlining these issues is entitled, ''Examining Post Acute Care Relationships in an Integrated Hospital System'' (available at *http://aspe.hhs.gov/health/reports/09/pacihs/report.pdf*). This report includes a summary of the most common PAC transition patterns for Medicare FFS Beneficiaries in 2006.

Comment: One commenter encouraged CMS to risk adjust all outcome measures.

Response: The proposed function quality measure, an Application of the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631, endorsed on July 23, 2015), is a process measure that focuses on the clinical process of completion of functional assessments and a care plan addressing function. Although the IMPACT Act requires that the cross-setting quality measures be risk-adjusted as determined appropriate by the Secretary, it does not limit the Secretary to adopting outcome measures. Some process measures are risk adjusted,[85] [86] However, in the development of an application of the measure, the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), the Technical Expert Panel considered, but did not recommend, the application of a risk adjustment model. We agree with that conclusion because the completion of a functional assessment, which includes the use of ''activity not attempted'' codes, is not affected by the medical and functional complexity of the resident. Therefore, we believe that risk adjustment of this quality measure is not warranted.

Comment: Several commenters noted additional areas of function that are key to residents, including cognition, communication, and swallowing. One commenter encouraged CMS to consider cognition and expressive and receptive language and swallowing as items of function and not exclusively as risk adjustors, and offered their expertise to CMS for discussions and to develop goals. Another commenter examined the SNF, IRF, HHA and LTCH assessment instruments and noted that cognitive function is measured differently across the settings in terms of content, scoring process, and intended calibration of each tool, and encouraged CMS to align items and quality measurement of cognition.

Response: We are working toward developing quality measures that assess areas of cognition and expression, recognizing that these quality topic domains are intrinsically linked or associated to the domain of function and cognitive function. We appreciate the commenter's offer for assistance and encourage the submission of comments and measure specification details to our comment email: *PACQualityInitiative@cms.hhs.gov*.

Comment: One commenter suggested that CMS remove some items from section G if section GG items are adopted. One commenter noted that the four late-loss activities of daily living (ADL) items from Section G should be retained and this commenter recognized that some items were needed for payment. The commenter noted differences in the rating scales for the items in section G and the items in section GG.

Response: We recognize that the items in section G serve many purposes such as those items that are used for payment, and will continue to take into consideration all factors pertaining to payment and quality.

Comment: One commenter was concerned that residents with missing data in their assessment records would be excluded from this measure. This commenter was concerned that this could present SNFs with an opportunity to purposefully exclude data.

Response: We thank the commenter for their comments and appreciate the concerns pertaining to intentionally excluded data. We would like to clarify that there are no resident exclusions criteria for this measure. Therefore, this potential for ''gaming'' does not exist for this measure. Nonetheless, as part of our compliance analysis we intend to carefully monitor rates of missing data across all facilities. Specifically, we are finalizing that for FY 2018, any SNF that does not meet the proposed requirement that 80 percent of all MDS assessments submitted contain 100 percent of all data items necessary to calculate the SNF QRP measures would be subject to a reduction of two percentage points to its FY 2018 market basket percentage. We hope this requirement will incentivize providers to submit complete MDS 3.0 assessments.

Comment: A commenter was concerned about the use of a consistent definition of the short-stay population, the denominator, in this function measure, as well as the other proposed measures for use in the SNF QRP. The commenter was also concerned about the alignment of measures with major CMS initiatives.

Response: We appreciate the commenters' comments pertaining to the differences in the function quality measure denominators by payer type across the IRF, SNF and LTCH settings and we have addressed this comment previously. We believe that quality care is best represented through the inclusion of all patient data regardless of payer source. We agree that consistency in the data would reduce confusion in data interpretation and enable a more comprehensive evaluation of quality and although we had not proposed all payer data collection through this current rulemaking, we will take into

[82] Gage, B., Morley, M., Ingber, M., & Smith, L. (2011). Post-Acute Care Episodes Expanded Analytic File: RTI International. Prepared for the Assistant Secretary for Planning and Evaluation. Retrieved from *http://aspe.hhs.gov/health/reports/09/pacihs/report.pdf.*

[83] Gage, B., Morley, M., Constantine, R., Spain, P., Allpress, J., Garrity, M., & Ingber, M. (2008). Examining Relationships in an Integrated Hospital System: RTI International. Prepared for the Assistant Secretary for Planning and Evaluation. Retrieved from *http://aspe.hhs.gov/health/reports/08/examine/report.html.*

[84] Gage, B., Pilkauskas, N., Dalton, K., Constantine, R., Leung, M., Hoover, S., & Green, J. (2007). Long-Term Care Hospital (LTCH) Payment System Monitoring and Evaluation Phase II Report RTI International. Prepared for the Centers for Medicare & Medicaid Services. Retrieved from *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/downloads/rti_ltchpps_final_rpt.pdf.*

[85] For example, in the NQF-endorsed process measure Percent of Residents Who Have/Had a Catheter Inserted and Left in Their Bladder (long stay) (NQF#0686) for which we are the steward, resident-level limited covariates (Frequent bowel incontinence, or always incontinent on prior assessment; and Pressure ulcers at stages II, III, or IV on prior assessment) are used in a logistic regression model to calculate a resident-level expected quality measure score.

[86] Peter C. Smith, Elias Mossialos, Irene Papanicolas and Sheila Leatherman. Performance Measurement for Health.

consideration the expansion of the SNF QRP to include all payer sources through future rulemaking.

Comment: Two commenters requested that CMS continue in its public engagement with stakeholders, and one requested increased engagement with regard to the IMPACT Act and measures it considers. Other commenters stated their appreciation for inclusion and opportunity to work with CMS during the implementation phases of the IMPACT Act. One commenter also recommended that CMS establish a more formal stakeholder group to include rehabilitation professionals who can provide expertise on the provision of rehabilitation therapy in NFs. This commenter noted that the more opportunities stakeholders have to engage in dialogue with and advise CMS on the quality measures, the greater the possibility that the measures will be accurate and helpful to determining care quality.

Response: We appreciate the continued involvement of stakeholders in all phases of measure development and implementation, as we see the value in strong public-private partnerships. We also believe that ongoing stakeholder input is important to the success of the IMPACT Act and look forward to continued and regular input from the provider communities as we continue to implement the IMPACT Act.

Comment: One commenter suggested that the PAC PRD data was collected only by therapists, and expressed concern that the items had not been tested using other care providers. In addition, this commenter had specific questions about scoring different assessments during the time window proposed. This commenter also had specific questions about which SNF clinicians will complete the functional assessment items for this measure.

Response: We wish to clarify that during the PAC PRD, data were collected by clinicians from many different disciplines, including OTs, PTs, SLPs and RNs. Reliability testing included testing by discipline as well as by setting. However, the items were developed with the input of various personnel who would be performing the assessments, which included OTs, PTs, SLPs, and RNs. Regarding the questions about scoring assessments and staff that will be trained to complete functional assessments, we have historically provided training for providers. As we prepare for this type of training, we will make sure to have this type of information available to the public to increase transparency and readiness.

Comment: A commenter urged CMS to develop function measures that take resident quality of life into account. The commenter noted that function measures are not ''one size fits all.'' Another commenter suggested CMS focus on key concerns of beneficiaries with disabilities and chronic conditions, including, where appropriate: The ability to live as independently as possible, to function at the maximum extent possible, to return to employment where appropriate, to engage in recreational and athletic pursuits, to engage in community activities, and to maintain the highest quality of life possible.

Response: We believe that this proposed quality measure will have a high level of significance to residents and providers. The proposed function quality measure is a person and family-centered process measure that reports standardized functional assessment data at admission and discharge, as well as at least one functional status discharge goal, demonstrating person and family-centered care. The IMPACT Act specifically mentions goals of care as an important aspect of the use of standardized assessment data, quality measures, and resource use to inform discharge planning and incorporate resident preference. However, we are always open to stakeholder feedback on measure development and encourage everyone to submit comments to our comment email: *PACQualityInitiative@cms.hhs.gov*.

Comment: One commenter recommended that CMS exclude section GG data from all medical review organizations or processes for the first three years.

Response: The item sets included in section GG are being proposed to satisfy measure domains under the IMPACT Act and are not being proposed for use in making payment determinations. The primary purpose of medical review is to validate medical necessity and to identify coding discrepancies to determine whether payment is appropriate. The item sets in Section GG are not being used for this purpose and are therefore not subject to medical review. A provider's failure to submit the data to complete section GG could result in a determination of noncompliance with the SNF QRP, resulting in a 2 percent reduction to the SNF's market basked percentage for the applicable fiscal year.

Final Decision: Having carefully considered the comments we received on the application of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015), we are finalizing the adoption of this measure for use in the SNF QRP.

f. SNF QRP Quality Measures Under Consideration for Future Years

TABLE 10—SNF QRP QUALITY MEASURES AND CONCEPTS UNDER CONSIDERATION FOR FUTURE YEARS

IMPACT Act Domain	Measures to reflect all-condition risk-adjusted potentially preventable hospital readmission rates.
Measures	(NQF #2510): *Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM).*
	(NQF #2512; NQF #2502): Application of the LTCH/IRF All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from LTCHs/IRFs.
IMPACT Act Domain	Resource Use, including total estimated Medicare spending per beneficiary.
Measure	(NQF #2158): Application of the Payment Standardized Medicare Spending Per Beneficiary (MSPB).
IMPACT Act Domain	Discharge to community.
Measure	Percentage residents/patients at discharge assessment, who are discharged to a higher level of care or to the community. Measure assesses if the patient/resident went to the community and whether they stayed there. Ideally, this measure would be paired with the 30-day all-cause readmission measure.

We invited comments on the measure domains and associated measures and measure concepts listed in Table 10. In addition, consistent with the requirements of the IMPACT Act to develop quality measures and standardize data for comparative purposes, we believe that evaluating outcomes across the post-acute care settings using standardized data is an important priority. Therefore, in addition to adopting a process-based measure for the IMPACT Act domain of ''Functional status, cognitive function, and changes in function and cognitive function'', which is included in this year's final rule, we also intend to develop outcomes-based quality

measures, including functional status and other quality outcome measures to further satisfy this domain. These measures will be proposed in future rulemaking in order to assess functional change for each care setting as well as across care settings. The comments we received on this topic, with their responses, appear below.

Comment: Several commenters urged CMS to consider future quality measures for the SNF QRP related to various topics including: Patient and family engagement; nutrition; key concerns related to a patient's quality of life following discharge from post-acute care; and workforce. One commenter requested that quality measures currently reported through Nursing Home Compare also be considered for future use in the SNF QRP.

Response: We agree that the suggested measure areas are important for quality of care in SNFs, and we would like to highlight that measures pertaining to nutrition, quality of life, patient and family engagement and person-centered care are known gaps in quality, and therefore, are among our priorities to address. Such measures align with our CMS Quality Strategy. We also agree with the importance of workforce related measures as we understand that quality outcomes are often directly linked with staffing and workforce. We agree that measures currently reported through Nursing Home Compare should also be considered for future use in the SNF QRP, and we are finalizing two measures currently reported through Nursing Home Compare (Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay) (NQF #0678) and an application of the measure Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674)) for the FY 2018 SNF QRP. We will consider the commenters' recommendations in our measure development and testing efforts, as well as in our ongoing efforts to identify and propose appropriate measures for the SNF QRP in the future.

Comment: One commenter supported the IMPACT Act requirement to measure and report on rehospitalization and discharge to community measures. However, the commenter expressed several concerns regarding the potential future measures identified by CMS and recommended several considerations for future measure development. The commenter did not believe that three potential future rehospitalization measures (Skilled Nursing Facility 30-Day All-Cause Readmission Measure (NQF #2510), Application of the LTCH/IRF All-Cause Unplanned Readmission Measure for 30 Days Post Discharge from LTCHs/IRFs (NQF #2512; NQF #2502)) comply with IMPACT Act requirements because the measures have different numerator and denominator definitions and exclusions. The commenter is also concerned that while the three measures are NQF-endorsed in each of their respective settings, they are not yet endorsed as cross-setting measures. Finally, the commenter states that these measures should not be restricted to Medicare FFS beneficiaries as this is inconsistent with the IMPACT Act. To comply with the IMPACT Act requirements, this commenter recommended that CMS develop an all-cause all payer rehospitalization measure that (a) is not restricted to Medicare FFS beneficiaries, and (b) has the same numerator and denominator definitions, but may use different risk adjustment variables, in each PAC setting. The commenter further suggests that pairing the proposed rehospitalization measure with the discharge to community measure would not be appropriate.

When developing the Discharge to Community measure, the commenter recommends that CMS consider differences across PAC providers, and the implications of those differences on measure specification. An additional commenter also supported the Discharge to Community measure, which is under consideration for future years.

The commenter also recommended that when developing a resource measure, CMS should collect information from NQF on prior work done to address challenges related to developing a reliable and valid resource measure that measures total Medicare spending per beneficiary. Finally, the commenter stated that CMS needs to begin working on a medication reconciliation measure as listed in the IMPACT Act.

Response: We believe that we have the discretion to implement either a within stay readmission measure, or a post-PAC discharge readmission measure in satisfaction of the IMPACT Act. Therefore, both measure concepts listed could be applicable. We appreciate the suggestion that such a measure not be paired with the discharge to community measure and will take this under consideration. With regard to the suggested development of an all-cause all payer rehospitalization measure that is not restricted to Medicare FFS beneficiaries, has uniform numerators and denominators and is appropriately risk adjusted in each PAC setting, we appreciate the commenter's suggestions and generally agree to the importance of all payer data. That said, consistent with the other PAC settings' post-discharge hospital readmission measures, such a cross-setting measure for this setting is currently under development as a claims based measure thereby limiting its denominator to Medicare claims data and we intend to standardize denominator and numerator definitions. With regard to NQF endorsement as a cross-setting measure, as mentioned previously, when possible we will propose and adopt a measure that has been endorsed by the NQF. However, when this is not feasible, the IMPACT Act in section 1899B(e)(2)(B), permits the Secretary to adopt a measure for the QRPs that is not NQF-endorsed. We want to clarify that the IMPACT Act does allow for program-related risk adjustment, as appropriate, and we intend to risk adjust the readmission measure intended to satisfy the IMPACT Act domain, which is an all-condition risk-adjusted potentially preventable hospital readmission rate. We appreciate the commenter's concern that CMS ensure the development of a medication reconciliation measure and although the Medication Reconciliation domain of the IMPACT Act was not addressed in this year's SNF proposed rule, we are currently in the process of developing a cross-setting measure to address this domain of care.

Comment: One commenter made several suggestions regarding the process CMS should use when developing future measures. The commenter recommended that CMS seek additional stakeholder input as it develops more detailed specifications for the measures under consideration for future years and that CMS seek NQF endorsement for future measures prior to including them in rulemaking.

Response: We will take the recommendations into consideration in our measure development and testing efforts, as well as in our ongoing efforts to identify and propose appropriate measures for the SNF QRP in the future. We recognize the need for transparency as we move forward to implement the provisions of the IMPACT Act and plan to continue to engage stakeholders to ensure that our approach to implementation is communicated in an open and informative manner.

Comment: Two commenters requested that CMS consider the CARE–C and CARE–F items based on the National Outcomes Measurement System (NOMS) to capture communication, cognition, and swallowing as additional measures to be adopted in post-acute care settings for future measures. One commenter encourages CMS and other measure developers to consider

functional items such as velocity or gait speed which may provide a more meaningful picture of the quality of mobility performance versus ambulation distance.

Response: We note that comments on the addition of areas of function, including cognition, communication, and swallowing are addressed further in section III.D.3.e. iii., Quality Measure Addressing the Domain of Functional Status, Cognitive Function, and Changes in Function and Cognitive Function: Application of Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631; endorsed on July 23, 2015). We appreciate the suggestion that we consider functional items such as velocity or gait speed which may provide a more meaningful picture of the quality of mobility performance versus ambulation distance. We will consider these recommendations in our item and measure development and testing efforts for both measure development as well as standardized assessment domain development.

g. Form, Manner, and Timing of Quality Data Submission

(1) Participation/Timing for New SNFs

Beginning with the submission of data required for the FY 2018 payment determination, we proposed that a new SNF would be required to begin reporting data on any quality measures finalized for that program year by no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter. For example, for FY 2018 payment determinations, if a SNF received its CCN on August 28, 2016, and 30 days are added (for example, August 28 + 30 days = September 27), the SNF would be required to submit data for residents who are admitted beginning on October 1, 2016.

We invited public comments on this proposed timing for new SNFs to begin reporting quality data under the SNF QRP. However we received no comments on this proposal.

Final Decision: We are finalizing our proposal pertaining to the Participation/Timing for New SNFs as proposed.

(2) Data Collection Timelines and Requirements for the FY 2018 Payment Determination and Subsequent Years

As discussed previously, we proposed that SNFs would submit data on the proposed functional status, skin integrity, and incidence of major falls measures by completing items on the MDS and then submitting the MDS to CMS through the Quality Improvement and Evaluation System (QIES), Assessment Submission and Processing System (ASAP) system. We sought comment on the proposed method of data collection.

We received no comments on the use of the MDS as the proposed method for data collection and the QIES ASAP system for data submission. Therefore, we are finalizing this approach as proposed.

Currently, there is no discharge assessment required when a resident is discharged from the SNF Medicare Part A covered stay but does not leave the facility, and we are aware that this affects nearly 30 percent of all SNF residents. To collect the data at the time these beneficiaries are discharged from the SNF Part A covered stay, we proposed to add an item set in addition to the 5-Day PPS Assessment. Further, to collect the data elements required to calculate the function quality measure (an application of Percent of Long-Term Care Hospital Patients With an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function [NQF #2631; endorsed on July 23, 2015]) at the time of a residents admission, we also proposed to add the necessary items to the 5-day PPS Assessment.

A list of the data items that we are proposed to add to the SNF PPS Part A Discharge and the 5-Day PPS Assessments is available on our Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*. We recognize that there may be instances where SNFs want to combine the SNF PPS Part A Discharge Assessment with other required assessments, as happens with other PPS and OBRA assessments, or scenarios in which the end of the Part A covered stay occurs at the same time as a scheduled PPS assessment. Therefore, we invited public comment on any situations where assessments may be combined or interact, which should be considered in implementing the SNF PPS Part A Discharge Assessment with a view toward addressing any issues that we may identify through the public comment process as requiring additional clarification.

We invited public comments on our proposed SNF QRP Data Collection Requirements for the FY 2018 Payment Determination and Subsequent Years.

Comment: One commenter recommended that CMS shorten the MDS discharge assessment to only information needed to construct the measures since the information will not be used in patient care, suggesting that its use pertained to the IMPACT Act requirements for collecting information at admission and discharge for measurement purposes. The commenter also recommended that the OBRA Admission assessment should be completed as a dually coded assessment with the PPS 5-day assessments in order that admission assessments for measures are aligned for all Medicare and Non-Medicare beneficiaries, such as Medicare Advantage beneficiaries.

Response: The discharge assessment is intended to collect the standardized data used to calculate the measures. Therefore, the SNF PPS Part A Discharge includes only the discharge assessment data needed to inform current and future SNF QRP measures and the calculation of those measures. With regard to the commenter's recommendation that the OBRA Admission assessment be dually coded with the 5-day assessment, we note that this type of combination is possible under the current system, though not required.

Comment: Several commenters suggested that the MDS was designed as an assessment for adults and does not address the needs of individuals under 21 years of age, specifically children with complex medical needs like an intellectual or developmental disability. Though NFs that treat pediatric residents complete the MDS for those residents, it is not an appropriate tool to measure resident needs or to use as the basis of a comprehensive care plan for pediatric residents. Thus, the commenter requested that pediatric NFs be exempted from completing the MDS for their residents, and that data from the MDS not be utilized for the quality measures of pediatric NFs, or that CMS adopt an assessment instrument for pediatric SNFs that reflect the unique areas of focus.

In addition, one commenter suggests that residents of a sub-acute SNF unit are at elevated risk for medical complications due to their chronic, long-term, acute illnesses, when compared to residents of other SNF units. Due to the differences between residents of sub-acute SNF units and ''regular'' SNFs, the commenter requests that an additional field be added to the MDS to identify sub-acute SNF residents.

Response: The MDS was designed with numerous groups in mind, including pediatric nursing home

residents and their caregivers. In addition, data submission to CMS for the purposes of the SNF QRP requires the submission of such data while the resident is under a Part A covered stay. Regarding the comment on sub-acute units, we will take the recommendation into consideration.

Comment: One commenter expressed concerns about the accuracy of the MDS data that will be used to calculate the new quality measures. The commenter noted that the MDS 3.0 Focused Survey Pilot conducted by CMS found ''room for improvement in MDS 3.0 assessment agreement with a resident's medical record, especially in the reporting of the severity and frequency of falls, late loss ADL status, pressure ulcer status, restraint use, and coding of certain diagnoses including UTI.'' The commenter suggested that additional steps are necessary to improve data accuracy, such as revising and testing revisions to the survey protocol, drafting additional guidance and requiring additional training for surveyors, conducting special surveys of resident assessments, reporting on Nursing Home Compare when data are invalid, and promulgating regulations to require penalties for violations of assessment requirements.

Response: We agree that training is critical to assure both provider accuracy and understanding of the assessment and data collection requirements. We appreciate the commenter's suggestions pertaining to use of various means to ensure accuracy, such as surveyor-related protocols and activities as well as the use of Nursing Home Compare for the reporting of data and will take these into consideration. We discuss below our intention to develop a data validation program to ensure that SNF QRP data is accurately reported.

Comment: One commenter expressed that it is unclear about the timeframe in which additional items will be added to the MDS item sets. The commenter recommended that CMS standardize and align the PAC assessments (MDS, OASIS, IRF–PAI, and LTCH–CARE) prior to finalizing the proposed quality measures. The commenter suggested that after the PAC assessments are aligned, CMS should utilize a period of testing for the proposed measures. The commenter also suggested that the quarterly reporting of claims data requires that hospital claims and PAC provider claims be tracked simultaneously and will likely delay the production of data which can be reported to providers if provider claims are not submitted in a timely manner.

Response: We appreciate the commenter's interest in clarification on the timelines related to implementation of the assessment changes required for the submission of the standardized data for measures finalized in this rule. The implementation of the revised assessment instruments for data collection of the finalized measures is October 1, 2016. We appreciate the suggestion to standardize the post-acute assessment instruments prior to finalizing the measures; however, such an approach may not be feasible when, for example, the modification of the instruments is a result of a new measure using new items. In that instance, rulemaking is necessary to finalize such measures before subsequent assessment changes can be determined. That said, we will attempt to develop measures where appropriate from existing items. We agree that testing is imperative and through ongoing measure development and maintenance we apply such testing and intend to continue to do so. Additionally, we attempt to use endorsed measures where able, however, under certain circumstances, for reasons discussed earlier and under our authority to do so, we may elect to propose measures that are not endorsed. We appreciate the commenter's concern regarding the quarterly reporting of claims data and potential delays, although we do not foresee such an issue. Nonetheless, we will monitor for this possibility.

Comment: Several commenters suggested that we had inaccurately estimated the economic impact associated with the burden of collection of the new assessment items used to calculate the proposed quality measures. Commenters suggested that the assessment of 0.5 minutes of nursing staff time per each new item was too low because it didn't take into account the time for a beneficiary to complete tasks associated with self-care or mobility, or the time necessary to navigate through a data entry system. One commenter also noted that the function items take into account a person's *usual* function, over the course of days 1 to 3 days, which they feel implies that activities need to be assessed multiple times, adding burden. Another commenter stated that the economic impact analysis did not account for staff training. Similarly, commenters stated that the economic analysis did not factor in the providers' software and hardware costs. We also received a comment pertaining to changes in payer source during a resident's stay, noting a concern that adding additional payer sources could also add additional burden. We also received a comment requesting that CMS provide additional payment to the providers during the time that they implement the new assessment items.

Response: We appreciate the concerns related to the assessment of costs associated with the data collection for the SNF QRP. In response to commenters' concerns regarding our estimate of nursing facility staff time per item, we would like to clarify that this is an estimate only of the time spent determining and documenting the score following the observation of the patient. The burden-related estimates used to evaluate the economic impact are based on assessment data coding and would not take into account computer system delays or other such features. In response to the comment regarding multiple assessments required to assess usual function by the new section GG function items, we would like to clarify that only one score is reported for each item in section GG, the resident's usual performance. Clinicians assess the resident's functional abilities once or several times during an assessment period as part of routine practice. Consistent with the current function items in the MDS (section G), section GG considers the resident's ability to perform an activity across the entire assessment period. Such clinical assessment and data collection is based upon customary and best practices that we believe would be occurring. We also note that, to minimize burden on providers, these items are only required for data collection at the time of admission and discharge. Further, to ensure minimal burden the new items found in section GG, we include several gateway questions that allow the clinician to skip questions in the data set that are not appropriate for an individual patient in order to reduce burden. We have instituted skip options so that the final number of items assessed per patient is limited depending on their complexity and capabilities. Therefore, although all of the items are available for assessment, we have built in mechanism that enables the assessor to include assessment information as, and when, appropriate.

With regard to the commenter's concerns surrounding training and software/hardware costs, we recognize that with item set changes, there are necessary training and software updates that may be needed. Although the burden estimate would not be a reflection of individual provider training needs, or those related to software and hardware, we do include in the cost estimates cost pertaining to overhead. That said, CMS provides free of charge the submission specifications,

as well as free, downloadable software to providers and we intend to provide provider based training that would be free of charge, as we have done in the past. With regard to increased costs associated with all payer data capture, there already exists administrative-related data capture in the MDS 3.0, and therefore, such data capture, should we require all payer data in the future, would not come with additional burden.

We believe that we have accounted for the costs of reporting data in our burden estimates, as they are doubled to provide for overhead and fringe benefits, which should include costs associated with any required staff training related to the collection of new items. However, additionally, we do not include in our burden estimates the time that it takes providers to enter the data into their systems, as this is a part of routine clinical care and medical charting, and the data we require providers to report is routine in this respect as well.

Having carefully considered the comments we received on our proposal pertaining to the Data Collection Requirements for the FY 2018 Payment Determination and Subsequent Years, we are finalizing the policy as proposed.

For the FY 2018 payment determination, we proposed that SNFs submit data on the three proposed quality measures for residents who are admitted to the SNF on and after October 1, 2016, and discharged from the SNF up to and including December 31, 2016, using the data submission schedule that we proposed in this section.

We proposed to collect a single quarter of data for FY 2018 to remain consistent with the usual October release schedule for the MDS, to give SNFs a sufficient amount of time to update their systems so that they can comply with the new data reporting requirements, and to give CMS a sufficient amount of time to determine compliance for the FY 2018 program. The proposed use of one quarter of data for the initial year of quality reporting is consistent with the approach we used to implement a number of other QRPs, including the LTCH, IRF, and Hospice QRPs.

We also proposed that following the close of the reporting quarter, October 1, 2016, through December 31, 2016, for the FY 2018 payment determination, SNFs would have an additional 5½ months to correct and/or submit their quality data. Consistent with the IRF QRP, we proposed that the final deadline for submitting data for the FY 2018 payment determination would be May 15, 2017. We further proposed that for the FY 2019 payment determination, we would collect data from the 2nd through 4th quarters of FY 2017 (that is, data for residents who are admitted from January 1st and discharged up to and including September 30th) to determine whether a SNF has met its quality reporting requirements for that FY. Beginning with the FY 2020 payment determination, we proposed to move to a full year of FY data collection. We intended to propose the FY 2019 payment determination quality reporting data submission deadlines in future rulemaking.

TABLE 11—PROPOSED MEASURES, DATA COLLECTION SOURCE, DATA COLLECTION PERIOD AND DATA SUBMISSION DEADLINES AFFECTING THE FY 2018 PAYMENT DETERMINATION

Quality measure	Data collection source	Proposed data collection period	Proposed data submission deadline for FY 2018 payment determination
NQF #0678: Percent of Patients or Residents with Pressure Ulcers that are New or Worsened.	MDS	10/01/16–12/31/16	May 15, 2017.
NQF #0674: Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).	MDS	10/01/16–12/31/16	May 15, 2017.
NQF #2631:* Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function.	MDS	10/01/16–12/31/16	May 15, 2017.

* Status: NQF-endorsed on July 23, 2015, please see: *http://www.qualityforum.org/ProjectMeasures.aspx?projectID=73867*, see NQF #2631.

We invited public comment on Proposed Measures, Data Collection Source, Data Collection Period and Data Submission Deadlines Affecting the FY 2018 Payment Determination. The comments we received on this topic, with their responses, appear below.

Comment: One commenter expressed support for CMS's proposed timing for new SNFs to begin reporting quality data. One commenter requested that data from the MDS be made publicly available sooner than 2 years after the specified application date for the measure. The commenter suggested that collecting only one quarter of data between October 1 and December 31, 2016 is not sufficient to establish data trending. The commenter requested that at least 2 quarters be used for FY 2018 payment determination, and by FY 2019 a full year's worth of data should be used. Another commenter expressed that facilities should not be given 5½ months to submit or correct their quarterly data.

Response: We appreciate the suggestion regarding extending the timing of data collection to establish sufficient data trending. We proposed to collect a single quarter of data for FY 2018 to remain consistent with the usual October release for the MDS, to give SNFs a sufficient amount of time to update their systems so that they can comply with the new data reporting requirements, and to give CMS a sufficient amount of time to determine compliance for the FY 2018 program. The proposed use of one quarter of data for the initial year of quality reporting is consistent with the approach we used to implement a number of other QRPs, including LTCH, IRF, and Hospice QRPs. With regard to the 5½ month post-data collection period, this Proposed Data Submission timeframe and final deadline for FY 2018 Payment Determination is to allow providers an opportunity to ensure that the data from the collection period has been submitted and is accurate and corrections, where necessary, have been made. We have aligned these timeframes with the LTCH, and IRF and other QRPs. We appreciate and will take into consideration the commenter's suggestion to implement public reporting sooner.

Final Decision: Having carefully considered the comments we received on Proposed Measures, Data Collection Source, Data Collection Period and Data Submission Deadlines Affecting the FY 2018 Payment Determination we are finalizing the policy as proposed.

h. SNF QRP Data Completion Thresholds for the FY 2018 Payment Determination and Subsequent Years

We proposed that, beginning with the FY 2018 payment determination, SNFs must report all of the data necessary to calculate the proposed quality measures on at least 80 percent of the MDS assessments that they submit. We proposed that a SNF has reported all of the data necessary to calculate the measures if the data actually can be used for purposes of calculating the quality measures, as opposed to, for example, the use of a dash [-], to indicate that the SNF was unable to perform a pressure ulcer assessment.

We believe that because SNFs have long been required to submit MDS assessments for other purposes, SNFs should easily be able to meet this proposed requirement for the SNF QRP. Our proposal to set reporting thresholds is consistent with policies we have adopted for the Long-Term Care Hospital (79 FR 50314), Inpatient-Rehabilitation Hospital (79 FR 45923) and Home Health (79 FR 66079) QRPs.

Although we proposed to adopt an 80 percent threshold initially, we stated our intention to propose to raise the threshold level for subsequent program years through future rulemaking.

We also proposed that for the FY 2018 SNF QRP, any SNF that does not meet the proposed requirement that 80 percent of all MDS assessments submitted contain 100 percent of all data items necessary to calculate the SNF QRP measures would be subject to a reduction of 2 percentage points to its FY 2018 market basket percentage.

We invited comment on the proposed SNF QRP data completion requirements. The comments we received on this topic, with their responses, appear below.

Comment: One commenter expressed support for the application of a 2 percent penalty for incomplete reporting of the quality data necessary to calculate NQF endorsed measures. This commenter states that this support extends only to those measures with NQF endorsement as they believe that the 2 percent incentive would ensure that providers are collecting data necessary to implement the IMPACT Act.

Response: Section 1888(e)(6)(A)(i) of the Act requires that, for FYs beginning with FY 2018, if a SNF does not submit data, as applicable, on quality and resource use and other measures in accordance with section 1888(e)(6)(B)(i)(II) of the Act and standardized patient assessment in accordance with section 1888(e)(6)(B)(i)(III) of the Act for such FY, the Secretary must reduce the SNF's market basket percentage described in section 1888(e)(5)(B)(ii) of the Act by 2 percentage points. As we have discussed above, we are not limited to adopting for the SNF QRP only measures that have been endorsed by the NQF, and to the extent that a SNF fails to satisfactorily report one or more SNF QRP measures that are not NQF-endorsed, we would be statutorily obligated to reduce the SNF's market basket percentage for the applicable fiscal year by 2 percentage points.

Comment: One commenter does not support the proposed 80 percent threshold for completion of all of the data necessary to calculate the quality measure. This commenter expressed concern that data could be omitted resulting in negative quality measure results. Their recommendation is to increase the threshold to 90 percent. Another commenter recommended lowering the threshold from 80 percent to 40 percent during the first 2 years of data collection.

Response: Our proposal to set reporting thresholds is consistent with policies we have adopted for the Long-Term Care Hospital (79 FR 50314), Inpatient-Rehabilitation Hospital (79 FR 45923) and Home Health (79 FR 66079) QRPs. SNF providers have been submitting the MDS for many years and we disagree that we should lower the submission threshold as suggested. However, we intend to reevaluate our threshold over time and will propose to modify it, if warranted, based on our analysis.

Comment: One commenter requested clarification on what constitutes data that is ''satisfactorily'' submitted.

Response: We are finalizing that data will have been satisfactorily submitted for the FY 2018 SNF QRP if the SNF has reported all of the data necessary to calculate the finalized measures and that the data can actually be used for purposes of calculating the quality measures, as opposed to, for example, the use of a dash [-], to indicate that the SNF was unable to perform a pressure ulcer assessment.

After consideration of the public comments received, we are finalizing the adoption of the policy for SNF QRP Data Completion Thresholds for the FY 2018 Payment Determination and Subsequent Years as proposed.

i. SNF QRP Data Validation Requirements for the FY 2018 Payment Determination and Subsequent Years

To ensure the reliability and accuracy of the data submitted under the SNF QRP, we proposed to adopt policies and processes for validating the data submitted under the SNF QRP in future rulemaking. We received the following comments on elements we should consider including in such a process:

Comment: One commenter expressed concern that CMS is not ensuring that the data submitted by SNFs is accurate. Specifically, the commenter suggested that self-reported MDS data are unreliable and are subject to gaming and that a variety of media outlets and CMS itself have reported on data accuracy concerns. The commenter suggested that facilities may electively omit data for residents whose health is deteriorating. The commenter supported CMS asking for the identification of elements to validate the data that SNFs submit and suggested several ways that CMS may validate the data. Another commenter recommended that CMS revisit the 2014 MDS-focused survey process assessing MDS Version 3.0 coding practices to help inform SNF QRP validation requirements.

Response: We appreciate the concerns pertaining to gaming and note that we will apply a threshold for reporting of complete resident data for the FY 2018 SNF QRP. As part of our compliance analysis, we intend to carefully monitor rates of missing data across all facilities. Further, we intend to align with other QRPs and propose through future rulemaking data validation policies.

Comment: One commenter suggested several recommendations for elements CMS should include to ensure the reliability and accuracy of data submitted for the SNF QRP. CMS should explore a combination of pure data checks to identify inconsistencies that exist between items relevant to the SNF QRP and other items reported in the MDS and audit suspicious data patterns. Another commenter suggested providing a list of validation checks that could be used by both providers and vendors to help improve the accuracy of data. Another commenter recommended public reporting on Nursing Home Compare when facilities submit invalid data and stricter regulations that require specific penalties for violations of resident assessment requirements.

Response: We appreciate the commenters' suggestions to ensure data accuracy such as a combination of pure data checks to identify inconsistencies. We agree with this approach and intend to perform such monitoring as part of overall programmatic monitoring and evaluation. We encourage providers to engage in available opportunities to improve the accuracy of their data. We appreciate the suggestion that we make public on Nursing Home Compare when facilities submit to CMS invalid data,

and will also take under consideration the suggestion that we implement additional regulatory requirements on this issue.

We thank the commenters for their input on policies that we should consider pertaining to data validation and accuracy analysis.

j. SNF QRP Submission Exception and Extension Requirements for the FY 2018 Payment Determination and Subsequent Years

Our experience with other QRPs has shown that there are times when providers are unable to submit quality data due to extraordinary circumstances beyond their control (for example, natural, or man-made disasters). Other extenuating circumstances are reviewed on a case-by-case basis. We have defined a ''disaster'' as any natural or man-made catastrophe which causes damages of sufficient severity and magnitude to partially or completely destroy or delay access to medical records and associated documentation. Natural disasters could include events such as hurricanes, tornadoes, earthquakes, volcanic eruptions, fires, mudslides, snowstorms, and tsunamis. Man-made disasters could include such events as terrorist attacks, bombings, floods caused by man-made actions, civil disorders, and explosions. A disaster may be widespread and impact multiple structures or be isolated and impact a single site only.

In certain instances of either natural or man-made disasters, a SNF may have the ability to conduct a full resident assessment, and record and save the associated data either during or before the occurrence of the extraordinary event. In this case, the extraordinary event has not caused the facility's data files to be destroyed, but it could hinder the SNF's ability to meet the QRP's data submission deadlines. In this scenario, the SNF would potentially have the ability to report the data at a later date, after the emergency has passed. In such cases, a temporary extension of the deadlines for reporting might be appropriate.

In other circumstances of natural or man-made disaster, a SNF may not have had the ability to conduct a full resident assessment, or to record and save the associated data before the occurrence of the extraordinary event. In such a scenario, the facility may not have complete data to submit to CMS. We believe that it may be appropriate, in these situations, to grant a full exception to the reporting requirements for a specific period of time.

We do not wish to penalize SNFs in these circumstances or to unduly increase their burden during these times. Therefore, we proposed a process for SNFs to request and for us to grant exceptions and extensions with respect to the quality data reporting requirements of the SNF QRP for one or more quarters, beginning with the FY 2018 payment determination, when there are certain extraordinary circumstances beyond the control of the SNF. When an exception or extension is granted, we would not reduce the SNF's PPS payment for failure to comply with the requirements of the SNF QRP.

We proposed that if a SNF seeks to request an exception or extension for the SNF QRP, the SNF should request an exception or extension within 90 days of the date that the extraordinary circumstances occurred. The SNF may request an exception or extension for one or more quarters by submitting a written request to CMS that contains the information noted below, via email to the SNF Exception and Extension mailbox at *SNFQRPReconsiderations@cms.hhs.gov*. Requests sent to CMS through any other channel will not be considered as valid requests for an exception or extension from the SNF QRP's reporting requirements for any payment determination.

We note that the subject of the email must read ''SNF QRP Exception or Extension Request'' and the email must contain the following information:

- SNF CCN;
- SNF name;
- CEO or CEO-designated personnel contact information including name, telephone number, email address, and mailing address (the address must be a physical address, not a post office box);
- SNF's reason for requesting an exception or extension;
- Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles; and
- A date when the SNF believes it will be able to again submit SNF QRP data and a justification for the proposed date.

We proposed that exception and extension requests be signed by the SNF's CEO or CEO-designated personnel, and that if the CEO designates an individual to sign the request, the CEO-designated individual has the appropriate authority to submit such a request on behalf of the SNF. Following receipt of the email, we will: (1) Provide a written acknowledgement, using the contact information provided in the email, to the CEO or CEO-designated contact notifying them that the request has been received; and (2) provide a formal response to the CEO or any CEO-designated SNF personnel, using the contact information provided in the email, indicating our decision.

This proposal does not preclude us from granting exceptions or extensions to SNFs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature, affects an entire region or locale. If we make the determination to grant an exception or extension to all SNFs in a region or locale, we proposed to communicate this decision through routine communication channels to SNF s and vendors, including, but not limited to, issuing memos, emails, and notices on our SNF QRP Web site once it is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-QR-Reconsideration-and-ExceptionExtension.html*.

We also proposed that we may grant an exception or extension to SNFs if we determine that a systemic problem with one of our data collection systems directly affected the ability of the SNF to submit data. Because we do not anticipate that these types of systemic errors will happen often, we do not anticipate granting an exception or extension on this basis frequently.

If a SNF is granted an exception, we will not require that the SNF submit any measure data for the period of time specified in the exception request decision. If we grant an extension to a SNF, the SNF will still remain responsible for submitting quality data collected during the timeframe in question, although we will specify a revised deadline by which the SNF must submit this quality data.

We also proposed that any exception or extension requests submitted for purposes of the SNF QRP will apply to that program only, and not to any other program we administer for SNFs such as survey and certification. MDS requirements, including electronic submission, during Declared Public Health Emergencies can be found at FAQs K–5, K–6, and K–9 on the following link: *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/downloads/AllHazardsFAQs.pdf*.

We intend to provide additional information pertaining to exceptions and extensions for the SNF QRP, including any additional guidance, on the SNFQRP Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-QR-Reconsideration-and-ExceptionExtension.html*. We invited public comment on these proposals for seeking and being granted exceptions

and extensions to the quality reporting requirements. The following is a summary of the comments received and our responses.

Comment: Many commenters expressed strong support for the creation of an exception and extension request process for SNFs that experience disasters or other extraordinary circumstances.

Response: We thank the commenters for their comments and support.

After consideration of the public comments received, we are finalizing the adoption of the policy for SNF QRP Submission Exception and Extension Requirements for the FY 2018 Payment Determination and Subsequent Years.

k. SNF QRP Reconsideration and Appeals Procedures for the FY 2018 Payment Determination and Subsequent Years

At the conclusion of the required quality data reporting and submission period, we will review the data received from each SNF during that reporting period to determine if the SNF met the quality data reporting requirements. SNFs that are found to be noncompliant with the reporting requirements for the applicable FY will receive a 2 percentage point reduction to their market basket percentage update for that FY.

We are aware that some of our other QRPs, such as the HIQR Program, the LTCHQR Program, and the IRF QRP include an opportunity for the providers to request a reconsideration of our initial non-compliance determination. Therefore, to be consistent with other established QRPs and to provide an opportunity for SNFs to seek reconsideration of our initial non-compliance decision, we proposed a process that will enable a SNF to request reconsideration of our initial non-compliance decision in the event that it believes that it was incorrectly identified as being non-compliant with the SNF QRP reporting requirements for a particular FY.

For the FY 2018 payment determination, and that of subsequent years, we proposed that a SNF would receive a notification of noncompliance if we determine that the SNF did not submit data in accordance with the data reporting requirements with respect to the applicable FY. The purpose of this notification is to put the SNF on notice of the following: (1) That the SNF has been identified as being non-compliant with the SNF QRP's reporting requirements for the applicable FY; (2) that the SNF will be scheduled to receive a reduction in the amount of two percentage points to its market basket percentage update for the applicable FY; (3) that the SNF may file a request for reconsideration if it believes that the finding of noncompliance is erroneous, has submitted a request for an extension or exception that has not yet been decided, or has been granted an extension or exception; and (4) that the SNF must follow a defined process on how to file a request for reconsideration, which will be described in the notification. We would only consider requests for reconsideration after an SNF has been found to be noncompliant.

Notifications of noncompliance and any subsequent notifications from CMS would be sent via a traceable delivery method, such as certified U.S. mail or registered U.S. mail, or through other practicable notification processes, such as a report from CMS to the provider as a Certification and Survey Provider Enhanced Reports (CASPER) report, that will provide information pertaining to their compliance with the reporting requirements for the given reporting cycle. To obtain the CASPER report, providers should access the CASPER Reporting Application. Information on how to access the CASPER Reporting Application is available on the Quality Improvement Evaluation System (QIES) Technical Support Office Web site (direct link), *https://web.qiesnet.org/qiestosuccess/*. Once access is established providers can select ''CASPER Reports'' link. The ''CASPER Reports'' link will connect a SNF to the QIES National System Login page for CASPER Reporting.

We invited comments on the most preferable delivery method for the notice of non-compliance, such as U.S. Mail, email, CASPER, etc. The comments we received on this topic, with their responses, appear below.

Comment: One commenter suggested the use of QIES to communicate notices of non-compliance. Another commenter suggested that non-compliance notifications be sent via multiple mechanisms to ensure delivery, including CASPER reports and a traceable delivery method.

Response: We intend to provide further guidance regarding the delivery method for the notices of non-compliance in future rulemaking.

We proposed to disseminate communications regarding the availability of compliance reports in the CASPER reports through routine channels to SNFs and vendors, including, but not limited to issuing memos, emails, Medicare Learning Network (MLN) announcements, and notices on our SNF QRP Web site once it is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-QR-Reconsideration-and-ExceptionExtension.html*.

A SNF would have 30 days from the date of the initial notification of noncompliance to submit to us a request for reconsideration. This proposed time frame allows us to balance our desire to ensure that SNFs have the opportunity to request reconsideration with our need to complete the process and provide SNFs with our reconsideration decision in a timely manner. We proposed that a SNF may withdraw its request at any time and may file an updated request within the proposed 30-day deadline. We also proposed that, in very limited circumstances, we may grant a request by a SNF to extend the proposed deadline for reconsideration requests. It would be the responsibility of a SNF to request an extension and demonstrate that extenuating circumstances existed that prevented the filing of the reconsideration request by the proposed deadline.

We also proposed that as part of the SNF's request for reconsideration, the SNF would be required to submit all supporting documentation and evidence demonstrating full compliance with all SNF QRP reporting requirements for the applicable FY, that the SNF has requested an extension or exception for which a decision has not yet been made, that the SNF has been granted an extension or exception, or has experienced an extenuating circumstance as defined in section III.D.3.j. of this rule but failed to file a timely request of exception. We proposed that we would not review any reconsideration request that fails to provide the necessary documentation and evidence along with the request.

The documentation and evidence may include copies of any communications that demonstrate the SNF's compliance with the SNF QRP, as well as any other records that support the SNF's rationale for seeking reconsideration, but should not include any protected health information (PHI). We intended to provide a sample list of acceptable supporting documentation and evidence, as well as instructions for SNFs on how to retrieve copies of the data submitted to CMS for the appropriate program year in the future on our SNF QRP Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-QR-Reconsideration-and-ExceptionExtension.html*.

We proposed that a SNF wishing to request a reconsideration of our initial

noncompliance determination would be required to do so by submitting an email to the following email address: *SNFQRPReconsiderations@cms.hhs.gov*. Any request for reconsideration submitted to us by a SNF would be required to follow the guidelines outlined on our SNF QRP Web site once it is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-QR-Reconsideration-and-ExceptionExtension.html*.

All emails must contain a subject line that reads ''SNF QRP Reconsideration Request.'' Electronic email submission is the only form of reconsideration request submission that will be accepted by us. Any reconsideration requests communicated through another channel including, but not limited to, U.S. Postal Service or phone, will not be considered as a valid reconsideration request.

We proposed that a reconsideration request include the following information:

- SNF CMS Certification Number (CCN);
- SNF Business Name;
- SNF Business Address;
- The CEO contact information including name, email address, telephone number and physical mailing address; or

The CEO-designated representative contact information including name, title, email address, telephone number and physical mailing address; and

- CMS identified reason(s) for non-compliance from the non-compliance notification; and
- The reason(s) for requesting reconsideration

The request for reconsideration must be accompanied by supporting documentation demonstrating compliance.

Following receipt of a request for reconsideration, we will provide an email acknowledgment, using the contact information provided in the reconsideration request, to the CEO or CEO-designated representative that the request has been received. Once we have reached a decision regarding the reconsideration request, an email will be sent to the SNF CEO or CEO-designated representative, using the contact information provided in the reconsideration request, notifying the SNF of our decision.

We also proposed that the notifications of our decision regarding reconsideration requests may be made available through the use of CASPER reports or through a traceable delivery method, such as certified U.S. mail or registered U.S. mail. If the SNF is dissatisfied with the decision rendered at the reconsideration level, the SNF may appeal the decision to the PRRB under 42 CFR 405.1835. We believe this proposed process is more efficient and less costly for CMS and for SNFs because it decreases the number of PRRB appeals by resolving issues earlier in the process. Additional information about the reconsideration process including details for submitting a reconsideration request will be posted in the future to our SNF QRP Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-QR-Reconsideration-and-ExceptionExtension.html*. We invited public comment on the proposed procedures for reconsideration and appeals. The following is a summary of the comments received and our responses.

Comment: Many commenters supported the policy to allow SNFs an opportunity to submit reconsideration requests. One commenter recommended extending the appeal timeline from 30 to 45 days if CMS does not provide for a timely notification method.

Response: To remain consistent with our other QRPs which have successfully implemented a reconsideration process, we believe that 30 days is sufficient.

Final Decision: After consideration of the public comments received, we are finalizing the adoption of the policy for SNF QRP Reconsideration and Appeals Procedure for the FY 2018 Payment Determination and Subsequent Years.

l. Public Display of Quality Measure Data for the SNF QRP

Section 1899B(g)(1) of the Act requires the Secretary to provide for the public reporting of SNF provider performance on the quality measures specified under subsection (c)(1) and the resource use and other measures specified under subsection (d)(1) by establishing procedures for making available to the public data and information on the performance of individual SNFs with respect to the measures. Under section 1899B(g)(2) of the Act, such procedures must be consistent with those under section 1886(b)(3)(B)(viii)(VII) of the Act and also allow SNFs the opportunity to review and submit corrections to the data and other information before it is made public. Section 1899B(g)(3) of the Act requires that the data and information be made publicly available not later than 2 years after the specified application date applicable to such a measure and provider. Finally, section 1899B(g)(4)(B) of the Act requires such procedures be consistent with sections 1819(i) and 1919(i) of the Act. We stated our intention to propose details related to the public display of quality measures in the future. The following is a summary of the comments received and our responses.

Comment: One commenter suggested that CMS replace or add to the existing measures on Nursing Home Compare when measures that meet the IMPACT Act requirements are adopted. This commenter further suggested adjustment to the thresholds used in assigning Star Ratings to the quality measures, and cautioned CMS to compare SNFs against performance of meaningful scores on the quality measures rather than against their respective rankings. The commenter also suggested the formation of a TEP to develop a method on how to publicly report in a single cross-setting report that compares PAC performance across PAC providers, as well as assist in the development of meaningful targets on quality measures. One commenter stated that the imposition of a financial penalty should be publicly reported.

Response: We will take these recommendations into consideration as we develop the process for the public display of data and information on the performance of individual SNFs with respect to the measures.

m. Mechanism for Providing Feedback Reports to SNFs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to post-acute care providers on their performance with respect to the measures specified under subsections (c)(1) and (d)(1), beginning 1 year after the specified application date that applies to such measures and PAC providers. We intended to provide detailed procedures to SNFs on how to obtain their confidential feedback reports on the SNF QRP Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting.html*. The following is a summary of the comments received and our responses.

Comment: One commenter recommended that CMS use the same mechanism currently used by SNFs for previewing Five Star data and allow SNFs to preview all of the quality measures on Nursing Home Compare. The commenter also suggested that CMS use the QIES system so that all SNFs can preview their individual reports on a weekly basis.

Response: We will take the suggestion into consideration as we develop the mechanism for providing feedback reports to SNFs.

4. Staffing Data Collection

a. Background and Statutory Authority

Section 1819(d)(1)(A) of the Act for SNFs and section 1919(d)(1)(A) of the Act for NFs each state that, in general, a facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. Sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act give the Secretary authority to issue rules, for SNFs and NFs respectively, relating to the health, safety and well-being of residents and relating to the physical facilities thereof.

The Affordable Care Act of 2010 (Pub. L. 111–148, March 23, 2010) added a new section 1128I to the Act to promote greater accountability for LTC facilities (defined under section 1128I(a) of the Act as SNFs and nursing facilities). As added by the Affordable Care Act, section 1128I(g) pertains to the submission of staffing data by LTC facilities, and specifies that the Secretary, after consulting with state long-term care ombudsman programs, consumer advocacy groups, provider stakeholder groups, employees and their representatives and other parties the Secretary deems appropriate, shall require a facility to electronically submit to the Secretary direct care staffing information, including information for agency and contract staff, based on payroll and other verifiable and auditable data in a uniform format according to specifications established by the Secretary in consultation with such programs, groups, and parties. The statute further requires that the specifications established by the Secretary specify the category of work a certified employee performs (such as whether the employee is a registered nurse, licensed practical nurse, licensed vocational nurse, certified nursing assistant, therapist, or other medical personnel), include resident census data and information on resident case mix, be reported on a regular schedule, and include information on employee turnover and tenure and on the hours of care provided by each category of certified employees per resident per day. Section 1128I(g) of the Act establishes that the Secretary may require submission of information for specific categories, such as nursing staff, before other categories of certified employees, and requires that information for agency and contract staff be kept separate from information on employee staffing.

b. Provisions of the Proposed Rule and Response to Comments

As part of the FY 2016 SNF PPS proposed rule, we proposed to implement the new statutory requirement in section 1128I(g) of the Act. Specifically, we proposed to modify current regulations applicable to LTC facilities that participate in Medicare and Medicaid by amending the requirements for the administration of a LTC facility at § 483.75 to add a new paragraph (u), Mandatory submission of staffing information based on payroll data in a uniform format.

During the 60-day comment period on the proposed rule, we received approximately 22 timely comments on the staffing data collection proposal from individuals, providers, national and regional health care professional associations and advocacy groups. Summaries of the proposed provisions, as well as the public comments and our responses, are set forth below.

(1) Consultation on Specifications

As discussed in the FY 2016 SNF PPS proposed rule, we adopted a multi-pronged strategy to comply with section 1128I(g) of the Act's consultation requirement that includes both soliciting input from all interested parties through the rulemaking process and ongoing consultation with the statutorily identified entities regarding the sub-regulatory reporting specifications that we will establish. We invited public comment on our proposed methods for consultation on the submission specifications. The comments we received on this topic, with their responses, appear below.

Comment: One commenter suggested that CMS convene a TEP to design a structure and to clearly articulate the goals and purpose of the collected information prior to mandated reporting. Another commenter asked where it indicated in the rule that the specifications of staffing data would be based upon ''. . . consultation with long-term care ombudsman programs, consumer advocacy groups, provider stakeholder groups, employees and their representatives.'' This commenter proposed that CMS provide the result of those consultations with the aforementioned groups. Commenters further stated that it would seem such information could be valuable in the formation of a rational implementation of this particular provision of the Affordable Care Act. Other commenters stated that the designing of the reporting process should take into account differences among LTC providers, such as variations in size, location, management and operations, including differences among payroll and time and attendance systems. Those commenters urged CMS, when implementing this new requirement, to assure opportunity for feedback and provider representation and participation across the full spectrum of nursing home structures and organization types, such as large, small, urban, rural, freestanding and multiple-site facilities, as well as regional companies and large companies.

Response: We are committed to consulting with stakeholders, including LTC facilities, consumer advocates, and other related groups. Through this rulemaking, we solicited input from all of the statutorily identified entities and this final rule reflects the outcome of that consultation. We are continuing our consultation on the sub-regulatory specifications through a variety of mechanisms. We have a regular dialogue with stakeholders through individual and national calls. These stakeholders represent a wide range of facilities throughout the country, including large and small, rural and urban, independently-owned facilities and national chains, and we have consulted with facilities with varying types of payroll and time keeping systems. In addition, we published a Draft Policy Manual (''1.0'') for the electronic staffing data submission payroll-based journal (''Draft PBJ Policy Manual'') that offers more details of planned technical specifications and invited comments that we continue to take into account as we develop and refine the specifications to implement this final rule. This manual is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Staffing-Data-Submission-PBJ.html*. We encourage stakeholders to email comments and requests to *NHStaffing@cms.hhs.gov* as another opportunity for consultation. We appreciate the suggestions from commenters on other mechanisms for consultation with stakeholders on our subregulatory specifications and we will consider these options as we continue our dialogue and engagement efforts throughout implementation.

(2) Scope of Submission Requirements

As noted above, section 1128(g) of the Act mandates that the Secretary require LTC facilities ''to ''to electronically submit to the Secretary direct care staffing information, including information for agency and contract staff, based on payroll and other verifiable and auditable data in a uniform format.'' The proposed rule

used the statutory term ''direct care staffing information'' without elaboration. We received a number of comments regarding the scope of this term. Those comments and our responses are set forth below.

Comment: Several commenters asked that CMS define ''direct care staff'' and clarify the types of staff in the nursing facilities that are included in this reporting. Several commenters recommended we use the following definition; ''Direct care staff means those individuals who provide care and services enabling the resident to receive the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care, as specified in § 483.25.'' A few commenters recommended using the definition from the preamble of the October 2005 *Final Rule on Posting of Nurse Staffing Information* (70 FR 62065 available at *http://www.gpo.gov/fdsys/pkg/FR-2005-10-28/pdf/05-21278.pdf*), which states that direct care means that an individual is directly responsible for resident care, which includes, but is not limited to, such activities as assisting with activities of daily living (ADLs), performing gastro-intestinal feeds, giving medications, supervising the care given by CNAs, and performing nursing assessments to admit residents or notify physicians about a change in condition. Another commenter recommended defining direct care staff as staff having ''hands on'' care of a patient.

Several commenters expressed concern that the Draft PBJ Policy Manual suggested CMS planned to interpret the proposed regulation to require reporting of information on non-direct care employees and opined that this interpretation would go beyond what Congress intended. One commenter stated that nowhere in the Affordable Care Act, or the proposed rule, is there mention of the non-direct patient care services as direct care staff. They opined that some of the employee categories listed in the Draft PBJ Policy Manual, such as housekeeping and dietary, are generally not considered to be individuals that perform direct care. Commenters stated that it was not the intent of Congress to require reporting for individuals providing non-direct care services and that CMS's interpretation would increase the burden beyond what is necessary, while at the same time not adding information that is helpful to the overall goal of the program. They stated that the interpretation by CMS of definitions of direct care staff in the Draft PBJ Policy Manual broadens the scope and breadth of data required, and does so to an unnecessary extent that exhibits overreach of the legislative directive. They urged CMS to maintain internal consistency with the definitions in section 6106 of the Affordable Care Act, the proposed rule, the Draft PBJ Policy Manual and ultimately the final rule, and limit this data collection to direct patient care staff information. Commenters stated that the final rule should clarify that direct care staffing excludes non-direct care services. In addition, they recommended that references to non-direct care services be removed from the Draft PBJ Policy Manual to avoid confusion and unnecessary administrative costs for providers. Some examples the commenters provided as extraneous to the direct care staff normally employed by nursing homes (and that they advise should be reevaluated with stakeholder consultation and input) are blood service workers and vocational service workers.

Another commenter urged that CMS only collect staffing data about direct care staff that are typically employed (or contracted by) in nursing centers, including trained medication aides (where permitted by state law), and not all types of staff that are currently reflected in the CMS Form 671 (for example, housekeeping staff, administration and storage of blood, vocational services). They also recommended that CMS collect staffing data about additional direct care staff such as Certified Respiratory Therapists, all therapy staff (Speech and Language Pathologists, Physical Therapists, Occupational Therapists, PT/OT Assistants and Aides) therapeutic recreation staff, medical social workers, physicians and non-physician practitioners (NPPs). Another commenter asked that CMS clearly delineate all staff categories, including physical therapist and physical therapist assistants. Additional comments request that CMS clarify what categories of employees are included in ''therapist and other type of medical personnel''.

Response: We believe that the statutory term ''direct care staffing information'' as used in the proposed rule is self-explanatory. As noted in the preamble to the proposed rule, facilities have a statutory obligation to be administered in a manner that enables it to use its resources efficiently and effectively to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident. We also noted that the statutory requirement to report direct care staffing information was added to promote greater accountability for LTC facilities in meeting this obligation. In addition, the Congress gave context for the term ''direct care staffing information'' by including a non-exclusive list of the categories of work that may be performed by individuals whose information would be reported. We incorporated this non-exclusive list into the proposed rule. Accordingly, we believe that it was clear from the proposed rule that the reporting requirement would apply to the subset of staff at a LTC facility whose work directly advances resident well-being. However, we appreciate commenters desire to have specificity in the regulation. Based on the comments received, in this final rule we add a definition of ''Direct Care Staff'' at § 483.75(u)(1). This definition is grounded in the statutory text cited in the proposed rule and incorporates specific text offered by commenters. ''Direct Care Staff'' is defined as those individuals who, through interpersonal contact with residents or resident care management, provide care and services to residents to allow them to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Direct care staff does not include individuals whose primary duty is maintaining the physical environment of the long term care facility (for example, housekeeping). In this definition, we do not exclude individuals who spend time on duties that are not always ''hands on,'' such as supervising nurses or medication management, as these types of duties directly impact a resident's care. Therefore, the definition focuses primarily on whether the staff person in question provides care or services either through ''hands on'' care or through resident care management, with the intention of benefiting the resident's well-being. We further note that there can be significant variation in the level and type of direct care that many staff provide. For example, a certified nurse assistant may spend the bulk of their time delivering hands-on care directly at the bedside, while an activities director may spend less time delivering hands-on bedside care. As such, we intend to collect staffing data on any staff that provides any amount of direct care.

Although comments on the Draft PBJ Policy Manual are beyond the scope of this rulemaking, we appreciate commenters' feedback on how this draft guidance would implement the regulatory obligations established under this rule. We agree with commenters who stated that the reporting obligation under this regulation should not extend

to non-direct care staff, as well as their assertion that individuals who provide housekeeping are not direct care staff. As explained above, we are following commenters' recommendation to add a definition of direct care staff. As commenters requested, the definition of direct care staff expressly excludes housekeeping staff as well as any other individuals whose services are primarily related to maintaining the physical environment of the long term care facility. We believe this definition clarifies how CMS intends to interpret the scope of the reporting requirement. We agree with commenters who observed the reporting requirement should be consistently interpreted from the statute to the regulation to the implementing guidance. We believe the regulation is fully consistent with the statute and we will revise our subregulatory guidance to align with provisions of this final regulation. Finally, we note that we will take into account commenters' feedback on the categories of direct care staff as we refine the Draft PBJ Policy Manual.

(3) Hours Worked and Hours of Care

We proposed language for the new § 483.75(u)(1)(iii) that would require facilities to submit information on staff turnover and tenure and on the hours of care provided by each category of staff per resident per day (including, but limited to start date, end date (as applicable) and hours worked for each individual.

We noted that section 1128I(g)(4) of the Act requires LTC facilities to report on the hours of care provided by each category of certified employees per resident per day. We expressed our belief that the obligation to submit information on ''hours of care'' is satisfied by requiring facilities to submit hours worked by staff. In addition, we noted that although section 1128I(g)(2) of the Act requires the submission of resident case mix information, the proposed rule did not include a provision to implement this requirement because existing regulations at § 483.20 require LTC facilities to meet this statutory requirement through the required submission of the Minimum Data Set (MDS). Details of the comments we received on submission requirements, with our responses, appear below.

Comment: One commenter urged CMS to be consistent with language in the preamble and in the federal law related to ''hours worked'' and to eliminate language requiring the reporting of hours of care provided. Another commenter stated that they believe that CMS must find a way to better capture hours provided than to equate it to hours worked. This commenter suggested one approach might be to conduct time studies to estimate the average amount of time CNAs, LPNs and RNs spend on non-direct care tasks and subtract that time from their total hours worked. Two commenters stated that CMS should require submission of time employees are taking personal leave during the work day (for example, for meals, breaks), and stated that these should not be recorded as hours worked as they are not hours of care. They further stated that although the language of CMS's proposed rule either quotes or paraphrases the statutory language, proposed at § 483.75(u), the preamble suggests that ''the obligation to submit information on 'hours of care' is satisfied by requiring facilities to submit hours worked by staff.'' (80 FR 22081). Those commenters strongly disagree with the approach to collect hours of care worked as equivalent to hours of care. They observed that there could be a considerable difference between hours of care actually provided and hours of care worked. They stated that all staff, as a matter of practice and by law, have time when they are paid but are not working—meal and other mandated breaks, mandatory in-service training, etc. They observed that in an eight-hour workday, some time is devoted to meal and other mandated breaks and although staff may be paid for this time, but they are not providing care to residents. The commenters opined that if CMS is unwilling to require facilities to submit hours of direct care actually provided, then it must delete at least one hour from total hours worked in order to reflect the time at work that is not dedicated to resident care. Another commenter stated that CMS should require submission of time employees are absent from the facility on work-related leave if they are unavailable to fulfill direct care responsibilities. The commenter stated that this should include time nurse aides spend transporting individual residents to medical appointments since they are unavailable to provide services to other residents during that time. Other commenters expressed support for the proposed reporting of hours worked, but questioned how the reporting will distinguish between direct care hours worked and hours worked on management and other responsibilities by a salaried employee, as might be the case for nurse managers who split their time between direct care and management functions. One commenter remarked that they support the many job classifications for which the Draft PBJ Policy Manual proposes to collect staffing information, but for both nursing and non-nursing job classifications there needs to be more specification on how to distinguish hours of care versus mandatory breaks or other non-direct care duties.

Other commenters supported the reporting of hours worked, but stated that submission specifications should account for actual hours worked by salaried/exempt staff. They observed that exempt direct care employees can frequently work more than the salaried time period (for example, 40-hour basis) for which they are paid. While alternate compensation for any additional hours will not be evident in a payroll-based system, they suggested that the CMS staffing data collection process should account for this additional time to accurately reflect direct care staffing and coverage. Similarly, another commenter observed that there are data elements that are not captured in payroll data alone, such as time worked off of the clock for contract employees, or the actual hours worked by the salaried employee. The commenter stated that capturing data that includes productivity standards and time allocated for indirect patient care would further illuminate quality patient care that is not intuitive to payroll data alone. The commenter suggested that this can be calculated by collecting data for direct patient contact time, which is captured in the MDS and/or medical record. The commenter recommended the inclusion of direct patient contact time, as reported by speech language pathologists or derived from the billable minutes provided on the date of service.

Response: In our proposed approach, and in this final regulation, we give deference to the statutory requirement that the staffing data be reported ''based on payroll and other verifiable and auditable data in a uniform format (according to specifications established by the Secretary . . .).'' Payrolls represent the primary source of verifiable and auditable information, and are explicitly referenced in the statute as such. Payroll systems contain the key information organized as ''hours worked,'' and provide the most effective foundation for electronic reporting. We have therefore maintained ''hours worked''.

We appreciate commenters' observation that payroll systems record vacation, sick time, and certain other absences that are time other than ''hours worked.'' Therefore, when LTC facilities report total hours worked by direct care staff (based on payroll and other verifiable and auditable data as

specified by CMS), these data should not include paid time off (for example, vacation, sick leave, etc.).

At the same time, we recognize that nursing home staff engage in other non-care and direct care activities throughout their day, such as breaks. Although outside the scope of this rulemaking, we appreciate that in calculating quality measures we may need to adopt some statistical refinements that allow for reasonable estimates of such time in order to afford the public the information that will enable recognition of the time that staff are engaged in non-care or non-direct care activities. Also, as required in the statute, we require that the primary care area of each staff person (as well as each individual's hours) be reported. Such categorization will allow the public to identify which care areas are most important to them, as well as to focus on the types of staff who provide most of the hands-on care. We thank the commenters for identifying these issues, and will take this feedback into account when assessing future uses of the data, such as quality measures.

We further note that the regulation does not limit collection of information to payroll data exclusively. In fact, the regulation specifies that the information will be ''based on payroll *and* other verifiable and auditable data'' (emphasis added). Although beyond the scope of this rulemaking, we do not rule out the possibility that future implementation specifications could require submission of information from time studies or other methods, in addition to payroll data, if CMS determines that other data capture methods are auditable and verifiable. For example, if at a future date CMS concludes there are auditable and verifiable data regarding extra hours worked by salaried employees or hours worked that are extraneous to the care of residents, CMS may revise the implementation specifications to address the submission of these data that permit refinement of the payroll data. However, as indicated in the draft subregulatory guidance implementing this regulation, we anticipate that initial reporting will be limited to the payroll-reported data for each individual who meets the definition of direct care staff. We plan to continue to work with stakeholders to further develop the initial specifications to implement this final rule and to make any future refinements to this subregulatory guidance.

Comment: A few commenters recognized the value of collecting and reporting staffing information but were concerned about the administrative burden resulting from this new reporting requirement, in particular for hospital-based skilled-nursing facilities, where many staff may work in both the SNF and other departments of the hospital and health system, and where payroll systems are integrated. They urged CMS to test the proposed data collection system specifically in SNFs operated as distinct parts of acute care hospitals to address any unique issues that might arise in that setting. Another commenter observed that in their facility, attached to a hospital, the housekeeping, laundry, maintenance, dietary, and administrative services are provided by staff that conduct hospital and nursing home services. The commenter explained that at their facility only the nursing time is directly allocated to the nursing home on a timesheet; the times worked in the other departments are allocated to their individual departments. The commenter observed that at the end of the year when the cost report is prepared, their time is separated out to the revenue producing departments (nursing home, medical/surgical, ER, lab, radiology, etc.) based on meals served, square footage, pounds of laundry, etc. The commenter stated that, currently, this information will not be able to be sent directly from their payroll system and that it will be extremely time consuming to figure out the percentage of time a support service department employee worked for the nursing home each day and manually enter it into the Payroll-Based Journal system. The commenter observed that the cost report already provides a summary of staffing salaries and hours, and suggested that the cost report could be modified to conform to all the Affordable Care Act requirements. Another commenter stated that to require distinct part SNFs to collect data on the services not related to direct patient care, duties which are shared with the institutions where they are housed, will create unnecessary administrative burden to separate data for services, which are by definition shared. This works against the entire principle behind distinct part SNFs, and is, in fact, impossible to accomplish without hours of manual labor. For example, the commenter observed that in their 125-bed facility they have a 38-bed ventilator assist unit, with approximately 140 direct care staff with a 10-hour per patient day ratio. They stated that the amount of time to submit staffing information on this unit alone would require an inordinate amount of resources. A hospital association stated they are concerned that the requirement will be administratively burdensome, particularly in light of the challenges of attributing hours worked to the distinct part unit as opposed to the hospital generally. They opined that therapy staff hours are now kept by department and allocated retrospectively as part of the facility's cost report. The association stated that the payroll system for these hospitals does not support the automated submission of data as envisioned in this regulatory proposal. For these types of facilities, they encouraged CMS to consider alternative mechanisms—such as adaptions of the current cost reporting system—to demonstrate compliance with the requirements of the statute. Finally, a commenter stated that one of the issues involved in reporting hours worked for non-direct care staff involves SNFs that are hospital or retirement community based. The commenter stated that non-direct care staff provides services to the whole organization and there is no way to determine the number of hours specific to the SNF and indicated that Medicare cost report methodology allows reporting of these ''overhead'' areas based on various statistics that have no relationship to hours. The commenter opined that to attempt to determine the SNF related hours would result in inaccurate estimates that would not be meaningful and would be a cumbersome manual process.

Response: We are aware that hospital-based facilities and other facilities such as nursing homes adjacent to assisted living facilities or part of retirement communities have staff that work in multiple areas of the broader entity. In response to these and other comments, in this final rule we have added a definition of ''direct care staff'' that excludes certain facility support staff. We believe that this adjustment will help address a large portion of the staff issues that distinct part and other conjoined entities would otherwise face with staff who have duties in multiple entities. For the staff who do meet the new definition of direct care staff, facilities will still need to report the hours that are allocated to the SNF/NF residents only, and not include hours for staff allocated for providing services to residents in non-certified SNF/NF beds. Data reported should be auditable and able to be verified through either payroll, invoices, and/or tied back to a contract. Facilities must use a reasonable methodology for calculating and reporting the number of hours allocated to providing services on site to the SNF/NF residents, and exclude hours allocated for providing services to other individuals in other settings. These types of facilities are encouraged

to participate in the voluntary program beginning on October 1, 2015. Voluntary submission will allow facilities to work through their processes to submit the data in advance of the mandatory submission period. We also note that Medicare cost reports are not an appropriate means to comply with this staffing reporting requirement because, among other concerns, they do not contain all of the data needed to comply with the Act, such as information on turnover and tenure.

Comment: Several commenters opined on how the submission schedule should apply to resident census data. Several commenters recommended that CMS collect resident census data in a time frame consistent with collection of other staffing data under this requirement. That is, they recommended that if staffing data is collected quarterly, census data should be collected quarterly. Some commenters suggested that data regarding resident census should reflect shorter time periods than quarterly. For example, several commenters recommended that the resident census data submitted each quarter should include three data points that reflect each month's total patient days in order to accurately reflect the hours of direct care per patient per day. Another commenter urged CMS to require facilities to collect and submit daily resident census data to capture fluctuations around facilities' surveys when many facilities temporarily increase staff; to reflect reduced staffing hours caused by higher absenteeism during certain periods such as holidays; and to reflect periods when census unexpectedly increases, such as accommodation of residents displaced by a facility closure. Another commenter remarked that it is their understanding that based on the specifications contained in the Draft PBJ Policy Manual CMS intended to interpret the proposed regulation to require submission of census data based on the resident population as of the last date of each month of each quarter. The commenter expressed strong objection and concern with this approach as misrepresentative and unreliable in depicting the hours of direct care provided per resident per day. The commenter opined that that collection of census information must be compared to and consistent with the data collected for hours worked during the same submission period. The commenter expressed the view that calculation and use of the average daily census for each month in a quarterly submission period was strongly favored over the current CMS proposal. Another commenter recommended that resident census also be submitted on a daily basis to capture fluctuations in staff-to-resident ratios that may occur during a 30-day period that would not be recorded if data were reported only on the last day of the month; for example, the period around the annual survey or during a ban on admissions or closure. One commenter stated that it is unclear how the number of days will be gathered from the submitted data for purposes of determining hours of care per resident day. Given the desired level of accuracy in reporting of hours worked, they advocated for an accurate and unobtrusive method for collecting information on the number of resident days provided in each reporting period. Finally, a commenter stated that CMS proposes that resident census data should be collected on the last day of each of the 3 months within a quarter. The commenter recommended staffing data should be collected on a daily basis, because the lack of daily resident census data could lead to inaccurate calculation of staffing levels, and potential inflation of staffing level averages. The commenter observed that resident census fluctuates continually throughout the month, and it would not be a burden for facilities to report this information since this information is readily available at SNFs. They stated that primary purpose of payroll-based staffing data collection is to provide as accurate as possible staffing level information for consumers, rather than the current system which is fairly unreliable for several facilities as facilities ''staff-up'' near their expected inspection survey.

Response: We recognize that a facility's census fluctuates throughout each month and appreciate suggestions intended to promote the utility of the census data submitted under this regulation. However, while the requirement to submit census information is within the scope of this rule, the specifications for this submission are not. Therefore, these comments will be taken into account as we revise the Draft PBJ Policy Manual and other subregulatory guidance. For example, we will analyze the average census of a facility based on the last day of each month as compared to the average census based on the daily census. We will ensure that any eventual quality measure will be statistically sound in representing a facility's census. This may involve altering the data we propose to collect (for example, from once a month, to daily) or collecting this information through other means. We note that the method to submit census data described in the current draft guidance was recommended by stakeholders who participated in the pilot in 2012 and was structured to reduce provider burden as much as possible.

Comment: Two commenters strongly supported the submission of nurse staffing hours by shift to capture what they describe as the dangerous decline that occurs in many facilities on the afternoon and night shifts. They expressed that sufficient direct care nursing staff on one or two shifts averaged over three shifts may hide critically deficient nursing levels on the other(s), when residents are at increased risk of serious harm from missed care, falls, abuse, elopement, missed meals, and lack of assistance with toileting. They further commented that shift-level nurse staffing hours per resident day would yield far more important evidence of quality than minor variations in case mix in typical nursing homes. They also noted that the *Staffing Quality Measure* (SQM) project evaluated the feasibility of collecting shift level data, concluding that it could be done and would allow calculation of ''more detailed staffing measures, such as shift-level staffing ratios or the proportion of shifts for which at least one registered nurse was present.'' One commenter additionally remarked that CMS should collect nurse staffing data by unit. They concluded from the SQM Final Report that researchers gave only cursory attention to requiring facilities to submit data by units. They asserted that at a time when the industry is creating special subacute care or rehab units to maximize Medicare census and reduce rehospitalization rates, adequate or exceptional staffing in a subacute unit can create a false picture of levels in other units whose residents have similar needs. They stated that without such data, case mix adjustment would be more likely to obscure staffing hours than to clarify them. Another commenter recommended that staffing data be collected by shift and unit, especially as more facilities are developing Medicare/rehabilitation units and subacute units.

Response: We agree that data regarding staffing patterns at the shift and/or unit level would be valuable when assessing how LTC facilities are administered; however, these implementation specifications are beyond the scope of this rulemaking. We will continue to look at this as we develop subregulatory guidance and will evaluate the feasibility of collecting these data elements in the future.

Comment: One commenter recommended that CMS reconsider case-mix adjustment of staffing hours. Another commenter expressed opposition to making any adjustment for case mix. The commenter suggested that, at a minimum, the non-adjusted staffing level data should be publicly available. The commenter stated that the case-mix of residents is changing constantly, and consumers want to know if facilities are truly staffing near the recommended level of 4.1 hours per resident day, or are they only near this standard due to the case-mix adjustment. One commenter strongly objected to any language in regulations that would require or imply that CMS will use MDS data to adjust staffing information that is reported on Nursing Home Compare. In passing legislation to replace inaccurate, self-reported staffing data with information from auditable payroll records, the commenter stated that Congress intended to ensure that the public has *accurate* information about staffing hours, and that the Congress did not intend to have information from the new system degraded by consolidation with data from another self-reported source that is frequently inaccurate and even fraudulent. The commenter acknowledged and welcomed the fact that CMS is implementing nationwide, focused MDS surveys in response to criticism of the use of MDS data to construct Quality Measures (that are displayed on the CMS *Nursing Home Compare* Web site), but noted that such focused surveys will not be conducted in all nursing homes, and that they will be subject to the same limitations as other surveys (such as surveyor turnover, pressure from supervisors not to cite deficiencies, and weak enforcement).

Response: We thank commenters for their suggestions but note that the use of case-mix or MDS data is outside the scope of this rule. We will work with stakeholders prior to formulating publicly posted quality measures. We will consider making both adjusted and unadjusted data available. However, we believe that case mix adjustments are important for the very reasons the commenters observe—that the risk profile of a nursing home's resident population does change over time, and is also different from one facility to another. We would expect that a nursing home that has a population with a higher risk profile should generally have an overall higher staffing level, or a staffing complement that matches the risk profile (for example, higher RN levels for a nursing home with a population that has a higher acuity level compared to other nursing homes). We appreciate that the MDS data have limitations but at this time we believe MDS reporting does meet the statutory requirement for LTC facilities to submit information on resident case-mix that are auditable and verifiable. We will also continue to monitor the results of the new nationwide sample of targeted MDS surveys to determine if additional actions are advisable.

Comment: One commenter stated that if the Congress' intent was to ensure that payroll data and staffing quality measures would conform with the minimum staffing requirements of the Nursing Home Reform Law, which require care to be provided by Licensed Health Professionals and nurse aides who meet the law's 75-hour training, competency evaluation, and registry requirements, then they recommend that CMS define ''certified employees'' as staff who are licensed health professionals and/or who meet the requirements for nurse aides, as defined in section 1819(b)(5) of the Act.

Response: The requirement for reporting staffing data is not limited to licensed health care professionals and nurse aides. Direct care staff includes other staff that meet the definition of direct care staff. That said, we will provide definitions for certain categories of staff, such as nurse aides, through implementing guidance.

(4) Distinguishing Employees From Agency and Contract Staff

Under section 1128I(g) of the Act's requirement that information for agency and contract staff be kept separate from information on employee staffing, we proposed to add a new § 483.75(u)(2) to establish that, when reporting direct care staffing information for an individual, a facility must specify whether the individual is an employee of the facility or is engaged by the facility as contract or agency staff. We believe the statute's intent is to require LTC facilities to submit staffing information in a manner that can enable us to distinguish those staff that are employed by the facility from those that are engaged by the facility under a contract or through an agency. We do not believe the statute requires such data to be submitted at separate times or through separate systems, which would merely engender unnecessary costs and burden, so we intend to collect all facility staffing information at the same time and through the same system, employing a mechanism by which LTC facilities will clearly specify whether staff members are employees of the facility, or engaged under contract or through an agency.

The comments we received on this topic, with their responses, appear below.

Comment: One commenter requested that CMS further clarify in the Draft Payroll-Based Journal Policy Manual that ''floaters'' or other employees that work at multiple facilities for the same operator should be categorized as contract staff. Another commenter agreed that facilities must indicate whether an employee is a direct employee of the facility (exempt or non-exempt), or employed under contract paid by the facility or through an agency. The commenter stated that CMS should consider defining ''floaters''—individuals employed by the corporation who may work for the same employer but in different facilities at different times—as agency employees. Another commenter asked what the applicable start and end dates would be that a facility would report for contract and agency staff, since these workers can be used intermittently over indeterminate time periods.

Response: We appreciate the commenter's insights into these implementation issues. Although these details are beyond the scope of this regulation; we believe they are appropriate for implementation specifications. We will take these comments into account when issuing the revised Draft PBJ Policy Manual and other subregulatory guidance.

(5) Data Format

We proposed to add a new § 483.75(u)(3) to establish that a facility must submit direct care staffing information in the format specified by CMS. This provision would implement the requirement in section 1128I(g) of the Act that facilities submit direct care staffing information in a uniform format. As noted, we are consulting with stakeholders on potential format specifications. The data that we proposed for submission are similar to those already submitted by LTC facilities to CMS on the forms CMS–671 and CMS–672 (we intended for this proposed new information collection to eventually supplant the data collections via the CMS–671 and CMS–672). In advance of the proposed July 1, 2016 implementation date, we will publicize the established format specifications and will offer training to help facilities and other interested parties (for example, payroll vendors) prepare to meet the requirement.

The comments we received on this topic, with their responses, appear below.

Comment: One commenter stated that there should not be an unreasonable financial burden placed on the providers to report the information that would be required, since providers are already being negatively affected by the sequestration and the managed care plans. The commenter stated that even though it is a good thing to keep costs down for the federal budget and the taxpayers, it is only the adjustment for cost increases that has helped to minimize the negative impact for the providers. The commenter observed that many providers have multiple types of staff, which includes different types of payment types from paychecks to payables. The commenter explained that this means that for many it is not one combined system for all of the detail, since not all of this information had been required, so it will require either a lot of hours to prepare or a lot of hours to program or possibly both in order to provide the information. The commenter further stated that not all providers benefited from the incentives for moving to an electronic record. Many were excluded from participation, but had to bear the costs anyway due to the sharing of patients (also called residents, clients, etc.) and the requirement to provide the information electronically. The commenter opined that this placed an undue hardship on them. Another commenter remarked that CMS has not adequately considered and accounted for the costs to SNFs to comply with the proposed data collection. Several commenters recommended that CMS complete a regulatory analysis addressing these costs. The commenters stated that the interpretation of the legislation by CMS through the proposed rule would be overly burdensome, redundant, and would create unnecessary and costly expense to distinct part SNFs. They asserted that the steps required to supply the data outlined in the proposal requires technical expertise, labor, and payroll system vendors in order to meet expectations. Another commenter expressed concern regarding the time to comply with this system proposed by CMS. The commenter strongly encouraged CMS to solicit input from a broad variety of providers to develop an approach that meets the requirements of the Affordable Care Act and also is more reasonable to providers in terms of labor and cost. The commenter expressed concern that cost of the requirements would be obtained from the cost of direct patient care given, as that reimbursement would not likely be increased. The commenter stated that, if high costs were incurred, then it would be highly unlikely that additional data requirements would have a positive effect on the quality of nursing home services but, instead, the potential to decrease quality is significant as more and more resources are directed to regulatory mandates that do not affect direct patient care. The commenter stated that they were unaware of any CMS research or data analysis that demonstrates a direct relationship between this level of data and quality outcomes. Finally, the commenter stated that required reporting of non-direct patient care staffing data reduces the ability to provide quality care, as resources are diverted to administrative reporting, away from direct patient care. Another commenter opined that the proposed rule and the inclusion of the additional staffing data required by the Draft PBJ Policy Manual extend beyond the intent and language of the Affordable Care Act and that this is an unreasonable and costly additional administrative burden which does not improve patient care at a time when delivering quality care at a reasonable cost is paramount public policy; adding undue hardship which does not improve quality will have a definite negative impact on care. One commenter recommended that CMS recognize that this new process is occurring at the same time as several other mandates that require significant resource investment, including the initiation of ICD–10 and the training and software preparation needed. The commenter identified other concurrent provider efforts including initiation of the collection of data for the Quality Reporting Program related to the IMPACT Act, the initiation of 30-day all-cause, all-condition rehospitalization reporting, ongoing transition to electronic health records at many facilities, and the initiation of computerized physician order entry (CPOE) at facilities and all while providers work to increased interoperability so that data can be exchanged. One commenter supported the electronic collection of staffing data by CMS but noted that the system for doing this should be reasonable and achievable and as simple as possible. Commenters were also concerned that payroll vendors were not yet prepared to accommodate the required reporting and that providers would incur compliance costs associated with modifying their own payroll systems or from vendors needing to make these modifications. One commenter stated that every employee will need to have a unique employee number assigned for tracking and reporting purposes that may require payroll and other systems modifications. Another commenter suggested CMS delay the mandatory electronic submission of staffing data until CMS has adequately tested the submission system and determined the cost and burden to providers to comply with this proposed regulation. The commenter observed that only the volunteer facilities will have had an opportunity to test the new system prior to the mandatory report date of July 1, 2016 that applies to all facilities.

Response: We appreciate commenters concerns about the costs associated with submitting direct care staffing information but note that this reporting obligation mandated by section 1128I(g) of the Act. We believe this final rule is fully consistent with the intent and text of the statute and represents the best approach to minimize the burdens associated with implementing the statutory reporting requirement. Based on the comments received, we have included information on the estimated costs and burden of this regulation to facilities in section V. of this final rule. As noted above, we will continue our consultation with LTC facilities and other stakeholders as we revised the Draft PBJ Policy Manual and other implementation guidance to implement this regulation.

Comment: Several commenters suggested that CMS modify already-existing reports and/or reporting systems to develop the uniform format to be used for staff reporting submission under this new regulation. Many commenters suggested that their cost reports could be modified to conform to all the Affordable Care Act requirements. One commenter stated that CMS should consider using staffing data that is collected for other programs which could, with minor adjustments, be used to meet the requirements of the Affordable Care Act. The commenter suggested that Medicare Cost Reports collect similar data which is obtained on a regular basis and a modified format of this form would result in less burden for providers and fewer opportunities for discrepancies in information provided in multiple reporting forms. Two commenters stated that the requirements of section 6106 of the Affordable Care Act could be met, consistent with the intent of the Congress, through the existing resident case-mix report without creating an additional duplicative report. The commenters stated that the report could be expanded to include the other requirements of the Affordable Care Act: Aggregate nursing hours, number of patient days, and staff turnover to be reported quarterly. Another commenter

suggested CMS work with states already collecting this information to reduce the reporting burden for facilities.

Response: In order to comply with section 1128I(g) of the Act, the final rule mandates that there be a uniform national method of electronically collecting specific staffing data that can be applied for both Medicare SNFs and Medicaid nursing facilities. When implementing this regulation we will adopt a system that will accommodate this requirement. We do not agree that the Medicare cost reports or existing state-based systems will satisfy the requirements of the law. For example, Medicare cost reports do not contain the data needed to comply with the Act, such as information on turnover and tenure.

Comment: One commenter suggested in § 483.75(u)(3) after the heading adding ''uniform'' before ''format'' for consistency between the statutory and regulatory text and for clarity in the requirement for submission of data in a uniform format.

Response: We agree. For consistency purposes, we have added ''uniform'' before ''format'' in the text of § 483.75(u)(3)

(6) Effective Date for Submission Requirement

In the proposed rule, we indicated that the regulation would take effect on July 1, 2016. We explained that prior to this effective data, we would establish a voluntary submission period whereby facilities can submit staffing information on a voluntary basis to become familiar with the system and to provide feedback to CMS on systems issues in advance of the mandatory submission date.

Comment: We received several comments regarding a phase-in or postponement of the mandatory submission date. One commenter recommended calling for a wider-range testing and evaluation period and/or phase-in of the data collection system. The commenter stated that this testing period would not only allow a broader spectrum of providers to gain understanding and familiarity with the process prior to final implementation, but would add information regarding cost and burden associated with meeting the submission requirements. For example, information could be collected on the implementation of required, but unanticipated system modifications and the potential investment of additional staff and/or documentation time. Another commenter suggested CMS phase in the reporting process over time and to initially only require reporting of the nursing staff and to add other staff such as therapists at a later time. Another commenter suggested that as part of CMS's consultation on the submission specifications, they should include an informal period of ''testing'' that will allow all providers (not just those who may volunteer for a ''pilot'') the opportunity to work within the system to determine how it interfaces with their center's system or to learn how to confidently input the required data (for those centers unable to automatically upload their information). The commenter suggested this proposal to provide centers and CMS a clearer understanding of the burden associated with the submission requirements. Another commenter stated that contingent on the outcomes and/or results of the voluntary submission period, CMS should consider postponement or a phase-in of the intended July 1, 2016 mandatory submission date pending resolution of identified problems or glitches. The commenter believes that all providers should have the opportunity to test their respective payroll and time and attendance processes and gain familiarity with the CMS submission requirements. The commenter further stated that CMS should again consider a phase-in or ''grace period'' approach within the planned mandatory reporting implementation that includes deferral of 5-Star calculation and scoring for initial submissions. The commenter concluded that, at a minimum, given the limits of the currently planned data collection system trial, the allowance for post-submission review and opportunity for correction should continue for at least the first year of mandatory implementation.

Response: We are establishing a voluntary submission period beginning in October 2015. The voluntary submission period will include a phased approach to registration and training which will allow facilities to test their submission methods in advance of the July 1, 2016 effective date of the regulation. In order to meet the requirements of section 6106 of the Affordable Care Act as soon as possible, we believe that July 1, 2016 is an appropriate start date. However, we appreciate that in any new, large system of this nature, implementation challenges may arise and adjustments likely will need to be made in both the receiving and sending systems. Therefore, we do not plan to use the results of the reported data in the CMS *Five Star Quality Rating System* in CY 2016. During the implementation we plan to maintain a feedback loop with nursing homes regarding the data submitted, issues identified, and adjustments made or needed to the implementation specifications. We also plan to maintain use of the existing CMS Form 671 annual paper-based form during the initial implementation so that the results of the traditional and the new system can inform the learning process.

(7) Submission Schedule

Section 1128I(g)(3) of the Act requires that facilities submit direct care staffing information on a regular reporting schedule. At § 483.75(u)(4) we proposed to establish that a facility must submit direct care staffing information on the schedule specified by CMS, but no less frequently than quarterly. Comments we received on this topic and our responses appear elsewhere in this preamble.

(8) Compliance and Enforcement

In the proposed rule we noted that § 483.75(u) would establish that these new reporting requirements would be conditions a LTC facility must meet to qualify to participate as a SNF in the Medicare program or a NF in the Medicaid program. As such, we explained that we planned to enforce the requirements under this new regulation through 42 CFR part 488 and non-compliance with the proposed § 483.75(u), could result in CMS or the state imposing one or more remedies available to address noncompliance with the requirements for LTC facilities.

The comments we received on this topic, with our responses, appear below.

Comments: One commenter proposed that if a SNF is found to be non-compliant with the reporting requirements, there should be an expedited appeals process afforded to the SNF prior to imposition of a civil monetary fine or exclusion from a federal healthcare program. Other commenters stated that it would be more fruitful to lay out specific sanctions that CMS will impose if a facility fails to comply with the new reporting requirement. One commenter suggested, for example, that if a facility fails to provide required staffing data within 30 days of the deadline, CMS would send a warning letter; if the facility did not provide the data within 20 days of the warning letter, CMS would levy daily civil monetary penalties of $X,000 per day starting on the 21st day after the warning letter; if the facility continued to fail to provide staffing data at the 40th day following the warning letter, CMS would institute a hold on new admissions. The commenter stated that such a sanctioning approach would result in more immediate compliance and clearer

expectations for the providers. The commenter further noted that if CMS or the state determines that a facility has intentionally provided inaccurate staffing data, the non-compliance should considered a material false claim to the government for which payment is sought and damages should be available under the False Claims Act. The commenters recommended internal audits conducted by CMS, with non-compliance remedies of a significant downgrading of Five Star Quality Ratings while the facility is out of compliance, a significant per day Civil Monetary Penalty, and denial of payment for new admissions until compliance is achieved. Another commenter noted that, given the importance of this data, penalties should be imposed when a provider fails to submit staffing data as required or submits inaccurate or false data. The commenters recommended a per day Civil Monetary Penalty at a significant enough level to result in compliance. The commenters further suggested, a facility's penalty should be posted under ''Staffing'' on Nursing Home Compare so it is easily visible to consumers and others researching the facility. Still another commenter stated that they were concerned about the lack of specificity with regard to remedies for noncompliance and the potential for flexibility, inconsistency, and lenience that are unfortunately common in enforcement of other requirements of participation. The commenter noted that the statement that CMS or the state *may* impose one or more remedies underscores our concern—sanctions should be certain. Moreover, the commenters believe the instructions are ambiguous about when a deficiency and remedy are triggered. Another commenter urged CMS to provide greater clarity about how compliance with the proposed regulation will be determined. One commenter suggested that CMS clarify the possible enforcement actions that may be considered for aberrant data.

Response: We appreciate commenters' interest in additional information regarding how the agency will assess compliance with this regulation and what specific enforcement actions the agency will pursue when it identifies noncompliance. Discussion of implementation specifications and how the agency will apply its enforcement are beyond the scope of this rulemaking. We will take these comments into account as we develop guidance at a later date. We note, however, that nothing in section 1128I(g) of the Act or this final rule establishes that the staff reporting requirement is a condition of payment.

Comment: One commenter opposed the data collection requirement's inclusion as a requirement for participation in Medicare, because the timeline for implementation does not afford all providers the opportunity to test the CMS system and identify problems that may occur when interfacing with the facility's software and systems. Additionally, the commenter noted that CMS has not clearly stated within the proposed rule how it will determine compliance with the proposed regulation. Another commenter urged CMS to eliminate the staffing data collection designation as a requirement of participation, since such a designation will make compliance subject to the full array of enforcement actions. The commenter stated that it is premature to make this collection a requirement of participation since the system for submission of the staffing data is new and not adequately tested.

Response: As we stated in the proposed rule, we believe that the inclusion of the staffing data collection as a requirement of participation is appropriate and desirable, to meet the legislative goal of greater accountability for LTC facilities, given the importance of staffing to the quality of care and safety of the nursing home residents. We further believe that the full array of remedies available to enforce compliance with other conditions of participation should be available to enforce this regulation and ensure that the Act's requirements are met. This regulation is necessary to carry out CMS's and the state's obligation to ensure compliance with other conditions of participation (COPs) as specified in the Act. For example, section 1819(b)(4) of the Act includes requirements for staff such as nursing services, pharmaceutical services, dietary services and other services facilities are required to provide, and collection of the staffing data helps verify compliance with these requirements. However, we appreciate there will be a learning curve as the new reporting system is implemented. We therefore plan to be careful when assessing compliance to distinguish between the effects of newness in the initial implementation and failure to implement the system and ensure accuracy and adequacy of reporting.

Comment: One commenter remarked that the proposed rule did not include provisions for adjustment and/or correction to submitted data. The commenter noted that electronic staffing data submission will serve to eliminate current inconsistencies and mistakes common to manual completion of the 671 form, but cited examples of errors were still possible under an automated system. The commenter stated that automated payroll systems frequently ''lock down'' once a payroll period ends and have to be re-entered manually for changes or updates. The commenter further stated that there can also be occasional clock breakdowns or clocking oversights, for example, if an individual clocks out, is asked to stay, but fails to clock back in, all hours worked may not be captured in real time. The commenter explained that similarly, some providers have adopted universal worker practices, with those employees performing, for example, non-nursing or other functions at different points, again resulting in potential clocking oversights or omissions. The commenter stated that in any of these circumstances, hours worked would at least initially be documented somewhere other than the payroll system and, if identified after a payroll period has closed and/or data transmission to CMS, adjustment would be required to accurately reflect staffing and coverage. The commenter believes a defined process should be incorporated into the collection and reporting system to allow providers to make documented, verifiable, and auditable data-based adjustments/corrections to submitted staffing information. The commenter stated that these adjustments/corrections should be permitted within the respective quarter to assure accurate documentation and calculation of staff hours worked and direct care services provided.

Response: We appreciate the commenter's observations about areas of ongoing data vulnerability and providers' interest in making corrections when they identify errors with previously submitted data. We anticipate that our reporting system when fully implemented will include functionality to submit data corrections. We will address this issue in further detail through guidance.

(9) Other Comments

Comment: Several commenters requested that CMS provide a written report on the results of the 2012 Staffing Data Collection Pilot to providers in advance of finalizing this rule. The commenters stated that CMS references the 6-month staffing data collection pilot conducted in 2012 as a strategy component in engaging in ongoing consultation with all relevant parties and stakeholders; however, no report regarding the results and outcomes of this pilot has ever been released for review and feedback by these entities.

The commenters believe that knowledge of the challenges and successes that were determined based on this pilot would be very beneficial in terms of ''lessons learned'', enabling greater understanding of the requirements being proposed and final implementation of the currently drafted ''Electronic Staffing Data submission Payroll-based Journal'' (PBJ) system.

Response: As part of our on-going consultation with stakeholders, we will make information from this project available on the CMS Staffing Data Submission Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Staffing-Data-Submission-PBJ.html*. However, it is important to note that this information relates to the implementation specifications, not the regulatory requirement, and therefore CMS is proceeding with finalization of the rule at this time but hopes the data from the project will facilitate dialogue as the agency develops implementation guidance.

Comment: One commenter stated that further clarification is needed regarding the voluntary submission process referenced in the preamble of the proposed rule to be conducted beginning in October 2015. The commenter stated that it is not clear whether these submissions will be instead of, or in addition to, the CMS 671 form, and or whether the information collected during this period will be data of record, thereby subject to 5-Star Nursing Home Rating System calculations and potential remedies if noncompliance is determined. The commenter stated that modifications will have to be made to virtually all homes' payroll and time and attendance processes to accommodate the provisions of this rule, and not all homes will be able to begin submission during the voluntary period to test their own systems against the CMS data collection process. The commenter noted that again, with the variation in current payroll and time and attendance systems in nursing homes, providers must have some margin and flexibility to allow for unanticipated interface-related problems and need for further modifications that may occur with the junction of the PBJ and their respective processes. The commenter stated that the voluntary period will be the first wide-range, and to their understanding, the only testing opportunity for the CMS staffing data collection process. The commenter stated that the goal should be true evaluation and assessment, with the participating nursing homes not subject to Five-Star scoring or survey and enforcement actions based only on these initial preliminary submissions. The commenter stated that if voluntary submissions are to be considered data of record, at minimum there should be an accompanying allowance for post submission review as needed, with opportunity to rectify identified errors, misinterpretations, or omissions prior to final determinations.

Response: As stated in the preamble of the proposed rule, we intend to eventually supplant the form CMS–671 and CMS–672, however, facilities will still be required to complete these until further notice. Data submitted through the PBJ system during the voluntary submission period will not have any impact on a facility's Five-Star rating, or result in any enforcement remedies. Facilities will be provided with information about their voluntary submissions so they can make adjustments and be better prepared for the mandatory submission period. We do not plan on using the results of the reported data in the Five-Star Quality Rating System calculations in either CY 2015 or CY 2016 in order to accommodate both the voluntary phase and the initial months of mandatory reporting.

Comment: Several commenters expressed that manually uploaded data should not be permitted on an ongoing basis. The commenters noted that CMS should require facilities that want to submit some or all data manually to request a waiver documenting that they do not have the capability to report using an automated payroll system. The commenter stated that CMS should establish a deadline for facilities to have fully automated data reporting ability to meet the requirements of the law, after which manual submission would be noncompliant. The commenter recommended that waiver requests should be time-limited and require an annual re-application process in which the provider must document the steps taken to automate its system. Another commenter stated that CMS must ensure that staffing data come from verifiable, auditable sources and not self-reporting by facilities.

Response: The requirement in this regulation is for facilities to submit the data electronically, which facilities will do through the system we will provide. We note that regardless of whether a facility uploads their data from a payroll system, or enters it manually, all facilities are held to the same reporting requirements and standards.

Comment: One commenter remarked that data should be collected in an all-inclusive and meticulous manner that represents the complete assessment of care furnished in the SNF setting. The commenter strongly urged CMS to adhere to the following: (1) Only count staffing data that represent a complete episode of care from admission to discharge; (2) CMS should distinguish those cases in which an unexpected readmission or inpatient hospital stay occurred; and (3) provide feedback reports to all applicable facilities prior to public reporting and provide an appropriate timeframe for facilities to dispute any information they believe is inaccurate. Another commenter requested that CMS clarify how the data will be analyzed, the benchmark that will be used to define quality, and the additional uses or actions CMS anticipates as a result of collecting this data.

Response: We are not entirely clear on some of the commenter's suggestions and note that some issues raised by this commenter are outside of the scope of this rulemaking. The data collected under this regulation will not count episodes of care, but will reflect the staff in the facility and related average census. Although outside the scope of this rulemaking, we plan to provide feedback reports to providers and allow facilities to dispute information they believe to be inaccurate. In addition, we plan to discuss the uses of the data, including quality measures, with stakeholders prior to public posting.

Comment: One commenter requested that we eliminate the part-time/full-time distinction that appears in the Draft PBJ Policy Manual. The commenter stated that organizations vary in their definitions of part-time and full- time. The commenter believes in collecting staff hours worked for the purpose of interpreting staffing levels based on payroll and related auditable and verifiable data, it is irrelevant whether coverage is being provided by full or part-time employees.

Response: While this comment is directed at an issue outside the scope of this regulation, we agree. In response to feedback received, we have eliminated the part-time/full-time distinction described in the Draft PBJ Policy Manual.

Comment: One commenter requests that base hourly wage information be collected as part of this process, which can used to develop a SNF-specific wage index.

Response: We believe this request is outside of the scope of the rulemaking. Further, we do not believe that section 1128I(g) of the Act authorizes us to require the reporting of base hourly wages.

Comment: One commenter stated that in light of the importance of MDS

assessment accuracy for QM reporting, payment, and coordination of the resident care plan across the care continuum, we recommend that duties related to completion of the RAI be separated out in statistical reporting job category (RN, LPN, etc.). Licensed staff performing RAI work cannot be accurately identified in the current proposed structure. The commenter stated that it is very important that the nurse staffing data enable consumers and researchers to know who is actually conducting the RAI. The commenter noted that while the LVN/LPN is authorized to perform the RAI process and certify its accuracy, an RN is required to coordinate the RAI process and verify completion (F–278, § 483.20(h), Coordination: A registered nurse must conduct or coordinate each assessment with the appropriate participation of health professionals).

Response: This request relates to the implementation specifications and is beyond the scope of this rulemaking. As we develop subregulatory guidance, we will work with stakeholders to consider any additional types of staff that should be reported separately, including RAI or MDS Coordinators.

Comment: One commenter strongly recommended against conducting audits for compliance with this staffing reporting requirement as part of the survey process, either as regular or focused surveys.

Response: The operations of audits are outside the scope of this regulation. As a general matter, CMS seeks to ensure that the audits to assess compliance with reporting requirements are conducted in a manner that directly addresses the need to verify the data submitted by facilities. This includes having the audits conducted by individuals or entities who are subject matter experts in this area.

Comment: One commenter remarked that it is not clear when the payroll submissions are due (for example, how much time providers will be given after the end of the quarter to make their submission).

Response: We will communicate information on submission requirements through guidance. For example, the Draft PBJ Policy Manual states that providers have 45 days from the end of the quarter to submit their data. Please see the following Web site for more information: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Staffing-Data-Submission-PBJ.html.*

Comment: One commenter stated that reports must include the number and types of nursing staff on each shift, including mutually exclusive staff categories, in particular RNs versus LPNs. For example, in reporting staffing, LPNs with administrative duties are not to be combined with RNs with administrative duties.

Response: The reporting of data is outside the scope of this regulation. We will work with stakeholders prior to posting information or formulating quality measures.

Comment: One commenter cautioned that if a facility has low staffing levels, it would not necessarily equate to poor quality of care.

Response: While this comment is discussing proposed uses of the collected data which is outside the scope of this regulation, we agree that there are many factors that contribute to good quality of care. Families and residents should not only use a variety of information in making judgments about a facility (such as the various types of information available on the CMS Nursing Home Compare Web site), but above all should visit facilities, talk to residents and staff, and consult with other knowledgeable parties in the community (such as the State Survey Agency and the local Nursing Home Ombudsman Program).

Comment: Several commenters expressed support for the implementation of this rule and CMS' intent to ensure that accurate staffing data was being reported by LTC facilities.

Response: We thank these commenters for their support.

c. Provisions of the Final Rule

We are adopting the provisions of this final rule as proposed, with the following changes:

- In consideration of public comments, we added a definition of ''direct care staff'' at § 483.75(u)(1). We renumbered the subsections within § 483.75(u) accordingly. In addition, we made conforming changes to utilize the defined term in the provisions regarding the submission requirements at § 483.75(u)(2)(i) and (iii) in the final rule and the provision regarding distinguishing employee from agency and contract staff at § 483.75(u)(3) of this final rule.
- Finally, in consideration of public comment, we added the adjective ''uniform'' to describe the format requirement in the provision regarding data format in § 483.75(u)(4) of the final rule.

IV. Collection of Information Requirements

In the FY 2016 SNF PPS proposed rule (80 FR 22082), we solicited public comment on that rule's information collection requirements as they relate to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). However, of all of the comments received on the proposed rule, only one was related to our position that all of the proposed information collection requirements were exempt from the PRA. A summary of the comment and our response follows.

Consistent with the proposed rule, this final rule maintains that the information collection requirements are exempt from the PRA. We refer readers to the FY 2016 SNF PPS proposed rule for details.

Comment: One commenter disagreed with CMS's assertion that the PRA does not apply to the proposed staff reporting requirements. The commenter further stated that because the Affordable Care Act, not OBRA 1987, was the statute that established the staff reporting requirements, the requirements would likely not fall within the scope of OBRA 1987's PRA waivers.

Response: We respectfully disagree with the commenter's analysis. The staff reporting requirements are exempt from PRA because section 6106 of the Affordable Care Act (which added 1128I(g) of the Act) is related to the information required for the purposes of carrying out relevant sections of OBRA 1987's nursing home reform requirements. For example, section 1819(b)(4) of the Act includes requirements for staff such as nursing services, pharmaceutical services, dietary services, and other services facilities are required to provide, and the collection of the staffing data helps verify compliance with these requirements.

V. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this final 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 Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the 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 rule has been designated an economically significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis (RIA) as further discussed below. Also, the rule has been reviewed by OMB.

2. Statement of Need

This final rule would update the SNF prospective payment rates for FY 2015 as required under section 1888(e)(4)(E) of the Act. It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each FY, the unadjusted federal per diem rates, the case-mix classification system, and the factors to be applied in making the area wage adjustment. As these statutory provisions prescribe a detailed methodology for calculating and disseminating payment rates under the SNF PPS, we do not have the discretion to adopt an alternative approach. In addition, this final rule specifies a SNF all-cause all-condition hospital readmission measure, as well as adopts that measure for a new SNF VBP Program, and includes a discussion of SNF VBP Program policies we are considering for future rulemaking to promote higher quality and more efficient health care for Medicare beneficiaries. This final rule also implements a new quality reporting program for SNFs, as specified in the IMPACT Act. Finally, through this final rule, we are implementing section 1128I(g) of the Act, which requires the electronic submission of staffing information based on payroll and other verifiable and auditable data.

3. Overall Impacts

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2015 (79 FR 45628). Based on the above, we estimate that the aggregate impact would be an increase of $430 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, as adjusted by the applicable forecast error adjustment and by the MFP adjustment. The impact analysis of this final rule represents the projected effects of the changes in the SNF PPS from FY 2015 to FY 2016. Although the best data available are utilized, there is no attempt to predict behavioral responses to these changes, or to make adjustments for future changes in such variables as days or case-mix.

Certain events may occur to limit the scope or accuracy of our impact analysis, as this analysis is future-oriented and, thus, very susceptible to forecasting errors due to certain events that may occur within the assessed impact time period. Some examples of possible events may include newly-legislated general Medicare program funding changes by the Congress, or changes specifically related to SNFs. In addition, changes to the Medicare program may continue to be made as a result of previously-enacted legislation, or new statutory provisions. Although these changes may not be specific to the SNF PPS, the nature of the Medicare program is such that the changes may interact and, thus, the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon SNFs.

In accordance with sections 1888(e)(4)(E) and 1888(e)(5) of the Act, we update the FY 2015 payment rates by a factor equal to the market basket index percentage change adjusted by the FY 2014 forecast error and the MFP adjustment to determine the payment rates for FY 2016. As discussed previously, for FY 2012 and each subsequent FY, as required by section 1888(e)(5)(B) of the Act as amended by section 3401(b) of the Affordable Care Act, the market basket percentage is reduced by the MFP adjustment. The special AIDS add-on established by section 511 of the MMA remains in effect until such date as the Secretary certifies that there is an appropriate adjustment in the case mix. We have not provided a separate impact analysis for the MMA provision. Our latest estimates indicate that there are fewer than 4,800 beneficiaries who qualify for the add-on payment for residents with AIDS. The impact to Medicare is included in the total column of Table 12. In updating the SNF PPS rates for FY 2016, we made a number of standard annual revisions and clarifications mentioned elsewhere in this final rule (for example, the update to the wage and market basket indexes used for adjusting the federal rates).

The annual update set forth in this final rule applies to SNF PPS payments in FY 2016. Accordingly, the analysis that follows only describes the impact of this single year. In accordance with the requirements of the Act, we will publish a notice or rule for each subsequent FY that will provide for an update to the SNF PPS payment rates and include an associated impact analysis.

In accordance with sections 1888(g) and (h)(2)(A) of the Act, we are finalizing the adoption of a SNF 30-Day All-Cause Readmission Measure (SNFRM) for the SNF VBP Program. Because this measure is claims-based, its adoption under the SNF VBP Program would not result in any increased costs to SNFs.

However, we do not yet have preliminary data with which we could project economic impacts associated with the measure. We intend to make additional proposals for the SNF VBP Program in future rulemaking, and we will assess the impacts of the SNFRM and any associated SNF VBP Program proposals at that time.

The burden associated with the SNF QRP is the time and effort associated with data collection and reporting. In this final rule, we are finalizing three quality measures that meet the requirements of section 1888(e)(6)(B)(II) of the Act.

Our burden calculations take into account all ''new'' items required on the MDS 3.0 to support data collection and reporting for these three finalized measures. New items will be included on the following assessments: SNF PPS 5-Day, Swing Bed PPS 5-Day, OMRA—Start of Therapy Discharge, OMRA—Other Discharge, OBRA Discharge, Swing Bed OMRA—Start of Therapy Discharge, Swing Bed OMRA—Other Discharge, and Swing Bed Discharge on the MDS 3.0. The SNF QRP also requires the addition of a SNF PPS Part A Discharge Assessment, which will also include new items. New items include data elements required to identify whether pressure ulcers were present on admission, to inform future development of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), as well as changes in function and occurrence of falls with major injury. To the extent applicable, we will use standardized items to collect data for the three measures. For a copy of the data collection instrument, please visit: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html*.

We estimate a total additional burden of $30.00 per Medicare-covered SNF stay, based on the most recent data available, in this case FY 2014, that 15,421 SNFs had a total of 2,599,656 Medicare-covered stays for fee-for-service beneficiaries. This would equate

to 1,112,002.85 total added hours or 72.11 hours per SNF annually.

We anticipate that the additional MDS items we finalized will be completed by Registered Nurses (RN), Occupational Therapists (OT), and/or Physical Therapists (PT), depending on the item. We identified the staff type per item based on past LTCH and IRF burden calculations in conjunction with expert opinion. Our assumptions for staff type were based on the categories generally necessary to perform assessment: Registered Nurse (RN), Occupational Therapy (OT), and Physical Therapy (PT). Individual providers determine the staffing resources necessary, therefore, we averaged the national average for these labor types and established a composite cost estimate. We obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2013 National Occupational Employment and Wage Estimates (*http://www.bls.gov/oes/current/oes_nat.htm*), and to account for overhead and fringe benefits, we have doubled the mean hourly wage. The mean hourly wage for an RN is $33.13, doubled to $66.26 to account for overhead and fringe benefits. The mean hourly wage for an OT is $37.45, doubled to $74.90 to account for overhead and fringe benefits. The mean hourly wage for a PT is $39.51, doubled to $79.02 to account for overhead and fringe benefits.

To calculate the added burden, we first identified the total number of new items to be added into assessment instruments. We assume that each new item accounts for 0.5 minutes of nursing facility staff time. This assumption is consistent with burden calculations in past IRF and LTCH federal regulations. For each staff type, we then multiply the added burden in minutes with the number of times we believe that each item will be completed annually. To identify the number of times an item would be completed annually, we noted the number of total SNF FFS Medicare-covered stays in FY 2014, the most recent data available to us. We assume that if an item were added to all discharge assessments, then that item would be completed at least one time per SNF FFS Medicare-covered stay. For example, the time it takes to complete an item added to all discharge assessments (0.5 minutes) would be multiplied by the number of SNF FFS Medicare-covered stays in FY 2014 to identify the total added burden in minutes associated with that item. Items added only to the SNF PPS Part A Discharge were weighted to reflect the proportion of SNF stays for residents who switch payers, but are not physically discharged from the facility. Added burden in minutes per staff type was then converted to hours and multiplied by the doubled hourly wage to identify the annual cost per staff type. Given these wages and time estimates, the total cost related to the SNF PPS Part A Discharge Assessment and SNF QRP measures is estimated at $5,057.45 per SNF annually, or $78,011,166.25 for all SNFs annually. We received comments regarding the burden related to the SNF QRP, which we addressed in section III.D.3.g.(2). of this final rule.

We have also conducted an impact analysis with regard to the electronic submission of staffing information, which will be required under 42 CFR 483.75(u). While facilities have been reporting their staffing data for many years via an annual, paper-based system, we appreciate that the electronic submission of staffing data is something that facilities have not been required to do and that this new requirement will have financial and/or staff time implications. Like the implementation of many new programs, the level of effort will be higher upfront, but decline throughout subsequent years.

4. Detailed Economic Analysis

The FY 2016 SNF PPS payment impacts appear in Table 12. Using the most recently available data, in this case FY 2014, we apply the current FY 2015 wage index and labor-related share value to the number of payment days to simulate FY 2015 payments. Then, using the same FY 2014 data, we apply the FY 2016 wage index and labor-related share value to simulate FY 2016 payments. We tabulate the resulting payments according to the classifications in Table 12 (for example, facility type, geographic region, facility ownership), and compare the simulated FY 2015 payments to the simulated FY 2016 payments to determine the overall impact. The breakdown of the various categories of data in the table follows.

The first column shows the breakdown of all SNFs by urban or rural status, hospital-based or freestanding status, census region, and ownership.

The first row of figures describes the estimated effects of the various changes on all facilities. The next six rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The next nineteen rows show the effects on facilities by urban versus rural status by census region. The last three rows show the effects on facilities by ownership (that is, government, profit, and non-profit status).

The second column shows the number of facilities in the impact database.

The third column shows the effect of the annual update to the wage index. This represents the effect of using the most recent wage data available. The total impact of this change is zero percent; however, there are distributional effects of the change.

The fourth column shows the effect of all of the changes on the FY 2016 payments. The update of 1.2 percent (consisting of the market basket increase of 2.3 percentage points, reduced by the 0.6 percentage point forecast error adjustment and further reduced by the 0.5 percentage point MFP adjustment) is constant for all providers and, though not shown individually, is included in the total column. It is projected that aggregate payments will increase by 1.2 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 12, the combined effects of all of the changes vary by specific types of providers and by location. For example, due to changes finalized in this rule, providers in the rural Pacific region would experience a 1.4 percent increase in FY 2016 total payments.

TABLE 12—PROJECTED IMPACT TO THE SNF PPS FOR FY 2016

	Number of facilities FY 2016	Update wage data (%)	Total change (%)
Group:			
Total	15,425	0.0	1.2
Urban	10,888	0.1	1.3
Rural	4,537	−0.6	0.6
Hospital based urban	546	0.2	1.4
Freestanding urban	10,342	0.1	1.3

TABLE 12—PROJECTED IMPACT TO THE SNF PPS FOR FY 2016—Continued

	Number of facilities FY 2016	Update wage data (%)	Total change (%)
Hospital based rural	627	−0.6	0.6
Freestanding rural	3,910	−0.6	0.6
Urban by region:			
New England	801	0.5	1.7
Middle Atlantic	1,485	0.6	1.8
South Atlantic	1,853	−0.2	1.0
East North Central	2,068	−0.1	1.1
East South Central	544	0.0	1.2
West North Central	899	−0.5	0.6
West South Central	1,310	−0.1	1.1
Mountain	501	−0.4	0.8
Pacific	1,420	0.6	1.8
Outlying	7	−1.1	0.1
Rural by region:			
New England	142	−0.9	0.3
Middle Atlantic	222	−1.4	−0.3
South Atlantic	511	−0.1	1.1
East North Central	937	−0.1	1.1
East South Central	535	−0.5	0.7
West North Central	1,089	−0.9	0.3
West South Central	765	−1.3	−0.1
Mountain	233	−0.8	0.4
Pacific	103	0.2	1.4
Ownership:			
Government	882	0.0	1.2
Profit	10,862	0.0	1.2
Non-profit	3,681	−0.1	1.1

Note: The Total column includes the 2.3 percent market basket increase, reduced by the 0.6 percentage point forecast error adjustment and further reduced by the 0.5 percentage point MFP adjustment. Additionally, we found no SNFs in rural outlying areas.

We have also conducted an economic analysis with regard impact of the electronic submission of staffing information, which is required under 42 CFR 483.75(u). Factors affecting a facility's cost include the size of the facility, the number of employees of a facility, and the type of system a facility uses to report and submit data. To calculate the cost, we analyzed information from a staffing pilot conducted in 2012, including evaluating the type (for example, hours per day) and frequency (for example, quarterly) of the information to be submitted. For example, we estimate that a facility using a complex, automated payroll or time-keeping system would require some upfront and ongoing costs to configure their system to provide the data. We estimate these costs to be approximately $500 to $1,500 upfront, with an additional $500 to $1,500 in maintenance costs each year. Additionally, we estimate this type of facility would require an estimated 1 hour of in-house staff time per week, to oversee the process. Conversely, a facility without an automated time-keeping system would not have the upfront and ongoing costs associated with purchasing or configuring a system. However, this facility would require more time from in-house staff to enter and submit the data. We estimate this time to be approximately 4 hours per week. To help mitigate potential cost for facilities, we will be providing a system for facilities to enter and submit data manually and at no cost. Using the 2013 hourly wage estimate of $18.71 per hour for payroll and timekeeping employees in Skilled Nursing Facilities from the Bureau of Labor Statistics, we believe that the cost to facilities will range between $4,100 and $6,800 per facility for the first year of implementation. This includes one-time costs associated with configuring payroll or time-keeping systems to produce and submit the required data. Subsequent years would have lower costs ranging from $2,700 to $4,200 per facility per year. These estimates also include up to 16 hours per year for training staff on the submission of data.

5. Alternatives Considered

As described in this section, we estimate that the aggregate impact for FY 2016 would be an increase of $430 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, as adjusted by the applicable forecast error adjustment and by the MFP adjustment.

Section 1888(e) of the Act establishes the SNF PPS for the payment of Medicare SNF services for cost reporting periods beginning on or after July 1, 1998. This section of the statute prescribes a detailed formula for calculating payment rates under the SNF PPS, and does not provide for the use of any alternative methodology. It specifies that the base year cost data to be used for computing the SNF PPS payment rates must be from FY 1995 (October 1, 1994, through September 30, 1995). In accordance with the statute, we also incorporated a number of elements into the SNF PPS (for example, case-mix classification methodology, a market basket index, a wage index, and the urban and rural distinction used in the development or adjustment of the federal rates). Further, section 1888(e)(4)(H) of the Act specifically requires us to disseminate the payment rates for each new FY through the **Federal Register**, and to do so before the August 1 that precedes the start of the new FY. Accordingly, we are not pursuing alternatives for the payment methodology as discussed previously.

Section 1128I(g) of the Act establishes requirement for LTC facilities to submit direct care staffing information. This section of the statute specifically prescribes the data to be submitted. Accordingly we are not pursuing alternatives to the reporting requirement as discussed previously.

6. Accounting Statement

As required by OMB Circular A–4 (available online at *www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*), in Table 13, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Table 13 provides our best estimate of the possible changes in Medicare payments under the SNF PPS as a result of the policies in this final rule, based on the data for 15,425 SNFs in our database. All expenditures are classified as transfers to Medicare providers (that is, SNFs).

TABLE 13—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2015 SNF PPS FY TO THE 2016 SNF PPS FY

Category	Transfers
Annualized Monetized Transfers.	$430 million. *
From Whom To Whom?	Federal Government to SNF Medicare Providers.

* The net increase of $430 million in transfer payments is a result of the forecast error and MFP adjusted market basket increase of $430 million.

7. Conclusion

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2015 (79 FR 45628). Based on the above, we estimate the overall estimated payments for SNFs in FY 2016 are projected to increase by $430 million, or 1.2 percent, compared with those in FY 2015. We estimate that in FY 2016 under RUG–IV, SNFs in urban and rural areas would experience, on average, a 1.3 and 0.6 percent increase, respectively, in estimated payments compared with FY 2015. Providers in the urban Pacific and Middle Atlantic regions would experience the largest estimated increase in payments of approximately 1.8 percent. Providers in the rural Middle Atlantic region would experience a small decrease in payments of 0.3 percent.

B. Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, non-profit organizations, and small governmental jurisdictions. Most SNFs and most other providers and suppliers are small entities, either by reason of their non-profit status or by having revenues of $27.5 million or less in any 1 year. We utilized the revenues of individual SNF providers (from recent Medicare Cost Reports) to classify a small business, and not the revenue of a larger firm with which they may be affiliated. As a result, we estimate approximately 91 percent of SNFs are considered small businesses according to the Small Business Administration's latest size standards (NAICS 623110), with total revenues of $27.5 million or less in any 1 year. (For details, see the Small Business Administration's Web site at *http://www.sba.gov/category/navigation-structure/contracting/contracting-officials/eligibility-size-standards*). In addition, approximately 25 percent of SNFs classified as small entities are non-profit organizations. Finally, individuals and states are not included in the definition of a small entity.

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2015 (79 FR 45628). Based on the above, we estimate that the aggregate impact would be an increase of $430 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, as adjusted by the MFP adjustment and forecast error adjustment. While it is projected in Table 12 that most providers would experience a net increase in payments, we note that some individual providers within the same region or group may experience different impacts on payments than others due to the distributional impact of the FY 2016 wage indexes and the degree of Medicare utilization.

Guidance issued by the Department of Health and Human Services on the proper assessment of the impact on small entities in rulemakings, utilizes a cost or revenue impact of 3 to 5 percent as a significance threshold under the RFA. According to MedPAC, Medicare covers approximately 12 percent of total patient days in freestanding facilities and 22 percent of facility revenue (Report to the Congress: Medicare Payment Policy, March 2015, available at *http://medpac.gov/documents/reports/chapter-8-skilled-nursing-facility-services-(march-2015-report).pdf*). However, it is worth noting that the distribution of days and payments is highly variable. That is, the majority of SNFs have significantly lower Medicare utilization (Report to the Congress: Medicare Payment Policy, March 2015, available at *http://medpac.gov/documents/reports/chapter-8-skilled-nursing-facility-services-(march-2015-report).pdf*). As a result, for most facilities, when all payers are included in the revenue stream, the overall impact on total revenues should be substantially less than those impacts presented in Table 12. As indicated in Table 12, the effect on facilities is projected to be an aggregate positive impact of 1.2 percent. As the overall impact on the industry as a whole, and thus on small entities specifically, is less than the 3 to 5 percent threshold discussed previously, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This final rule will affect small rural hospitals that (1) furnish SNF services under a swing-bed agreement or (2) have a hospital-based SNF. We anticipate that the impact on small rural hospitals would be similar to the impact on SNF providers overall. Moreover, as noted in previous SNF PPS final rules (most recently the one for FY 2015 (79 FR 45658)), the category of small rural hospitals would be included within the analysis of the impact of this final rule on small entities in general. As indicated in Table 12, the effect on facilities is projected to be an aggregate positive impact of 1.2 percent. As the overall impact on the industry as a whole is less than the 3 to 5 percent threshold discussed above, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small rural hospitals.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately $144 million. This final rule would not impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector, of $144 million.

D. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This final rule will have no substantial direct effect on state and local governments, preempt state law, or otherwise have federalism implications.

E. Congressional Review Act

This final regulation 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 final rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 483

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 1. The authority citation for part 483 is revised to read as follows:

Authority: Secs. 1102, 1128I, 1819, 1871 and 1919 of the Social Security Act (42 U.S.C. 1302, 1320a-7, 1395i, 1395hh and 1396r).

■ 2. Section 483.75 is amended by adding paragraph (u) to read as follows:

§ 483.75 Administration.

* * * * *

(u) *Mandatory submission of staffing information based on payroll data in a uniform format.* Long-term care facilities must electronically submit to CMS complete and accurate direct care staffing information, including information for agency and contract staff, based on payroll and other verifiable and auditable data in a uniform format according to specifications established by CMS.

(1) *Direct Care Staff.* Direct Care Staff are those individuals who, through interpersonal contact with residents or resident care management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Direct care staff does not include individuals whose primary duty is maintaining the physical environment of the long term care facility (for example, housekeeping).

(2) *Submission requirements.* The facility must electronically submit to CMS complete and accurate direct care staffing information, including the following:

(i) The category of work for each person on direct care staff (including, but not limited to, whether the individual is a registered nurse, licensed practical nurse, licensed vocational nurse, certified nursing assistant, therapist, or other type of medical personnel as specified by CMS);

(ii) Resident census data; and

(iii) Information on direct care staff turnover and tenure, and on the hours of care provided by each category of staff per resident per day (including, but not limited to, start date, end date (as applicable), and hours worked for each individual).

(3) *Distinguishing employee from agency and contract staff.* When reporting information about direct care staff, the facility must specify whether the individual is an employee of the facility, or is engaged by the facility under contract or through an agency.

(4) *Data format.* The facility must submit direct care staffing information in the uniform format specified by CMS.

(5) *Submission schedule.* The facility must submit direct care staffing information on the schedule specified by CMS, but no less frequently than quarterly.

Dated: July 27, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: July 28, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–18950 Filed 7–30–15; 4:15 pm]

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Part III

Office of Management and Budget

North American Industry Classification System (NAICS)—Updates for 2017; Notice

OFFICE OF MANAGEMENT AND BUDGET

North American Industry Classification System (NAICS)—Updates for 2017

AGENCY: Executive Office of the President, Office of Management and Budget.

ACTION: Notice of Solicitation of Comments on the Economic Classification Policy Committee's Recommendations for the 2017 Revision of the North American Industry Classification System.

SUMMARY: Under the authority of the Budget and Accounting Procedures Act of 1950 (31 U.S.C. 1104(d)) and the Paperwork Reduction Act of 1995 (44 U.S.C. 3504(e)), the Office of Management and Budget (OMB) seeks public comment on the advisability of adopting the proposed North American Industry Classification System (NAICS) updates for 2017 recommended by its Economic Classification Policy Committee (ECPC), comprised of representatives of the Bureau of Economic Analysis, Bureau of Labor Statistics, and Census Bureau. The ECPC recommends an update of the industry classification system to clarify existing industry definitions and content, recognize new and emerging industries, and correct errors and omissions.

This notice: (1) Summarizes the background for the proposed revisions to NAICS 2012 in Part I, (2) contains a summary of public comments in Part II, (3) includes a list of title changes for NAICS industries that clarify, but do not change, the existing content of the industries in Part III, and (4) provides a comprehensive listing of proposed changes for national industries and their links to NAICS 2012 industries in Part IV.

OMB published a notification of intention to revise portions of NAICS in a May 22, 2014, **Federal Register** notice (79 FR 29626–29629). That notice solicited comments on the advisability of revising the NAICS 2012 structure for 2017: (1) To identify new and emerging industries, (2) to solicit comments on the desirability of maintaining a print manual, (3) to review the structure of the oil and gas extraction industries, (4) to solicit additional comments on the treatment of manufacturing units that outsource transformation, and (5) to make any required changes for errors and omissions in NAICS 2012. The deadline for submitting comments was July 21, 2014.

After considering all proposals from the public, consulting with U.S. data users and industry groups, and undertaking extensive discussions with Statistics Canada and Mexico's *Instituto Nacional de Estadística y Geografía* (INEGI), the ECPC—in collaboration with INEGI and Statistics Canada—developed recommendations for revisions to NAICS for 2017 that would apply to all three North American countries. These revisions focus on improving the description of current industries, identifying new and emerging industries, and recommending changes to industry content based on research and implementation experience.

The ECPC recommends that NAICS United States 2017 incorporate changes as shown in Parts III and IV of this notice.

Following an extensive process of development and discussions by the ECPC, with maximum possible public input, OMB seeks comment on the advisability of revising NAICS to incorporate the changes published in this notice. The revised NAICS would be employed in relevant data collections by all U.S. statistical agencies beginning with reference year 2017. Statistics Canada and INEGI are recommending acceptance of the proposed NAICS revisions for industry classification in the statistical programs of their national systems and are seeking comments in their respective countries. Representatives of the three countries will hold further discussions to consider public comments that they receive.

DATES: To ensure consideration of comments on the adoption and implementation of the NAICS revisions detailed in this notice, please submit all comments in writing as soon as possible, but no later than October 5, 2015. Please be aware of delays in mail processing at Federal facilities due to heightened security. Respondents are also encouraged to send both a hard copy and a second copy via FAX or email (discussed in **ADDRESSES** below). This proposed revision to NAICS would become effective in the U.S. for publication of establishment data that refer to periods beginning on or after January 1, 2017.

ADDRESSES: Please send correspondence about the adoption and implementation of proposed NAICS revisions as shown in this **Federal Register** notice to: Katherine K. Wallman, Chief Statistician, Office of Management and Budget, 10201 New Executive Office Building, Washington, DC 20503, telephone number: (202) 395–3093, fax number: (202) 395–7245. Please send email comments to *naics@omb.eop.gov* with subject NAICS17. Comments may also be sent via *http://www.regulations.gov*—a Federal E-Government Web site that allows the public to find, review, and submit comments on documents that agencies have published in the **Federal Register** and that are open for comment. Simply type ''(NAICS)—Updates for 2017'' (in quotes) in the ''Rules, Comments, Adjudications or Supporting Documents'' search box, click ''Search, click Comment Now!'', and follow the instructions for submitting comments.

All comments regarding this notice received via the Web site, email, fax, hardcopy, or other means, are part of the public record as submitted. For this reason, do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically saved and included as part of the comment that is placed in the public docket. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

Please include contact information and a phone number or email address with your comments to facilitate follow-up if necessary.

Please address inquiries about the content of industries or requests for electronic copies of the tables to: John Murphy, Chair, Economic Classification Policy Committee, Bureau of the Census, Room 8K157, Washington, DC 20233, telephone number: (301) 763–5172, email: *John.Burns.Murphy@census.gov.*

Electronic Availability and Comments: This document is available on the Internet from the Census Bureau Internet site, *http://www.census.gov/naics.* This site also contains previous NAICS United States **Federal Register** notices and related documents.

FOR FURTHER INFORMATION CONTACT: Paul Bugg, 10201 New Executive Office Building., Washington, DC 20503, email address: *pbugg@omb.eop.gov,* telephone number: (202) 395–3095, fax number: (202) 395–7245.

SUPPLEMENTARY INFORMATION:

Part I: Background of NAICS

NAICS is a system for classifying establishments (individual business locations) by type of economic activity. Its purposes are: (1) To facilitate the collection, tabulation, presentation, and analysis of data relating to

establishments, and (2) to promote uniformity and comparability in the presentation and analysis of statistical data describing the North American economy. NAICS is used by Federal statistical agencies that collect or publish data by industry. It is also widely used by State agencies, trade associations, private businesses, and other organizations.

Mexico's *Instituto Nacional de Estadística y Geografía,* Statistics Canada, and the United States Office of Management and Budget, through its Economic Classification Policy Committee, collaborated on NAICS to make the industry statistics produced by the three countries comparable. NAICS is the first industry classification system developed in accordance with a single principle of aggregation—the principle that producing units that use similar production processes should be grouped together in the classification.

NAICS also reflects, in a much more explicit way, the enormous changes in technology and in the growth and diversification of services that have marked recent decades. Industry statistics presented using NAICS are also comparable, to a limited extent, with statistics compiled according to the latest revision of the United Nations' International Standard Industrial Classification of All Economic Activities (ISIC, Revision 4).

For the three countries, NAICS provides a consistent framework for the collection, tabulation, presentation, and analysis of industry statistics used by government policy analysts, academics and researchers, the business community, and the public. However, because of different national economic and institutional structures as well as limited resources and time for constructing NAICS, its structure is not entirely comparable at the individual industry level across all three countries. For some sectors and subsectors, the statistical agencies of the three countries agreed to harmonize NAICS based on sectoral boundaries rather than on a detailed industry structure. NAICS comparability is limited to the sector level for wholesale trade, retail trade, and public administration.

The four principles of NAICS are:

(1) NAICS is erected on a production-oriented conceptual framework. This means that producing units that use the same or similar production processes are grouped together in NAICS.

(2) NAICS gives special attention to developing production-oriented classifications for (a) new and emerging industries, (b) service industries in general, and (c) industries engaged in the production of advanced technologies.

(3) The system aims to maintain time series continuity to the extent possible.

(4) The system strives for compatibility with the two-digit level of the United Nations' International Standard Industrial Classification of All Economic Activities (ISIC, Revision 4).

The ECPC is committed to maintaining the principles of NAICS during revisions. The May 22, 2014, solicitation for public comment on questions related to a potential revision of NAICS in 2017 was directly tied to the application of these four NAICS principles.

NAICS uses a hierarchical structure to classify establishments from the broadest level to the most detailed level using the following format of up to six digits:

Sector	2-digit	Sectors represent the highest level of aggregation. There are 20 sectors in NAICS representing broad levels of aggregation.
Subsector	3-digit	Subsectors represent the next, more detailed level of aggregation in NAICS. There are 99 subsectors in NAICS United States 2012.
Industry Group	4-digit	Industry groups are more detailed than subsectors. There are 312 industry groups in NAICS United States 2012.
NAICS Industry	5-digit	NAICS industries are the level that, in most cases, represents the lowest level of three country comparability. There are 713 five-digit industries in NAICS United States 2012.
National Industry	6-digit	National industries are the most detailed level of NAICS. These industries represent the national level detail for NAICS United States. There are 1,065 six-digit U.S. industries in NAICS United States 2012.

Part II: Summary of Public Comments Regarding Priorities for Changes to NAICS in 2017

In response to the May 22, 2014, **Federal Register** notice, the ECPC received approximately 22,000 individual comments addressing Part V of the notice—''Update on the Treatment of Manufacturing Units that Outsource Transformation.'' The disposition of these comments is addressed in OMB's August 8, 2014, **Federal Register** notice (79 FR 46558–46559), *Implementation of the Factoryless Goods Producer Classification in NAICS 2017*. In short, the notice announced that the Factoryless Goods Producer classification would not be implemented in 2017. OMB took this action to provide the relevant statistical agencies with the opportunity to complete the additional research, testing, and evaluation needed to determine the feasibility of developing methods for the consistent identification and classification of Factoryless Goods Producers that are accurate and reliable.

For the remaining 113 comments, each submission was assigned a unique docket number. These 113 comments addressed the questions included in Parts II–V of the May 22, 2014, notice and/or included comments proposing other changes to the structure of NAICS 2012.

The ECPC applied the following general guidance when considering changes to NAICS in 2017:

(1) Because of the cost of change and the disruption of statistical data series that have already resulted from the ongoing implementation of NAICS, the ECPC will limit the scope of NAICS changes for 2017 to those that significantly improve the relevance and efficiency of the classification system;

(2) The ECPC will recommend new and emerging industries identified through the comment process that are supported by the guiding principles of NAICS;

(3) The ECPC will undertake additional research and evaluation before making its recommendation on the classification of manufacturing units that outsource transformation, as announced by OMB in a **Federal Register** notice on August 8, 2014 (79 FR 46558–46559); and

(4) The ECPC will make changes to account for errors and omissions as well as recommend narrative improvements to clarify the content of existing industries.

The ECPC also considered the views of its member agencies (Bureau of Economic Analysis, Bureau of Labor Statistics, and Census Bureau) when evaluating specific proposals for changes to NAICS in 2017. The ECPC reviewed each individual proposal within the existing framework of the principles of NAICS. Additional

considerations that resulted in recommendations for or against change included issues of relevance, size, and time series continuity.

Comments received often addressed more than one issue. Of the 113 uniquely numbered comments received in response to the **Federal Register** notice, 53 supported comprehensive changes to create new industries and regroup a variety of existing industries that make up the ''outdoor trade industry,'' five requested new nanotechnology-related industries, five supported creating a NAICS industry for biogas production, four requested new industries and changes to existing industries for modeling and simulation, four addressed updating the structure of the oil and gas industries, three requested a new industry for acupuncture practices, two requested a new industry for building envelope consulting services, and single comments requested other new industries such as welding services, fire extinguisher installation and maintenance, pipeline inspection by type of utility (sanitary, electric, gas, etc.), freestanding urgent care centers and clinics, telehealth services, and offices of nurse practitioners. The balance of the comments requested revisions or clarifications of content of existing NAICS industries, such as industrial sand mining, sign manufacturing, and all other outpatient care centers. Finally, three comments supported continuing printed publication of NAICS 2017.

Each suggestion was carefully considered. Some suggestions were recommended for adoption but modified by the ECPC to better meet the objectives of NAICS. Based on public comments, the ECPC is recommending industry definition changes to explicitly classify certain activities and more clearly match accepted industry terminology.

Some suggestions were recommended to be incorporated as products rather than industries. Other suggestions for change were not best suited on the production-oriented basis of NAICS, or could not be implemented in statistical programs, for various reasons, and thus were not accepted. When a proposal was not accepted, it was usually because: (a) The resulting industry would have been too small in the U.S. or (b) the proposal did not meet the production-oriented criterion for forming an industry in NAICS. Detailed supporting documentation discussing the issues and rationale for reaching these recommendations is available at *www.census.gov/naics*.

Part III: ECPC Recommendations for Title Changes

The ECPC is recommending NAICS industry title changes to more clearly describe the existing content of industries. These title changes do not change the content of these industries, but rather refine how they are described.

NAICS Industry Group 7213, Rooming and Boarding Houses, would be changed to *''Rooming and Boarding Houses, Dormitories, and Workers' Camps.''*

NAICS 72131, Rooming and Boarding Houses, would be changed to *''Rooming and Boarding Houses, Dormitories, and Workers' Camps.''*

NAICS 721310, Rooming and Boarding Houses, would be changed to *''Rooming and Boarding Houses, Dormitories, and Workers' Camps.''*

Part IV: ECPC Recommendations for 2017 Changes to 2012 NAICS United States

Part IV presents the ECPC recommendations for content revisions to NAICS United States for 2017. Table 1 lists, in NAICS United States 2012 order, the disposition of all industries that the ECPC recommends for change and their resulting relationship to NAICS United States 2017 proposed industries. Table 2 presents the ECPC recommended NAICS 2017 industries in proposed NAICS United States 2017 order, cross-walked to their NAICS United States 2012 content.

TABLE 1—2012 NAICS UNITED STATES MATCHED TO ECPC RECOMMENDATIONS FOR 2017 NAICS UNITED STATES

2012 NAICS code	2012 NAICS description	Status code	2017 NAICS code	2017 NAICS description
211111	Crude Petroleum and Natural Gas Extraction			
	crude petroleum extraction		211120	Crude Petroleum Extraction.
	natural gas extraction	pt.	211130	Natural Gas Extraction.
211112	Natural Gas Liquid Extraction	pt.	211130	Natural Gas Extraction.
212231	Lead Ore and Zinc Ore Mining	pt.	212230	Copper, Nickel, Lead, and Zinc Mining.
212234	Copper Ore and Nickel Ore Mining	pt.	212230	Copper, Nickel, Lead, and Zinc Mining.
333911	Pump and Pumping Equipment Manufacturing	pt.	333914	Measuring, Dispensing, and Other Pumping Equipment Manufacturing.
333913	Measuring and Dispensing Pump Manufacturing.	pt.	333914	Measuring, Dispensing, and Other Pumping Equipment Manufacturing.
335221	Household Cooking Appliance Manufacturing	pt.	335220	Major Household Appliance Manufacturing.
335222	Household Refrigerator and Home Freezer Manufacturing.	pt.	335220	Major Household Appliance Manufacturing.
335224	Household Laundry Equipment Manufacturing	pt.	335220	Major Household Appliance Manufacturing.
335228	Other Major Household Appliance Manufacturing.	pt.	335220	Major Household Appliance Manufacturing.
452111	Department Stores (except Discount Department Stores).	pt.	452210	Department Stores.
452112	Discount Department Stores			
	insignificant perishable grocery sales	pt.	452210	Department Stores.
	significant perishable grocery sales	pt.	452311	Warehouse Clubs and Supercenters.
452910	Warehouse Clubs and Supercenters	pt.	452311	Warehouse Clubs and Supercenters.
452990	All Other General Merchandise Stores		452319	All Other General Merchandise Stores.
454111	Electronic Shopping	pt.	454110	Electronic Shopping and Mail-Order Houses.
454112	Electronic Auctions	pt.	454110	Electronic Shopping and Mail-Order Houses.
454113	Mail-Order Houses	pt.	454110	Electronic Shopping and Mail-Order Houses.
512210	Record Production	pt.	512250	Record Production and Distribution.
512220	Integrated Record Production/Distribution	pt.	512250	Record Production and Distribution.
517110	Wired Telecommunications Carriers		517311	Wired Telecommunications Carriers.

TABLE 1—2012 NAICS UNITED STATES MATCHED TO ECPC RECOMMENDATIONS FOR 2017 NAICS UNITED STATES—Continued

2012 NAICS code	2012 NAICS description	Status code	2017 NAICS code	2017 NAICS description
517210	Wireless Telecommunications Carriers (except Satellite).	.....	517312	Wireless Telecommunications Carriers (except Satellite).
532220	Formal Wear and Costume Rental	.....	532281	Formal Wear and Costume Rental.
532230	Video Tape and Disc Rental	.....	532282	Video Tape and Disc Rental.
532291	Home Health Equipment Rental	.....	532283	Home Health Equipment Rental.
532292	Recreational Goods Rental	.....	532284	Recreational Goods Rental.
532299	All Other Consumer Goods Rental	.....	532289	All Other Consumer Goods Rental.
541711	Research and Development in Biotechnology			
	nanobiotechnologies research and experimental development laboratories.	pt.	541713	Research and Development in Nanotechnology.
	except nanobiotechnologies research and experimental development laboratories.	.....	541714	Research and Development in Biotechnology (except Nanobiotechnology).
541712	Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)			
	nanotechnology research and experimental development laboratories.	pt.	541713	Research and Development in Nanotechnology.
	except nanotechnology research and experimental development laboratories.	.....	541715	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology).

pt.—Part of 2017 NAICS United States industry.

TABLE 2—ECPC RECOMMENDATIONS FOR 2017 NAICS UNITED STATES MATCHED TO 2012 NAICS UNITED STATES

2017 NAICS code	2017 NAICS description	Status code	2012 NAICS code	2012 NAICS description
21112	Crude Petroleum Extraction			
211120	Crude Petroleum Extraction	N	*211111	Crude Petroleum and Natural Gas Extraction—c*rude petroleum extraction*.
21113	Natural Gas Extraction			
211130	Natural Gas Extraction	N	*211111	Crude Petroleum and Natural Gas Extraction—*natural gas extraction*.
			211112	Natural Gas Liquid Extraction.
212230	Copper, Nickel, Lead, and Zinc Mining	N	212231	Lead Ore and Zinc Ore Mining.
			212234	Copper Ore and Nickel Ore Mining.
333914	Measuring, Dispensing, and Other Pumping	N	333911	Pump and Pumping Equipment Manufacturing.
	Equipment Manufacturing	.....	333913	Measuring and Dispensing Pump Manufacturing.
335220	Major Household Appliance Manufacturing	N	335221	Household Cooking Appliance Manufacturing.
			335222	Household Refrigerator and Home Freezer Manufacturing.
			335224	Household Laundry Equipment Manufacturing.
			335228	Other Major Household Appliance Manufacturing.
4522	Department Stores			
45221	Department Stores			
452210	Department Stores	N	452111	Department Stores (except Discount Department Stores).
			*452112	Discount Department Stores—*insignificant perishable grocery sales*.
4523	General Merchandise Stores, Including Warehouse Clubs and Supercenters			
45231	General Merchandise Stores, Including Warehouse			
	Clubs and Supercenters			
452311	Warehouse Clubs and Supercenters	N	452910	Warehouse Clubs and Supercenters.
			*452112	Discount Department Stores—*significant perishable grocery sales*.
452319	All Other General Merchandise Stores	N	452990	All Other General Merchandise Stores.
454110	Electronic Shopping and Mail-Order Houses	N	454111	Electronic Shopping.
			454112	Electronic Auctions.
			454113	Mail-Order Houses.
51225	Record Production and Distribution			
512250	Record Production and Distribution	N	512210	Record Production.
			512220	Integrated Record Production/Distribution.
51731	Wired and Wireless Telecommunications Carriers			

TABLE 2—ECPC RECOMMENDATIONS FOR 2017 NAICS UNITED STATES MATCHED TO 2012 NAICS UNITED STATES—Continued

2017 NAICS code	2017 NAICS description	Status code	2012 NAICS code	2012 NAICS description
517311	Wired Telecommunications Carriers	N	517110	Wired Telecommunications Carriers.
517312	Wireless Telecommunications Carriers (except Satellite).	N	517210	Wireless Telecommunications Carriers (except Satellite).
53228	Other Consumer Goods Rental			
532281	Formal Wear and Costume Rental	N	532220	Formal Wear and Costume Rental.
532282	Video Tape and Disc Rental	N	532230	Video Tape and Disc Rental.
532283	Home Health Equipment Rental	N	532291	Home Health Equipment Rental.
532284	Recreational Goods Rental	N	532292	Recreational Goods Rental.
532289	All Other Consumer Goods Rental	N	532299	All Other Consumer Goods Rental.
541713	Research and Development in Nanotechnology.	N	*541711	Research and Development in Biotechnology—*nanobiotechnologies research and experimental development laboratories*.
			*541712	Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)—*nanotechnology research and experimental development laboratories*.
541714	Research and Development in Biotechnology (except Nanobiotechnology).	N	*541711	Research and Development in Biotechnology—*except nanobiotechnologies research and experimental development laboratories*.
541715	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology).	N	*541712	Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology)—*except nanotechnology research and experimental development laboratories*.

N—new NAICS industry/code for 2017; *—Part of 2012 NAICS United States industry.

Howard A. Shelanski,

Administrator, Office of Information and Regulatory Affairs.

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