AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

FEDERAL REGISTER

Vol. 77 Friday,

No. 218 November 9, 2012

Pages 67239–67532

OFFICE OF THE FEDERAL REGISTER

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

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

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

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

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

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

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

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

How To Cite This Publication: Use the volume number and the page number. Example: 77 FR 12345.

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

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Paper or fiche	**202–741–6005**
Assistance with Federal agency subscriptions	**202–741–6005**

FEDERAL REGISTER WORKSHOP

THE FEDERAL REGISTER: WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, November 13, 2012
9 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

Printed on recycled paper.

Contents

Federal Register

Vol. 77, No. 218

Friday, November 9, 2012

Agricultural Marketing Service
RULES
National Organic Program:
Periodic Residue Testing, 67239–67251

Agriculture Department
See Agricultural Marketing Service
See Farm Service Agency
See Forest Service
See National Institute of Food and Agriculture

Alcohol and Tobacco Tax and Trade Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 67442–67447

Blind or Severely Disabled, Committee for Purchase From People Who Are
See Committee for Purchase From People Who Are Blind or Severely Disabled

Census Bureau
NOTICES
Annual Wholesale Trade Survey, 67331–67332

Centers for Medicare & Medicaid Services
RULES
Medicare Program:
End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for all Medicare Providers, 67450–67531
NOTICES
Medicare and Medicaid Programs:
Quarterly Listing of Program Issuances, 67368–67379

Coast Guard
PROPOSED RULES
Drawbridge Operations:
Lake Champlain, Swanton, VT, 67319–67322

Commerce Department
See Census Bureau
See International Trade Administration
See National Institute of Standards and Technology
See National Oceanic and Atmospheric Administration
See National Telecommunications and Information Administration

Committee for Purchase From People Who Are Blind or Severely Disabled
NOTICES
Procurement List; Additions and Deletions, 67343–67344

Consumer Product Safety Commission
NOTICES
Meetings; Sunshine Act, 67344

Corporation for National and Community Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 67344–67345

Defense Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals
Federal Acquisition Regulation; Quality Assurance Requirements, 67366–67367
Federal Acquisition Regulation; Travel Costs, 67366
Environmental Impact Statements; Availability, etc.:
Clearwater Program, 67345

Drug Enforcement Administration
NOTICES
Importers of Controlled Substances; Applications:
Fisher Clinical Services, Inc., 67396–67397
Importers of Controlled Substances; Registrations:
Boehringer Ingelheim Chemicals, Inc., 67397
Manufacturers of Controlled Substances; Applications:
Cody Laboratories, Inc., 67398
INB Hauser Pharmaceutical Services, Inc., 67398–67399
Johnson Matthey, Inc., 67397–67398
National Center for Natural Products Research, 67398
Noramco, Inc., 67397

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
2013–2014 Federal Student Aid Application, 67345–67348
Privacy Act; Systems of Records, 67348–67352

Employment and Training Administration
NOTICES
Certifications Regarding Eligibility to Apply for Worker Adjustment Assistance:
Hewlett–Packard Co., Corvallis, OR and Vancouver, WA, 67399–67400
RG Steel Wheeling, LLC, Beech Bottom, WV, 67400
State Street Corp., Quincy, MA, 67399
Trim Systems Operating Corp., Statesville, NC, 67399
Determinations Regarding Eligibility to Apply for Worker Adjustment Assistance, 67400–67406
Investigations Regarding Eligibility to Apply for Worker Adjustment Assistance, 67406–67407

Energy Department
See Federal Energy Regulatory Commission

Environmental Protection Agency
RULES
Dinotefuran; Pesticide Tolerances for Emergency Exemptions, 67282–67285
PROPOSED RULES
Revisions to the California State Implementation Plan:
Placer County Air Pollution Control District, 67322–67324
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Inform Hydraulic Fracturing Research Related to Drinking Water Resources, 67361–67362
Environmental Impact Statements; Availability, etc., 67362

Export–Import Bank
NOTICES
Applications for Final Commitments for Long-Term Loans or Financial Guarantees in Excess of $100 million, 67362–67363
Meetings; Sunshine Act, 67363

Farm Service Agency
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Agricultural Foreign Investment Disclosure Act, 67329
Servicing Minor Program Loans, 67329–67330

Federal Aviation Administration
RULES
Airworthiness Directives:
Aeronautical Accessories, Inc., High Landing Gear Forward Crosstube Assembly, 67261–67263
Airbus Airplanes, 67256–67261, 67263–67267
Bombardier, Inc. Airplanes, 67254–67256, 67267–67269
Special Conditions:
Boeing Model 757 Series Airplanes; Seats with Non-Traditional, Large, Non-Metallic Panels, 67251–67254
Voluntary Licensing of Amateur Rocket Operations; Withdrawal, 67269–67270
PROPOSED RULES
Special Conditions:
Embraer S.A., Model EMB–550 Airplane; Hydrophobic Coatings in Lieu of Windshield Wipers, 67308–67309
Embraer S.A., Model EMB–550 Airplanes; Flight Envelope Protection: Performance Credit for Automatic Takeoff Thrust Control System (ATTCS) During Go-Around, 67309–67313
NOTICES
Petitions for Exemptions; Summaries of Petitions Received, 67438–67439

Federal Communications Commission
RULES
Basic Service Tier Encryption Compatibility Between Cable Systems and Consumer Electronics Equipment, 67290–67302
NOTICES
Suspensions and Commencements of Proposed Debarment Proceedings:
Schools and Libraries Universal Service Support Mechanism, 67363–67365

Federal Emergency Management Agency
RULES
Debris Removal:
Eligibility of Force Account Labor Straight-Time Costs under the Public Assistance Program for Hurricane Sandy, 67285–67290
PROPOSED RULES
Flood Elevation Determinations; Correction, 67324–67327

Federal Energy Regulatory Commission
NOTICES
Applications:
City of New York, 67352
Lock+ Hydro Friends Fund XLII, LLC, 67352–67353
Combined Filings, 67353–67359
Environmental Assessments; Availability, etc.:
Wickiup Hydro Group, LLC, 67359
Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations:
EnergyMark, LLC, 67360
MP2 Energy IL LLC, 67359–67360
MP2 Energy NJ LLC, 67360
Preliminary Permit Applications:
Igiugig Village Council, 67360–67361

Federal Maritime Commission
NOTICES
Agreements Filed, 67365

Federal Reserve System
NOTICES
Changes in Bank Control:
Acquisitions of Shares of a Bank or Bank Holding Company, 67365–67366

Federal Transit Administration
NOTICES
Fiscal Year 2013 Public Transportation on Indian Reservations Program, 67439–67442

Fish and Wildlife Service
RULES
Endangered and Threatened Wildlife and Plants:
Termination of the Southern Sea Otter Translocation Program; Final Supplemental Environmental Impact Statement, 67302–67303
NOTICES
Meetings:
Conference of the Parties to the Convention on International Trade in Endangered Species of Wild Fauna and Flora, 67390–67391

Food and Drug Administration
NOTICES
Draft Guidance for Industry and Staff; Availability:
Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices, 67379–67380
Meetings:
Anesthetic and Analgesic Drug Products Advisory Committee, 67380

Foreign Assets Control Office
RULES
Yemen Sanctions Regulations, 67276–67282

Forest Service
NOTICES
Meetings:
Sitka Resource Advisory Committee, 67330

General Services Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals
Federal Acquisition Regulation; Quality Assurance Requirements, 67366–67367
Federal Acquisition Regulation; Travel Costs, 67366

Health and Human Services Department
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See National Institutes of Health
NOTICES
Physical Activity Guidelines Mid-course Report; Availability, 67367–67368

Homeland Security Department
See Coast Guard

See Federal Emergency Management Agency

Housing and Urban Development Department
NOTICES
Announcement of Funding Awards:
Indian Community Development Block Grant Program; Fiscal Year 2012, 67386–67389
Federal Properties Suitable as Facilities to Assist Homeless, 67389

Interior Department
See Fish and Wildlife Service
See Land Management Bureau
See Ocean Energy Management Bureau

International Trade Administration
NOTICES
Antidumping Duty Administrative Reviews; Results, Extensions, Amendments, etc.:
Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe from Romania, 67336–67337
Certain Steel Threaded Rod from the People's Republic of China, 67332–67334
Frontseating Service Valves from the People's Republic of China, 67334–67336
Final Results of Antidumping Duty Administrative Review:
Certain Activated Carbon from the People's Republic of China, 67337–67340

International Trade Commission
NOTICES
Investigations:
Corrosion-Resistant Carbon Steel Flat Products From Germany And Korea, 67395
Meetings; Sunshine Act, 67396

Justice Department
See Drug Enforcement Administration
NOTICES
Lodgings of Proposed Consent Decrees under CERCLA, 67396

Labor Department
See Employment and Training Administration
See Occupational Safety and Health Administration

Land Management Bureau
NOTICES
Plats of Surveys:
Eastern States; Mississippi, 67391
Public Land in Water Canyon, Humboldt County, NV, 67391–67394

National Aeronautics and Space Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals
Federal Acquisition Regulation; Quality Assurance Requirements, 67366–67367
Federal Acquisition Regulation; Travel Costs, 67366

National Institute of Food and Agriculture
NOTICES
Requests for Stakeholder Input:
Veterinary Medicine Loan Repayment Program, 67330–67331

National Institute of Standards and Technology
NOTICES
National Fire Codes:
Request for Comments on NFPA's Codes and Standards, 67340–67341

National Institutes of Health
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Ethical Dilemmas in Surgery and Utilization of Hospital Ethics Consultation Service; A Survey, 67380–67381
Government-Owned Inventions; Availability for Licensing, 67381–67385
Meetings:
Center for Scientific Review, 67385
National Human Genome Research Institute, 67385
National Institute of Allergy and Infectious Diseases, 67385–67386
National Institute of General Medical Sciences, 67385

National Oceanic and Atmospheric Administration
RULES
Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic:
Reef Fish Fishery of the Gulf of Mexico; Gray Triggerfish Management Measures, 67303–67305
Fisheries of the Northeastern United States:
Atlantic Mackerel, Squid, and Butterfish Fisheries; Specifications and Management Measures, 67305–67307
PROPOSED RULES
Fisheries Off West Coast States:
West Coast Salmon Fisheries, Amendment 17 to the Salmon Fishery Management Plan; Availability, 67327–67328
NOTICES
Applications:
Endangered Species; File No. 15809, 67341
Meetings:
Fisheries of the South Atlantic; Southeast Data, Assessment and Review, 67341–67342
North Pacific Fishery Management Council, 67342

National Science Foundation
NOTICES
Antarctic Conservation Act Permit Applications, 67407
Antarctic Conservation Act Permits, 67407–67408

National Telecommunications and Information Administration

NOTICES
Meetings:
First Responder Network Authority Board, 67342–67343

Occupational Safety and Health Administration
RULES
Exemption for Digger Derricks in Cranes and Derricks in Construction Standard, 67270–67276
PROPOSED RULES
Exemption for Digger Derricks in Cranes and Derricks in Construction Standard, 67313–67319

Ocean Energy Management Bureau
NOTICES
Oil and Gas Lease Sales:
Gulf of Mexico, Outer Continental Shelf; Western Planning Area 233 and Central Planning Area 231, 67394–67395

Securities and Exchange Commission
NOTICES
Meetings; Sunshine Act, 67408
Self-Regulatory Organizations; Proposed Rule Changes:
C2 Options Exchange, Inc., 67424–67427
Chicago Board Options Exchange, Inc., 67421–67424
ICE Clear Europe Limited, 67427–67429
NASDAQ Stock Market LLC, 67409–67410
National Securities Clearing Corp., 67410–67412
New York Stock Exchange LLC, 67431–67433
NYSE Arca, Inc., 67412–67418
NYSE MKT LLC, 67419–67420
Options Clearing Corp., 67429–67431

Small Business Administration
NOTICES
Community Advantage Pilot Program, 67433–67435

Social Security Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 67435–67438

State Department
NOTICES
Meetings:
Defense Trade Advisory Group, 67438

Surface Transportation Board
NOTICES
Temporary Trackage Rights Exemptions:
Northern Plains Railroad, Inc. from Soo Line Railroad Co., 67442
Soo Line Railroad Co. by BNSF Railway Co., 67442

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

Treasury Department
See Alcohol and Tobacco Tax and Trade Bureau
See Foreign Assets Control Office

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 67450–67531

Reader Aids

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

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

CFR PARTS AFFECTED IN THIS ISSUE

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

7 CFR
205 67239

14 CFR
25 67251
39 (5 documents) 67254, 67256, 67261, 67263, 67267
400 67269

Proposed Rules:
25 (2 documents) 67308, 67309

29 CFR
1926 67270

Proposed Rules:
1926 67313

31 CFR
552 67276

33 CFR

Proposed Rules:
117 67319

40 CFR
180 67282

Proposed Rules:
52 67322

42 CFR
413 67450
417 67450

44 CFR
206 67285

Proposed Rules:
67 (2 documents) 67324, 67325

47 CFR
76 67290

50 CFR
17 67302
622 67303
648 67305

Proposed Rules:
660 67327

Rules and Regulations

Federal Register
Vol. 77, No. 218
Friday, November 9, 2012

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

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS–NOP–10–0102; NOP–10–10FR]

RIN 0581–AD10

National Organic Program; Periodic Residue Testing

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule clarifies a provision of the Organic Foods Production Act of 1990 and the regulations issued thereunder that requires periodic residue testing of organically produced agricultural products by accredited certifying agents. The final rule amends the U.S. Department of Agriculture's (USDA) National Organic Program (NOP) regulations to make clear that accredited certifying agents must conduct periodic residue testing of agricultural products that are to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s)).'' The final rule expands the amount of residue testing of organically produced agricultural products by clarifying that sampling and testing are required on a regular basis. The final rule requires that certifying agents, on an annual basis, sample and conduct residue testing from a minimum of five percent of the operations that they certify. This action will help further ensure the integrity of products produced and handled under the NOP regulations.

DATES: *Effective Date:* This final rule is effective January 1, 2013.

FOR FURTHER INFORMATION CONTACT: Melissa R. Bailey, Ph.D., Director, Standards Division, Telephone: (202) 720–3252; Fax: (202) 205–7808.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 6511 of the Organic Foods Production Act of 1990 (OFPA), as amended, (7 U.S.C. 6501–6522), the National Organic Program (NOP) is authorized to implement regulations that require accredited certifying agents to conduct residue testing of organically produced agricultural products. Section 6506 of the OFPA also requires that the NOP include provisions for periodic residue testing by certifying agents of agricultural products produced or handled in accordance with the NOP.

Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the NOP and by discouraging the mislabeling of agricultural products. Testing of organically produced agricultural products is promulgated in section 205.670 of the NOP regulations (7 CFR part 205). This section provides that the Secretary, State organic programs, and certifying agents may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s))'' when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods.

The Agricultural Marketing Service (AMS) is issuing this final rule in response to an audit of the NOP which was conducted in March 2010 by the USDA Office of Inspector General (OIG).[1] As part of the audit, the OIG visited four certifying agents accredited by the NOP. The audit found that none of the four certifying agents visited conducted periodic residue testing. The OIG indicated that these certifying agents noted that they considered residue testing to be required by the regulations only under certain circumstances.

AMS conducted a review of this issue in response to the OIG audit. AMS concluded that, under section 6506 of the OFPA, accredited certifying agents are required to conduct residue testing of organic products on a regular and reoccurring basis, as well as when there is reason to believe contamination has occurred, and that the regulations be revised as provided for in this rulemaking.

On June 23 and June 24, 2010, the NOP conducted two webinar trainings with certifying agents on periodic residue testing under the NOP. The objective of the webinar was to present an overview of requirements for periodic residue testing under the OFPA and the NOP. The NOP also solicited feedback from the certifying agents who participated in the webinar. Of the certifying agents accredited at that time, 55 individuals registered to participate in the webinar. Ten participants in the webinar provided written feedback to the NOP in response to the information provided. These comments were considered in the development of this final rule.

On April 29, 2011, AMS published a proposed rule for periodic residue testing (76 FR 23914). The rule proposed that certifying agents, on an annual basis, must sample and conduct residue testing from a minimum of five percent of the operations that they certify. The proposed rule included a 60 day comment period. Comments were also specifically requested on the information collection burden that would result from the proposed action. The NOP received over 30 written comments in response to the proposed rule.

II. Comments on Proposed Rule

Comments in response to the proposed rule were received from certified organic operations, certifying agents, consumers, trade associations, organic associations, and various industry groups.

The majority of commenters supported residue testing in general, and offered comments regarding the role of the National Organic Standards Board (NOSB), sampling rates, sample selection, costs and costs estimates, testing methodology, data collection, and reporting requirements.

Four comments specifically addressed the information collection and recordkeeping requirements of this action pursuant to the Paperwork Reduction Act (44 U.S.C. 3501–3520) (PRA).

[1] U.S. Department of Agriculture, Office of Inspector General, Audit Report 01601–03-Hy, March 2010. Available at *http://www.usda.gov/oig/webdocs/01601-03-HY.pdf.*

AMS received one comment from a certifying agent requesting an extension of the comment period. Since the proposed rule included a 60 day comment period and because the NOP previously conducted two webinar trainings with certifying agents on periodic residue testing on June 23 and June 24, 2010, we did not agree that an extension of the comment period was warranted.

Authority To Issue Rule

Seven commenters indicated that they did not believe that AMS has the authority to issue a rule on residue testing under the OFPA without a recommendation from the NOSB.

The NOSB is a federal advisory committee established by the Secretary of Agriculture under section 6518 of the OFPA to assist in the development of standards for substances to be used in organic production and to advise the Secretary on other aspects of the implementation of the NOP.

The commenters cited section 6518 of the OFPA which states ''the Board shall advise the Secretary concerning the testing of organically produced agricultural products for residues caused by unavoidable residual environmental contamination.''

Additionally, two commenters cited a 1990 report of the U.S. Senate Committee on Agriculture, Nutrition, and Forestry, which indicates that the NOSB would be most knowledgeable on the subject of levels of acceptable residues of prohibited materials for organic food, and that the Committee intends that the NOSB shall advise the Secretary concerning appropriate residue levels and testing methods for organic products.[2]

AMS disagrees with the commenters' claims that AMS does not have the authority to issue a rule in this area. This final rule is issued under the authority of the OFPA at section 6506(a)(6) which requires periodic residue testing by certifying agents. This rule does not amend any provisions or thresholds related to the maximum allowable pesticide residue for organic food or thresholds related to unavoidable residual environmental contamination (UREC). The existing NOP regulations regarding UREC at section 205.671 were based on a recommendation adopted by the NOSB at its meeting June 1–4, 1994 in Santa Fe, New Mexico.[3] UREC is defined under section 205.2 of the NOP regulations as background levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances. This rule does not amend this existing definition.

Number of Samples

AMS received twelve comments on the issue of the amount of sampling or number of samples. The proposed rule indicated that certifying agents would be required, on an annual basis, to sample and conduct residue testing from a minimum of five percent of the operations that they certify. The proposed rule indicated that residue testing conducted for causative reasons, such as complaint-driven testing, or testing when there was reason to suspect contamination, would not be counted towards the minimum percentage required.

Based on the comments received, AMS believes that using a percentage of certified operations to determine sample selection offers the simplest implementation for certifying agents and ensures that all certifying agents conduct a minimal level of residue testing. Further discussion of the comments received is provided below.

Number of Samples—Changes Based on Comments

AMS received five comments requesting that all residue testing conducted by a certifying agent be counted towards the five percent minimum requirement, including compliance testing, investigative testing, risk-based sampling, and random sampling. One commenter indicated that establishing random testing at five percent would make it more difficult to do other types of testing (e.g. risk-based, compliance testing) because of the costs involved. Several commenters indicated that compliance, investigative, and risk-based testing would yield more meaningful results than random testing.

One comment from a certifying agent indicated that it did not support revising the rule to include compliance or investigative testing as part of the five percent requirement. Based on experience in taking samples for both purposes, the commenter indicated that the concern from certifying agents that the proposed rule would be a disincentive to conduct compliance or investigative testing was unfounded.

The NOP accepts the majority of the commenters' suggestions to include all testing towards the minimum requirement. Any residue testing performed by a certifying agent may be counted towards the minimum requirement for residue testing, provided that the certifying agent samples and tests from a minimum of five percent of the operations it certifies on an annual basis.

AMS received two comments requesting a phase-in period for the testing requirements. One commenter suggested testing a portion of the five percent minimum percentage of operations in 2012, and the full percentage of operations in 2013. The commenter noted that a phase-in would enable certification agents to plan budgets, develop office procedures, and train staff and inspectors. The commenter also noted that a phase-in would enable the NOP to assess the effectiveness of the testing program. AMS received one comment requesting a phase-in of three percent for the first two years, which could be reevaluated and adjusted accordingly in the future.

AMS has considered the commenters' suggestion for a phase-in of the implementation and compliance date of the final rule and has issued this final rule with an effective date of January 1, 2013. Certifying agents must be fully compliant with the five percent requirement for the 2013 calendar year. The NOP understands that a minority of accredited certifying agents currently conduct residue testing on a regular, periodic basis. However, the NOP notes that certifying agents are already required, under section 205.504(b)(6) of the NOP regulations, to have procedures and trained staff in place for investigations of pesticide drift, complaints, or when reason to believe a product has come into contact with a prohibited substances. As evidence of their expertise and ability, certifying agents are also already required to submit a copy of the procedures to be used for sampling and residue testing pursuant to section 205.670 as an accreditation requirement.

Number of Samples—Changes Requested But Not Made

One commenter noted that the number of operations that would be sampled under the proposed rule was small relative to the total number of operations. The commenter noted that sampling based on the number of operations does not account for differences in sizes of the operations, and suggested that sampling be based upon size and quantity, rather than the number of operations. The commenter

[2] U.S. Senate, Committee on Agriculture, Nutrition, and Forestry. *Food, Agriculture, Conservation, and Trade Act of 1990,* S. Rpt. 101–357 to accompany S. 2830, July 6, 1990.

[3] National Organic Standards Board, Final Recommendations, Residue Testing, 1994. Available on the NOP Web site at *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=stelprdc5058863.*

suggested that AMS have an unbiased group determine sampling methodology using proper scientific and statistical techniques. The commenter noted that, unless AMS uses a sound basis in choosing the number, size, and site of the samples, any conclusions drawn from the testing would be invalid.

Another commenter suggested that AMS should require sampling based on a percentage of products, rather than a percentage of operations.

Two comments indicated that the five percent number was arbitrary and not statistically valid, but did not offer an alternative method for determining sampling size.

AMS disagrees. Basing sampling on a percentage of operations reduces the burden on the certifying agents by providing a clear and simple formula for how to comply with the regulations. The five percent requirement satisfies AMS's intent to discourage the mislabeling of agricultural products and provide a means for monitoring compliance with the NOP.

Under the final rule, certifying agents have the discretion to select operations for residue testing based on criteria such as size of operation, quantity of products produced, previous compliance issues, or other risk factors. Certifying agents are knowledgeable about the risk factors affecting the operations it certifies; therefore, it is appropriate for a certifying agent to determine what operations should be tested under this action.

AMS received three comments requesting that AMS lower the minimum percentage of operations to be tested from five percent to three percent due to costs. One of the commenters stated that the costs of testing would be passed on indirectly to farmers and processors in the form of higher certification fees. Another commenter stated that requiring three percent, rather than five percent, would allow the certifying agent more latitude for doing risk-based and compliance sampling.

In the final rule, AMS allows for both periodic testing and compliance sampling to be counted towards the minimum requirement, but has retained the minimum percentage of operations to be tested at five percent annually.

AMS has considered the comment that this action may indirectly increase costs to certified operations if certifying agents increase their certification fees to recover costs from increased residue testing. This action implements periodic residue testing in a way that should minimize the direct costs to certifying agents and any indirect costs to certified operations while still meeting the objectives of implementing periodic residue testing as required by OFPA. Additional details on the costs, benefits, and alternatives considered are discussed in the section titled *Executive Order 12866 and Executive Order 13563.*

AMS notes that lowering the percentage below five percent does not have an impact on the smallest quartile of certifying agents that certify fewer than thirty operations to the NOP per year, since they are required to sample a minimum of one operation under either scenario.

One comment from a consumer group indicated that AMS should reserve the right to raise the percentage for a specific certifying agent if residue testing shows that a certifying agent has an unusually high number of positive results. AMS believes that the regulations provide sufficient flexibility for the NOP to address issues that may arise on a case-by-case basis, and therefore, no modifications are necessary to the regulations.

One commenter requested that AMS review the residue testing data in five years to see if the percentage of operations tested could be reduced. AMS notes that the final rule does not prohibit AMS from reconsidering the percentage of operations required for compliance at a later date based on new information, but this would be under a separate rulemaking action.

AMS received one comment from a certifying agent regarding the role of State organic programs under the proposed rule. AMS currently has one State organic program in California. The commenter requested that testing conducted by a State program should offset the certifying agents' requirement in that State. AMS disagrees. Under the OFPA, certifying agents are required to conduct residue testing. AMS believes that requiring certifying agents to test from five percent of certified operations on an annual basis is reasonable, and that testing conducted by other organizations, including State organic programs or other private testing programs, should not offset this requirement under the OFPA.

Operation Selection and Conflict of Interest—Changes Requested But Not Made

AMS received nine comments regarding the selection of operations for residue testing. Several commenters requested clarification on selection of operations and whether it is AMS' intent to have certifying agents select operations at random or use other criteria. It is not AMS' intent for this final rule to require certifying agents to select operations at random. AMS is not specifying how certifying agents should select operations for residue testing in order to provide flexibility to the certifying agency. Instead, AMS is providing discretion to the certifying agent to select operations. Operation selection for residue testing may include risk factors such as number of products produced, split operations, size of the operation, high-value or high-risk crops, or other criteria deemed appropriate by the certifying agent.

Three commenters indicated that certifying agents should not select the operations for residue testing since this may be an inherent conflict of interest. Commenters suggested that the NOP or other third-party groups select the operations. AMS disagrees. Certifying agents are already required to implement procedures to prevent conflict of interests as a condition of accreditation under the NOP regulations (§ 205.501(a)(11)). AMS also conducts regular audits of certifying agents to ensure compliance with NOP accreditation requirements including preventing conflicts of interest. AMS does not have reason to believe that selection of operations for purposes of periodic residue testing would be different from any other certification work carried out by certifying agents with respect to conflict of interest.

Several commenters suggested utilizing a system of statistical sampling methods for operation selection, such as that used by the AMS Pesticide Data Program. AMS disagrees. It is not AMS' intent to assemble data and draw conclusions based on statistical sampling techniques, as the sampling performed by certifying agents will vary considerably due to the worldwide diversity of operations which are certified to the NOP. Certifying agents have the discretion to sample from higher risk operations, which may yield results that are not representative of all organic operations.

Types of Samples—Changes Based on Comments

AMS received eight comments regarding the selection of samples for residue testing. The commenters requested changes in the rule to clarify that residue sampling may be performed on samples which are not finished products, such as soil samples, tissue samples, or water.

Commenters noted that preharvest sampling may be more meaningful when sampling is risk-based or for investigative testing (e.g., when use of a prohibited substance is suspected). In addition, commenters suggested that preharvest testing of tissue samples,

soil, or water may be more appropriate at certain times during the growing season.

AMS agrees with the commenters' suggestions and has amended the regulatory text accordingly to clarify that testing may be conducted preharvest or postharvest, and that residue testing is not limited to salable products only. The final rule specifies the types of materials for sampling that are currently listed in section 205.403(c)(3) for on-site inspections. This may include collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. AMS notes that, in the case of pesticide residue testing, tolerances are established by the Environmental Protection Agency (EPA) for specific harvested commodities. These tolerances enable the certifying agent to take appropriate enforcement action, if warranted, for the harvested commodity. If a prohibited residue is detected in a sample where there is not an established tolerance, such as soil, water, or other plant tissues, follow-up testing of the harvestable product may be needed for the certifying agent to determine the appropriate enforcement action.

Additionally, AMS notes that certifying agents currently have the authority to collect samples under section 205.403(c) which states that ''The on-site inspection of an operation must verify: (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.''

Types of Samples—Changes Requested But Not Made

AMS received one comment requesting that processed products which are to be sold or labeled as ''organic'' or ''made with organic (specified ingredients or food group(s))'' be excluded from residue testing requirements. The commenter states that testing would not pinpoint the source of contaminants in processed, multi-ingredient products. In certain cases, the source of a residue detected in a multi-ingredient processed product may be more difficult to identify; however, we have retained the allowance for testing processed products to allow certifying agents the flexibility of sampling processed products when it may be useful to determine compliance with the regulations.

Reporting Requirements

AMS received eight comments regarding reporting requirements. Several commenters requested clarification on the use of the term ''promptly'' in reporting results to the AMS Administrator (Administrator). The proposed rule did not specify a reporting time period and retained the term ''promptly'' from the existing NOP requirements at section 205.670.

Several commenters also requested a distinction between reporting violative versus non-violative sample results. The commenters suggested that violative samples (i.e., samples with residues detected) could be reported to the Administrator as the information was received, but requested that non-violative samples (i.e., where no residues are detected) be reported on a more infrequent basis, such as quarterly or annually. One commenter requested that reporting be required on at least an annual basis, but not more than twice annually. Two commenters requested that the NOP require all results to be reported and incorporated into a dataset that would be available to the public.

After further consideration, AMS has amended the reporting requirements required under section 205.670 in order to reduce the reporting burden on certifying agents. This rule eliminates the requirement that certifying agents must submit all residue testing results to the Administrator or State organic program's governing State official. AMS does not intend to consolidate residue testing data from certifying agents and does not need reporting of residue testing results as the mechanism to ensure that certifying agents are meeting the requirement periodic residue testing.

AMS intends to verify compliance of certifying agents with the requirements for periodic residue testing as part of the existing accreditation process. Accreditation requirements at section 205.504(b)(6) require certifying agents to have administrative policies and procedures, including procedures to be used for sampling and residue testing pursuant to § 205.670. Certifying agents are also required to submit an annual report to the Administrator on or before the anniversary date of the issuance of notification of accreditation which includes a complete and accurate update of information submitted pursuant to §§ 205.503 and 205.504. In order to verify that certifying agents are implementing this rule in advance of regularly scheduled on-site audits, AMS intends to require, as authorized under section 205.510(a)(3), certifying agents to submit in their next annual report a description of the measures implemented in the previous year and any measures to be implemented in the coming years to meet the requirements in this rule for periodic residue testing. In addition, AMS notes that certifying agents should continue to maintain the complete results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and three preceding calendar years, as required by section 205.504(b)(5)(iii).

The final rule also clarifies the reporting requirements when test results indicate that a specific agricultural product contains pesticide residues or environmental contaminates that exceed the Food and Drug Administration's (FDA) or EPA's regulatory tolerances. Under section 6506 of the OFPA, certifying agents, to the extent that they are aware of a violation of applicable laws relating to food safety, are required to report such violation to the appropriate health agencies. This is promulgated in section 205.670(e), amended by this final rule at 205.670(g), of the NOP regulations, which requires reporting to the Federal health agency whose regulatory tolerance or action level has been exceeded. The NOP issued a policy memo on reporting health and safety violations to stakeholders and interested parties.[4] This final rule clarifies the reporting requirements at 205.670(g), but does not change the responsibility for reporting by certifying agents when residues are found in excess of federal regulatory tolerances established by EPA or FDA. The final rule indicates that certain residue testing results that are in violation of EPA or FDA requirements must be reported to the appropriate State health agency or foreign equivalent. This change in the regulations is intended to recognize the role of State agencies, or their foreign equivalents, in responding to residues in violation of tolerance requirements.

One comment from a certifying agent that operates outside of the United States indicated that reporting test results that exceed federal regulatory tolerances is under the operator's responsibility. The commenter indicated that, as a certifying agent, it would check to make sure reporting was done correctly by the operation, and that the certifying agent would inform the NOP. AMS disagrees. Under the OFPA (7 U.S.C. 6506), certifying agents, to the extent that they are aware of a

[4] NOP Policy Memo 11–6, Reporting Health & Safety Violations, revised October 31, 2011. Available at *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088951.*

violation of applicable laws relating to food safety, are required to report such violation to the appropriate health agencies. This requirement is promulgated at section 205.670 of the regulations. This final rule clarifies the reporting requirements, but does not change the responsibility for reporting by certifying agents.

In addition to the reporting requirements outlined in the final rule, the NOP published, on June 13, 2011 in the **Federal Register** (76 FR 34180), the availability of draft guidance entitled, NOP 5028—Responding to Results from Pesticide Residue Testing, that outlines the actions to be taken by accredited certifying agents if test results from residue analysis show evidence of prohibited substance(s) in or on the product. The notice included a 60-day comment period, which closed on August 12, 2011. After review of the comments received, the NOP intends to publish final guidance on this issue in the NOP Handbook, as described under *Related Documents.* Under section 205.671, when residue testing detects prohibited substances that are greater than five percent of the EPA's tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced. This final rule does not change this existing requirement. The draft guidance document provides information to certifying agents on how to respond to results that indicate residues of prohibited substances and how to report results that are in violation of FDA or EPA's regulatory tolerances as required by section 205.670(g).

Wild Crops—Changes Requested But Not Made

AMS received one comment from a certified operation regarding the testing of wild crops. The commenter requested an exemption from the requirement for periodic residue testing for wild crops on the basis that EPA tolerances are not established for most herbs in commerce. The commenter suggests that the absence of established tolerances places wild crops at disproportionate risk of enforcement actions as a result of the detection of trace amounts of unavoidable contamination (e.g., drift) of unknown origin. AMS disagrees. One of the purposes of periodic residue testing is to provide a means for monitoring compliance with the NOP by discouraging the mislabeling of agricultural products. AMS has determined that all crops should be included within the scope of periodic residue testing to serve as a deterrent for mislabeling (e.g., to deter substitution of conventionally produced herbs for organic wild-crop harvested herbs).

The commenter also requested written clarification as to how unavoidable pesticide residue contamination of wild crops would be addressed under the regulation in the absence of EPA-established tolerances for most plant species. A clarification is included in the draft guidance NOP 5028—Responding to Results from Pesticide Residue Testing, as described below under *Related Documents.*

International Trade

AMS received one comment from an organic industry group in Canada which opposed the proposed rule. The commenter stated that the United States and Canada are currently signatories to an equivalency determination for organic products, and that the imposition of a costly measure on the United States' side, without a corresponding rule in Canada, could lead the identification of this regulatory change as a critical variance which would impede trade. Residue testing is required under the European Union's (EU) organic standards and, in 2011, Canada and the EU signed an organic equivalency determination that does not include any critical variances related to residue testing. In addition, certifying agents accredited under the NOP must already conduct sampling and laboratory testing in instances where contamination is suspected under sections 205.403(c)(3) and 205.670(b). AMS does not anticipate that this requirement for periodic residue testing will impact the United States' equivalency determination with Canada.

Costs and Cost Estimates—Changes Requested But Not Made

AMS received eighteen comments regarding estimates of the costs of testing. In the proposed rule, AMS had estimated the cost at $500 per sample, and estimated that the costs may represent approximately 1% of a certifying agent's operating budget.

Several commenters stated their belief that residue testing at the certifying agent's own expense was a disincentive to residue testing, and that the OFPA did not directly address who must pay for testing. A comment from a certifying agent who certifies operations to the organic standards of the EU, the Japanese Agricultural Standard (JAS), and the NOP, indicated that the regulations of the EU and JAS do not oblige the certifying agent to pay for pesticide analyses; instead, the cost is directly passed on to the operator. The commenter suggested that the NOP adopt this same approach and indicated that it encourages certifying agents to take the amount of samples which is necessary, and not just what is required by the regulations. Another commenter expressed support for this model. Section 205.670(b) currently provides that preharvest and postharvest testing is conducted at a certifying agent's expense. Similar to that provision, it is reasonable that periodic residue testing also be conducted at the certifying agent's expense, and therefore no changes are made to the final rule based on these comments.

Several commenters requested a more thorough analysis of the costs of implementing periodic residue testing. A more detailed analysis of the costs associated with this action is provided under the section titled *Executive Order 12866 and Executive Order 13563.* AMS notes that a minority of certifying agents currently conduct periodic residue testing at or above the minimum levels established by this final rule and there would be no additional costs associated with this action for those certifying agents. The majority of certifying agents, however, would need to allocate additional resources for the costs associated with periodic residue testing. AMS received one comment from a certifying agent operating outside of the United States which indicates that it currently tests 20–25% of its certified operations, which is above the minimum level specified in this final rule.

One comment from a laboratory indicated that AMS' estimated $500 cost for analysis was high by a factor of two or more, and that it may be able to perform this analysis for certifying agents at $250 per sample or less. The commenter's estimate appears to be limited to the direct laboratory costs of residue analysis, and does not include the additional related costs that AMS has included in the estimated costs per sample.

Several commenters indicated that the costs may disproportionally affect smaller certifying agents, since they would not be able to receive quantity discounts. Some laboratories may offer discounts to its higher-volume clients, including certifying agents. However, AMS also notes that lowering the percentage below five percent does not have an impact on the smallest quartile of certifying agents that certify fewer than thirty operations per year, since they are required to sample a minimum of one operation annually.

One commenter suggested an alternative funding mechanism, such as having pesticide manufacturers and producers of genetically modified seed

pay for the costs of testing. AMS does not have the statutory authority to institute this type of third-party funding model.

Purpose of Testing—Changes Requested But Not Made

AMS received several comments requesting clarification on the purpose of residue testing.

AMS is publishing this final rule to implement the requirements of the OFPA for periodic residue testing by certifying agents. Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the NOP regulations and by discouraging the mislabeling of agricultural products.

AMS does not intend to integrate results into a single dataset, as was requested by some commenters. To minimize the reporting burden for certifying agents, this final rule does not require that certifying agents submit copies of test results to the Administrator; however, certifying agents continue to be required to report certain test results that are found in excess of federal regulatory tolerances or action levels for pesticide residues or environmental contaminants to the appropriate health agency under the section 205.670(g). This final rule does not require reporting of testing data to the Administrator since this action is not intended as a data collection mechanism to draw conclusions about residues in organic products in general. AMS will verify compliance of certifying agents with this rule under the existing requirements for accreditation as discussed in the response to comments on *Reporting Requirements.*

The NOP also notes that this final rule does not amend the existing requirement that results of all analyses and tests performed under section 205.670 be made available for public access, unless the testing is part of an ongoing compliance investigation. The public may access sampling results obtained by certifying agents under the existing regulations.

Types of Residues—Changes Requested But Not Made

AMS received four comments regarding types of residues that would be considered acceptable targets for testing under the rule.

On February 2, 2011, the NOP published NOP 2611–1, Prohibited Pesticides for NOP Residue Testing, on the NOP Web site in the NOP Handbook. This document provides a list of target pesticides to certifying agents that conduct pesticide residue testing of organically produced agricultural products. This document is available at the NOP Web site at *http://www.ams.usda.gov/nop* and is discussed below under *Related Documents.* AMS has not included a specific list of pesticide residues that could be tested for in the regulations. This is intended to allow flexibility in revising the list of target pesticide residues as new pesticides enter the market. In addition, this flexibility allows the NOP to respond more quickly to observed trends in detection of residues on specific commodities.

The NOP does not intend for certifying agents to test every sample for all residues on the list of target pesticides. Instead, the list is provided as a reference for a number of pesticides which are prohibited under the NOP regulations, and that may be detected by a laboratory that conducts multi-residue analysis of agricultural products.

AMS received one comment that indicated that this list would serve as a ''cheat sheet'' for operations seeking to willfully violate the NOP regulations. AMS disagrees. The document provides a list of pesticide residues most commonly found on conventional commodities, based on data obtained from the AMS Pesticide Data Program. This list is intended to instruct certifying agents and laboratories on which residues would be the most useful targets for multi-residue analysis of agricultural products. The regulations and guidance documents do not prohibit a certifying agent from testing for other residues if the presence of a specific pesticide is suspected.

Four commenters requested clarification on testing for genetically modified organisms (GMOs). AMS does not intend for the testing conducted under section 205.670 to be limited to pesticides residues. Under the existing provisions at section 205.670, certifying agents have the flexibility to test for a range of prohibited materials and excluded methods, including, but not limited to, pesticides, hormones, antibiotics, and GMOs. AMS notes that, under section 205.671, thresholds for unavoidable residual environmental contamination are established only for pesticides residues.

Testing Methodology

The final rule maintains the current requirement under section 205.670 that chemical analysis must be made in accordance with the methods described in the most current edition of the *Official Methods of Analysis of the AOAC International* [5] or other current applicable validated methodology for determining the presence of contaminants in agricultural products. On February 2, 2011, the NOP provided instructions on laboratory selection criteria for pesticide residue testing to certifying agents. These instructions are further described below under *Related Documents* and are available on the NOP Web site at *http://www.ams.usda.gov/nop.* AMS anticipates that these instructions will change over time in response to advances in testing methodology, analytical instrumentation, and residue detection techniques.

AMS received several comments regarding ISO 17025 accreditation of laboratories. This accreditation is mentioned in NOP 2611, Laboratory Selection Criteria for Pesticide Residue Testing, which is further discussed under *Related Documents* and is available on the NOP Web site at *http://www.ams.usda.gov/nop.* No comments requested the incorporation of ISO 17025 accreditation into the regulatory text. The comments are under consideration for future revision of the instruction documents and are not impacted by this rulemaking action.

Information Collection Burden

The proposed rule requested comments on the information collection and recordkeeping requirements required by the proposed amendments to section 205.670. Comments were specifically invited on (1) 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) 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) 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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

AMS received four comments specifically on the issue of information collection burden. Two comments indicated that they were unclear whether the estimated time is accurate and that more data and analysis was needed. One commenter suggested that the NOSB should hear from the various stakeholders in public forums before AMS considers the accuracy of the estimate. One commenter indicated that the estimate of 1.74 hours appears to be

[5] *http://www.aoac.org/.*

low, especially when foreign operations and imported products are considered, but did not offer an alternative estimate for the number of hours or data to support a different estimate.

Two comments indicated that submission of report copies, or laboratory summaries of test results, should be sufficient to demonstrate compliance with the requirement. In order to reduce the information collection burden on certifying agents, AMS has removed the requirement that test results be reported to the Administrator. AMS has retained the requirement that test results that indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the Food and Drug Administration's or the Environmental Protection Agency's regulatory tolerances be reported to the appropriate health agency.

AMS intends to verify compliance of certifying agents with the requirements for periodic residue testing as part of the existing accreditation process, rather than by requiring submission of residue testing results. Accreditation requirements at section 205.504(b)(6) require certifying agents to have administrative policies and procedures, including procedures to be used for sampling and residue testing pursuant to § 205.670. Certifying agents are also required to submit an annual report to the Administrator on or before the anniversary date of the issuance of notification of accreditation which includes a complete and accurate update of information submitted pursuant to §§ 205.503 and 205.504. In order to verify that certifying agents are implementing this rule in advance of regularly scheduled on-site audit of certifying agents, AMS intends to require, as authorized under section 205.510(a)(3), certifying agents to submit in their next annual report a description of the measures implemented in the previous year and any measures to be implemented in the coming years to meet the requirements in this rule for periodic residue testing.

AMS received one comment that indicated that the proposed rule did not identify what would be done with the information collected. A response is provided above under the section, *Purpose of Testing—Changes Requested But Not Made.*

One comment suggested that existing testing programs, such as the AMS Pesticide Data Program, should be used to the extent possible. The commenter also suggested that AMS should partner with the FDA and various State agencies that currently conduct residue testing programs. AMS notes that testing conducted by other third-parties does not eliminate the requirement under OFPA for residue testing by certifying agents. AMS believes that requiring certifying agents to conduct residue testing from a minimum of five percent of the operations they certify is a reasonable number which ensures that all certifying agents, regardless of the number of operations they certify, are responsible for some level of regular testing at reasonable cost.

One comment indicated that certifying agents would prefer to submit test results on a quarterly basis. In this final rule, AMS has removed the requirement for reporting results of residue testing, with the exception of results that exceed certain federal regulatory requirements established by EPA or FDA. AMS notes that certifying agents should maintain the complete results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and three preceding calendar years, as required by section 205.504(b)(5)(iii).

Comments on Instruction Documents

AMS received four comments on instruction documents that the NOP has published in the NOP Handbook regarding residue testing. The instruction documents are discussed under *Related Documents.* These comments are beyond the scope of this rulemaking; however, they are under consideration for future revision of the instruction documents through a separate action.

III. Related Documents

A proposed rule was published in the **Federal Register** on April 29, 2011 (76 FR 23914). Additional documents related to this final rule include the Organic Foods Production Act (OFPA), as amended (7 U.S.C. 6501–6522) and its implementing regulations (7 CFR part 205). The March 2010 USDA Office of Inspector General audit report of the National Organic Program is available as Audit Report 01601–03–Hy.[6]

The NOP has also published three instruction documents related to residue testing as part of the NOP Handbook: (1) Sampling Procedures for Residue Testing (NOP 2610), (2) Laboratory Selection Criteria for Pesticide Residue Testing (NOP 2611), and (3) Prohibited Pesticides for NOP Residue Testing (NOP 2611–1). The goal of the NOP Handbook is to provide those who own, manage, or certify organic operations with guidance, instructions, and policy memos that can assist them in complying with the NOP regulations. The most recent edition of the NOP Handbook is available for viewing and downloading through the NOP Web site at *http://www.ams.usda.gov/nop.*

The three instruction documents are meant to inform certifying agents about best practices for conducting residue testing of organically produced agricultural products. NOP 2610, Sampling Procedures for Residue Testing, contains recommended procedures for product sampling, including documentation, recommended sample sizes, shipping conditions to the laboratory, and chain of custody requirements. NOP 2611, Laboratory Selection Criteria for Pesticide Residue Testing, contains instructions for certifying agents in selecting a qualified laboratory for pesticide residue testing, including accreditation, quality assurance, proficiency testing, and reporting guidelines. NOP 2611–1, Prohibited Pesticides for NOP Residue Testing, is a list of pesticide residues that certifying agents can provide to laboratories which conduct pesticide residue testing of agricultural products. The three instruction documents were effective immediately upon their issuance and publication on February 2, 2011.

On June 13, 2011, the NOP published draft guidance, NOP 5028—Responding to Results from Pesticide Residue Testing, that outlines the actions to be taken by accredited certifying agents if test results from residue analysis show evidence of prohibited substance(s) in or on the product. A notice on the availability of draft guidance was published in the **Federal Register** (76 FR 34180) with a 60 day comment period. The comment period closed on August 12, 2011, and comments are under review by the NOP. After review of the comments received, the NOP intends to publish the final guidance in the NOP Handbook.

Members of the public who wish to request that the agency issue, reconsider, modify, or rescind a guidance or instruction document may do so by sending an email to *NOP.Guidance@ams.usda.gov* or by mailing a letter to Standards Division, National Organic Program, U.S. Department of Agriculture, Room 2646-So. (Stop 0268), 1400 Independence Ave. SW., Washington, DC 20250–0268.

IV. Statutory and Regulatory Authority

OFPA authorizes AMS to administer the NOP. Under the NOP, AMS oversees national standards for the production

[6] U.S. Department of Agriculture, Office of Inspector General, Audit Report 01601–03–Hy, March 2010. Available at *http://www.usda.gov/oig/webdocs/01601-03-HY.pdf.*

and handling of organically produced agricultural products.

Section 6506 of the OFPA requires periodic residue testing by certifying agents of agricultural products that have been produced on certified organic farms and handled through certified organic handling operations to determine whether such products contain any pesticide or other nonorganic residue or natural toxicants. This section also requires certifying agents to report violations of applicable laws relating to other federal tolerance requirements (e.g., pesticide residues in excess of FDA action levels or EPA tolerances) to the appropriate health agencies. Additional information on reporting health and safety violations has been previously provided by the NOP to stakeholders and interested parties.[7] This information is available on the NOP Web site at *http://www.ams.usda.gov/nop.*

Section 6511 of the OFPA requires the Secretary, the applicable governing State official, and the certifying agent to utilize a system of residue testing to test products sold or labeled as organically produced.

Section 6511 of the OFPA also allows the Secretary, the applicable governing State official, or the certifying agent to require preharvest tissue testing of any crop grown on soil suspected of harboring contaminants.

A. Executive Order 12866 and Executive Order 13563

Executive Orders 13563 and 12866 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 action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

Need for the Rule

NOP is authorized to implement regulations that require accredited certifying agents to conduct residue testing of organically produced agricultural products (7 U.S.C. 6511). In addition, section 6506 of the OFPA requires that the NOP include provisions for periodic residue testing by certifying agents of agricultural products produced or handled in accordance with the NOP. This final rule ensures that all certifying agents conduct a minimal level of residue testing.

Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the NOP and by discouraging the mislabeling of agricultural products. Testing of organically produced agricultural products is promulgated in section 205.670 of the NOP regulations. This section provides that the Secretary, State organic programs, and certifying agents may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s))'' when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods.

AMS is issuing this final rule in response to an audit of the NOP which was conducted in March 2010 by the USDA's OIG.[8] As part of the audit, the OIG visited four certifying agents accredited by the NOP. The OIG indicated that these certifying agents noted that they considered residue testing to be required by the regulations only under certain circumstances.

AMS conducted a review of this issue in response to the OIG audit. AMS concluded that, under 7 U.S.C. section 6506 of the OFPA, accredited certifying agents are required to conduct residue testing of organic products on a regular and reoccurring basis, as well as when there is reason to believe contamination has occurred.

Regulatory Objective

The primary objective of this rule is to align the NOP regulations with the requirement for residue testing of organic products under OFPA. This final rule ensures that all certifying agents conduct a minimum level of residue testing.

Alternatives Considered

Alternatives to this final rule that were considered include (1) maintaining the status quo; (2) distinguishing periodic residue testing from risk-based testing for purposes of calculating the percentage of operations to be tested annually; (3) requiring testing at an alternate level of 25% of the operations certified by a certifying agent; and (4) testing all certified operations annually.

In addition, proposals for testing at a reduced sampling rate, and testing scaled to the size of operation or to the number of certified organic products were suggested by commenters and are discussed under the above section, *Number of Samples—Changes Requested But Not Made.* AMS believes that calculating the samples based on a percentage of operations reduces the burden on the certifying agents by providing a clear and simple formula for how to comply with the regulations. AMS has not specified how certifying agents must select operations for residue testing to provide flexibility and discretion to the certifying agent in how to most efficiency and effectively implement the minimum testing required under the rule. Operation selection for residue testing may include risk factors such as number of products produced, split operations, size of the operation, split operations (i.e., operations that produce or handle both organic and nonorganic agricultural products), previous non-compliances, high-value or high-risk crops, or other criteria deemed appropriate by the certifying agent.

The first alternative of maintaining the status quo was not considered feasible due to a finding identified in an audit report issued by USDA's OIG in March 2010.[9] In response to the OIG audit, AMS conducted a review of the residue testing requirements in OFPA and the NOP regulations. AMS concluded that, under section 6506 of the OFPA, accredited certifying agents are required to conduct residue testing of organic products on a regular and reoccurring basis, as well as when there is reason to believe contamination has occurred, and that the regulations be revised as provided for in this rulemaking.

The second alternative distinguishes between periodic residue testing and risk-based testing for purposes of calculating the percentage of operations to be tested annually. This alternative was discussed in the proposed rule published April 29, 2011 (76 FR 23914). The proposed rule indicated that certifying agents would need to sample a minimum of five percent of their certified operations annually, and that such testing would be in addition to any testing conducted when there was

[7] NOP Policy Memo 11–6, Reporting Health & Safety Violations, revised October 31, 2011. Available at *http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088951.*

[8] U.S. Department of Agriculture, Office of Inspector General, Audit Report 01601–03-Hy, March 2010. Available at *http://www.usda.gov/oig/webdocs/01601-03-HY.pdf.*

[9] U.S. Department of Agriculture, Office of Inspector General, Audit Report 01601–03-Hy, March 2010. Available at *http://www.usda.gov/oig/webdocs/01601-03-HY.pdf.*

reason to believe that the agricultural product had come into contact with a prohibited substance (e.g., investigative or complaint-driven testing). This alternative would result in higher costs to the certifying agent, since costs associated with other types of testing would be in addition to costs for periodic testing. After consideration of the comments received, AMS believes that the final rule offers more flexibility by allowing both complaint-driven and periodic residue testing to count toward the sample minimum. This final rule should also minimize the burden on certifying agents by removing the need to distinguish between different types of testing.

The third alternative of requiring certifying agents to test 25% of the operations they certify annually was also considered. This target is based a statistically based sample size based upon the rate of detection of residues in organic products sampled through the AMS Pesticide Data Program (PDP). The costs associated with this alternative and that would be imposed on certifying agents are estimated at $3.70 million annually, based on an estimated $492 in costs to the certifying agent per operation tested across 7,530 certified operations (25% of 30,118). The costs associated with testing 25% of operations are significantly higher than the costs of sampling 5% of operations under the final rule. AMS determined that using a statistically based sample size is not necessary to achieve the regulatory objective of this action and would impose unnecessary additional direct costs to certifying agents.

The fourth alternative of sampling all operations annually was also considered as an alternative to the five percent minimum requirement. The costs associated with this alternative are estimated at $14.82 million annually, based on an estimated $492 in costs per operation for 30,118 certified operations. The objectives for periodic residue testing can be met by sampling a subset of operations annually, and therefore, the additional costs that would be required to test all operations are unnecessary.

Baseline

AMS is aware that a minority of accredited certifying agents are currently conducting periodic residue testing at or above the minimum levels established by this final rule. In 2011, the NOP received pesticide residue results from 13 accredited certifying agents. Seven of the certifying agents that reported results to the NOP were based in the United States and six were based internationally. The NOP also understands that there may be additional certifying agents that are currently conducting residue testing that do not report results to the NOP, or that submit results only when a prohibited residue is detected.

The number of results reported to the NOP in 2011 represents a sampling rate of less than 1% of certified operations. The majority of results reported to the NOP in 2011 were received from certifying agents which are headquartered outside of the United States, where periodic residue testing is a requirement under international organic standards (e.g., the EU). AMS received one comment on the proposed rule from a certifying agent operating outside of the United States which indicates that it currently tests 20–25% of its certified operations.

AMS received one comment from a certifying agent that indicated that it has a history of sampling and testing products for more than 20 years. This commenter supported the five percent testing requirement as outlined in the proposed rule and did not support revising the rule to include compliance or investigative testing as part of the five percent. AMS also received one comment from a certifying agent that had increased their testing program for residues within the last two years and requested that the proposed rule be revised to allow sampling from sources other than the agricultural product (e.g. samples of soil, water, seeds) to be counted towards the minimum testing requirement. Under this final rule, sampling from a range of sources as indicated in sections 205.670(b) and (c) may be counted towards the minimum testing requirement.

Benefits to the Final Rule

This final rule clarifies a provision of OFPA and the regulations issued thereunder that requires periodic residue testing of organically produced agricultural products by accredited certifying agents. The rule ensures consistency of the regulations with OFPA by ensuring that all certifying agents are conducting residue testing of organic products on a regular reoccurring basis. Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the NOP and by discouraging the mislabeling of agricultural products. This action further ensures the integrity of products produced and handled under the NOP regulations.

Costs of the Final Rule

This final rule increases the amount of residue testing currently conducted by most accredited certifying agents. Direct costs to the certifying agents include the cost of sample analysis (i.e., laboratory costs), sample packaging and shipping costs, and the staff costs associated with sample collection by an inspector, review and maintenance of sample results, and reporting costs. In addition, some certifying agents indicated that the proposed action would also increase their training costs for review staff and field inspectors. AMS is unable to ascertain how certification fees may shift in response to this action because of the diversity of fee structures used by certifying agents.

The total direct cost of this action is estimated to be $741,000 annually. This estimate is based on a sampling rate of five percent of certified operations. There were an estimated 30,118 operations certified under the NOP in 2011. The five percent sampling requirement would result in sample collection from approximately 1,506 operations per year. AMS has estimated the total costs to the certifying agent at $492 per sample as detailed in Table 1.

Sample collection costs (inspector costs) are estimated at $20.36 per sample. This estimate is based on an estimated 1.0 labor hour per sample at $20.36 per hour. The hourly rate is estimated based on the mean hourly wage for agricultural inspectors as published by the Bureau of Labor Statistics.[10] This classification was selected as an occupation with similar duties and responsibilities to that of an organic inspector. Such duties and responsibilities include inspection of agricultural commodities, processing equipment, and facilities, to ensure compliance with regulations and laws governing health, quality, and safety.

Sample shipping boxes and supplies are estimated at $40 per sample, based on a costs associated with a pilot project for pesticide residue sampling conducted by the NOP in conjunction with the AMS Pesticide Data Program. Shipping costs are estimated at $25 per sample. AMS notes that these costs are an average and may vary depending on the sample type and shipping distance to laboratory.

Labor costs associated with review of sample results are estimated at $16.21 per sample. This estimate is based on an estimated 0.5 labor hour per sample at $32.42 per hour. The hourly rate is estimated based on the mean hourly wage for auditors as published by the

[10] Mean Hourly Wage for Agricultural Inspector, U.S. Department of Labor, Bureau of Labor Statistics, *Occupational Employment and Wages,* May 2010. *http://bls.gov/oes/current/oes452011.htm.*

Bureau of Labor Statistics.[11] This classification was selected as an occupation with similar duties and responsibilities to that of a certifying agent. Such duties and responsibilities include conducting reviews of operations against accepted standards and evaluating audit or inspection findings for compliance.

If certifying agents receive sample results which are in excess of EPA or FDA regulatory tolerances, the certifying agent must promptly report such data to the Federal health agency (i.e., EPA or FDA) whose regulatory tolerance or action level has been exceeded. Test results that exceed federal regulatory tolerances must also be reported to the appropriate State health agency or foreign equivalent. This requirement is clarified in this final rule under § 205.670(g); however, this is not a new requirement under this action and additional costs not expected from this clarification. AMS expects that the majority of tested organic products will not have detectable residues of prohibited pesticide substances, based on historical data from the AMS Pesticide Data Program.

AMS believes that this rate of testing provides the benefits at reasonable cost to certifying agents. AMS recognizes that a minority of certifying agents conduct residue testing on a regular basis, and that certifying agents not currently conducting testing will need to account for these costs as a cost of doing business.

In consideration of training costs, the NOP notes that, while this action expands the amount of testing of organically produced agricultural products to include a requirement that is regular and periodic in scope, certifying agents are already required, under section 205.504(b)(6), to have procedures in place for sampling and residue testing pursuant to section 205.670. Certifying agents must already be conducting sampling and laboratory testing in instances where contamination is suspected under section 205.403(c)(3) and section 205.670(b). Therefore, AMS does not believe that additional training costs are imposed by this final rule.

TABLE 1—ESTIMATED COSTS PER SAMPLE COLLECTED

Item	Estimated cost per sample	Basis for estimate
Sample collection (inspector time)	$20.36	1 hour @ $20.36 per hour.
Sample shipping boxes and supplies	40.00	AMS Pesticide Data Program.
Shipping costs	25.00	Estimate for in-state shipping of 5 pound sample.
Laboratory costs for multi-residue analysis.	390.00	AMS Pesticide Data Program.
Review of Sample Results—Labor Costs	16.21	0.5 hour @ $32.42 per hour.
Total costs per sample	491.57	

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This final rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in section 6514(b) of the OFPA. States are also preempted under sections 6503 through 6507 of the OFPA from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 6507 of the OFPA, a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) Further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 6519 of the OFPA, this final rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301–392), nor the authority of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136–136(y)).

Section 6520 of the OFPA provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. district court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Executive Order 13175

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting

[11] U.S. Department of Labor, Bureau of Labor Statistics, *Occupational Employment and Wages,* May 2009. *http://www.bls.gov/oes/2009/may/oes132011.htm.*

barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small business will not be unduly or disproportionately burdened. Section 605 of RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set force in the RFA, AMS performed an economic impact analysis on small entities in the final rule published in the **Federal Register** on December 21, 2000 (65 FR 80548). AMS has also considered the economic impact of this final rule on small entities. AMS certifies that this rule would not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than $7,000,000 and small agricultural producers are defined as those having annual receipts of less than $750,000.

According to Economic Research Service (ERS) data, based on information from USDA accredited certifying agents, the number of certified U.S. organic crop and livestock operations totaled nearly 13,000 and certified organic acreage exceeded 4.8 million acres in 2008.[12] ERS, based upon the list of certified operations maintained by the NOP, estimated the number of certified handling operations was 3,225 in 2007.[13] AMS estimates that there were 30,118 operations certified to the NOP in 2011. USDA has 93 accredited certifying agents that provide certification services to producers and handlers under the NOP. A complete list of names and addresses of certifying agents may be found on the AMS NOP Web site at: *http://www.ams.usda.gov/nop*. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

This final rule will affect all certifying agents by requiring that each agent conduct residue testing from a minimum of five percent of the operations they certify on an annual basis. This level was chosen to ensure that all certifying agents, regardless of the number of operations they certify, are responsible for some level of regular residue testing at reasonable cost. Under section 205.670, certifying agents have been responsible for expenses associated with preharvest and postharvest testing; this requirement also applies to expenses for periodic residue testing in this final rule. To estimate the annual costs associated with instituting periodic residue testing, the NOP conducted a preliminary assessment of costs at different minimum testing requirements (i.e., 5%, 25%, and 100% of certified operations).

Under this new action with a five percent minimum testing requirement, the two certifying agents with the largest number of certified operations (approximately 2,100 operations each in 2009) are required to collect a minimum of 105 samples. Smaller certifying agents (those certifying fewer than 30 operations) are required to collect and test at least 1 sample on an annual basis. In 2010, approximately one-third of accredited certifying agents certified fewer than 30 operations to the NOP.[14] Over half of all certifying agents certified fewer than 200 operations in 2010 and are required to sample 10 or fewer operations annually under this final rule.

At a five percent minimum testing requirement, the costs of sampling are estimated from approximately $492 to 51,106 per certifying agent per year based on the average cost of $492 per sample and the range in the number of operations certified by different certifying agents. Additional costs may be required to follow up on results if prohibited substances are detected. AMS expects that the majority of results will be for samples with no prohibited residues detected, based on historical data from the AMS Pesticide Data Program.

AMS is establishing a five percent testing level in this final rule because this level is expected to be, in most cases, no more than two percent of a given certifying agent's operating budget, a level that can be considered a reasonable cost to the organic industry given the benefits of residue testing in discouraging the mislabeling of agricultural products. Furthermore, the number of samples required at a five percent level is consistent with the amount of residue sampling already being conducted by some certifying agents. As a percentage of a certifying agent's total operating costs, this estimate was revised upward from one percent to two percent, based on public comment received in response to the proposed rule. Comments included a summary of data from an association representing certifying agents, and included data from 25 certifying agents. The range of costs was reported at between 1% and 11% of a certifying agent's overall operating budget, with one certifying agent reporting that the cost of one sample would account for 11% of their total operating costs for the year and one certifying agent reporting that the cost for three samples would account for 1% of their total operating costs. The majority of these certifying agents estimated the costs associated with this action to account for no more than 2% of their operating budget annually.

Alternatives to this final rule that were considered include (1) maintaining the status quo; (2) distinguishing periodic residue testing from risk-based testing for purposes of calculating the percentage of operations to be tested annually; (3) requiring testing at an alternate level of 25% of the operations certified by a certifying agent; and (4) testing all certified operations annually.

These are discussed in detail above under *Alternatives Considered*. AMS determined that the alternatives of a statistically based sample size (i.e., 25% of operations annually) or testing all operations annually were not practical due to the costs and the uneven burden that could be placed upon smaller certifying agents in either scenario.

The U.S. sales of organic food and beverages have grown from $3.6 billion in 1997 to nearly $21.1 billion in 2008.[15] Between 1990 and 2008, organic food sales have historically demonstrated a growth rate between 15 to 24 percent each year. In 2010, organic food sales grew 7.7%.[16]

The NOP is authorized under OFPA to implement regulations that require accredited certifying agents to conduct residue testing of organically produced agricultural products (7 U.S.C. § 6511). In addition, the OFPA requires that the NOP include provisions for periodic residue testing by certifying agents of agricultural products produced or handled in accordance with the NOP (7

[12] U.S. Department of Agriculture, Economic Research Service. 2009. *Data Sets: U.S. Certified Organic Farmland Acreage, Livestock Numbers and Farm Operations, 1992–2008. http://www.ers.usda.gov/Data/Organic/*.

[13] U.S. Department of Agriculture, Economic Research Service, 2009. *Data Sets: Procurement and Contracting by Organic Handlers: Documentation. http://www.ers.usda.gov/Data/OrganicHandlers/Documentation.htm*.

[14] As reported by certifying agents during the 2010 certification year and available at *http://apps.ams.usda.gov/nop/*.

[15] Dimitri, C.; Oberholtzer, L. 2009. *Marketing U.S. Organic Foods: Recent Trends from Farms to Consumers*, Economic Information Bulletin No. 58, U.S. Department of Agriculture, Economic Research Service, *http://www.ers.usda.gov/Publications/EIB58*.

[16] Organic Trade Association's *2011 Organic Industry Survey, http://www.ota.com*.

U.S.C. § 6506). This final rule ensures that all certifying agents conduct a minimal level of residue testing.

Residue testing plays an important role in organic certification by providing a means for monitoring compliance with the NOP and by discouraging the mislabeling of agricultural products. Testing of organically produced agricultural products is promulgated in section 205.670 of the NOP regulations. This section provides that the Secretary, State organic programs, and certifying agents may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s))'' when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods.

However, AMS has concluded that, under 7 U.S.C. § 6506 of the OFPA, accredited certifying agents are required to conduct residue testing of organic products on a regular and reoccurring basis, as well as when there is reason to believe contamination has occurred.

The final rule is necessary to clarify a requirement of OFPA that certifying agents conduct periodic residue testing of organic products. The final rule will increase the amount of residue testing that certifying agents must conduct when compared to the current regulations. This final rule ensures that certifying agents are conducting a minimal level of residue testing on a regular and reoccurring basis.

The cost of testing is to be borne by the applicable certifying agent and is considered a cost of doing business.

The population that is directly impacted by this final rule is accredited certifying agents. The USDA has 93 certifying agents who provide certification services to producers and handlers under the NOP. A complete list of names and addresses of certifying agents may be found on the AMS NOP Web site at: *http://www.ams.usda.gov/nop.* AMS believes that most accredited certifying agents would be considered small entities under the criteria established by the SBA. Approximately 30,118 operations worldwide were certified to the NOP standard in 2011; certified operations may be indirectly impacted by this action as additional operations will be subject to residue testing by certifying agents.

For certifying agents who are not currently conducting residue testing at the minimum levels specified in the final rule, this action will increase costs. AMS has estimated costs at $492 per sample. At an estimated cost of $492 per sample and a sampling rate of 5% of certified operations, certifying agents would need to budget an estimated $25 per certified operation for testing costs. The total costs of residue testing are estimated at approximately $492 to $51,106 per certifying agent per year based on the average cost of $492 per sample and the range in the number of operations certified by different certifying agents. Additional costs may be required to follow up on results if prohibited substances are detected. The portion of the total estimated costs would be considered new or additional costs as a result of this action is not known, as a minority of certifying agents are already conducting residue testing of organic products and have budgeted for these costs under their existing fee structures. If these costs have not been previously budgeted for by the certifying agent, it will need to account for these costs as part of their cost of business.

To reduce additional inspector costs associated with sample collection, AMS has not specified which operations must be sampled annually or when the samples must be collected. This is intended to provide flexibility to the certifying agent implement a schedule for sample collection in the most efficient manner.

The final rule will increase costs for certifying agents who are not currently performing residue testing at the minimal levels specified in this rule. Some certifying agents may increase their certification fees for its clients to pay for additional costs associated with residue testing. At an estimated cost of $492 per sample and a sampling rate of 5% of certified operations, certifying agents would need to budget approximately $25 per operation for testing costs.

This final rule clarifies a provision of OFPA and the regulations issued thereunder that requires periodic residue testing of organically produced agricultural products by accredited certifying agents. The final rule expands the amount of residue testing of organically produced agricultural products by clarifying that sampling and testing are required on a regular basis. The final rule requires that certifying agents, on an annual basis, sample and conduct residue testing from a minimum of five percent of the operations that they certify.

AMS believes that the benefits of residue testing in protecting organic integrity and ensuring compliance with the regulations outweigh the estimated costs.

E. Paperwork Reduction Act

In accordance with Office of Management and Budget (OMB) regulations (5 CFR part 1320) that implement the Paperwork Reduction Act (44 U.S.C. 3501–3520) (PRA), the information collection requirements associated with the NOP have been previously approved by OMB and assigned OMB control number 0581–0191. A new information collection package was submitted to OMB at the proposed rule stage for approval of 776 hours in total burden hours to cover this new collection and recordkeeping burden of the amendments to section 205.670 of this final rule. Between the proposed rule and this final rule, there is a reduction of 350 hours based on comments received. Upon OMB's approval of this new information collection, the NOP intends to merge this collection into currently approved OMB Control Number 0581–0191.

AMS is committed to complying with the E-Government Act to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

F. Civil Rights Impact Analysis

AMS has reviewed this rule in accordance with the Department Regulation 4300–4, Civil Rights Impact Analysis (CRIA), to address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities. After a careful review of the rule's intent and provisions, AMS has determined that this rule has no potential for affecting certified operations or certifying agents in protected groups differently than the general population of certified operations and certifying agents. This rulemaking was initiated to clarify a regulatory requirement and enable consistent implementation and enforcement.

Protected individuals have the same opportunity to participate in the NOP as non-protected individuals. The NOP regulations prohibit discrimination by certifying agents. Specifically, section 205.501(d) of the current regulations for accreditation of certifying agents provides that ''No private or governmental entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of the NOP to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.'' Section 205.501(a)(2) requires

''certifying agents to demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart'' including the prohibition on discrimination. The granting of accreditation to certifying agents under section 205.506 requires the review of information submitted by the certifying agent and an on-site review of the certifying agent's operation. Further, if certification is denied, section 205.405(d) requires that the certifying agent notify the applicant of their right to file an appeal to the AMS Administrator in accordance with section 205.681. These regulations provide protections against discrimination, thereby permitting all handlers, regardless of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status, who voluntarily choose to adhere to the final rule and qualify, to be certified as meeting NOP requirements by an accredited certifying agent. This final rule in no way changes any of these protections against discrimination.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205 is amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

■ 1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501–6522.

■ 2. Section 205.670 is revised to read as follows:

§ 205.670 Inspection and testing of agricultural products to be sold or labeled as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s)).''

(a) All agricultural products that are to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s))'' must be made accessible by certified organic production or handling operations for examination by the Administrator, the applicable State organic program's governing State official, or the certifying agent.

(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s))'' when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

(c) A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients or food group(s)).'' Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense.

(d) A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number. A certifying agent that certifies fewer than thirty operations on an annual basis must sample and test from at least one operation annually. Tests conducted under paragraphs (b) and (c) of this section will apply to the minimum percentage of operations.

(e) Sample collection pursuant to paragraphs (b) and (c) of this section must be performed by an inspector representing the Administrator, applicable State organic program's governing State official, or certifying agent. Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory. Chemical analysis must be made in accordance with the methods described in the most current edition of the *Official Methods of Analysis of the AOAC International* or other current applicable validated methodology for determining the presence of contaminants in agricultural products.

(f) Results of all analyses and tests performed under this section will be available for public access, unless the testing is part of an ongoing compliance investigation.

(g) If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the Food and Drug Administration's or the Environmental Protection Agency's regulatory tolerances, the certifying agent must promptly report such data to the Federal health agency whose regulatory tolerance or action level has been exceeded. Test results that exceed federal regulatory tolerances must also be reported to the appropriate State health agency or foreign equivalent.

Dated: November 5, 2012.

David R. Shipman,

Administrator, Agricultural Marketing Service.

[FR Doc. 2012–27378 Filed 11–8–12; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2012–1194; Special Conditions No. 25–472–SC]

Special Conditions: Boeing Model 757 Series Airplanes; Seats with Non-Traditional, Large, Non-Metallic Panels

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special condition; request for comments.

SUMMARY: These special conditions are issued for the Boeing Model 757 series airplanes. These airplanes as modified by Flight Structures, Inc. will have novel or unusual design features associated with seats that include non-traditional, large, non-metallic panels that would affect survivability during a post-crash fire event. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is November 5, 2012. We must receive your comments by December 24, 2012.

ADDRESSES: Send comments identified by docket number [FAA–2012–1194] using any of the following methods:

• *Federal eRegulations 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 8 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: John Shelden, FAA, Airframe and Cabin Safety Branch, ANM–115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–2785; facsimile 425 227–1232; email *John.Shelden@faa.gov*.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions are impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected aircraft. In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon issuance.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On April 5, 2012, Flight Structures, Inc. applied for a supplemental type certificate for installing seats that include non-traditional, large, non-metallic panels in Boeing Model 757 series airplanes. The Boeing Model 757 series airplanes, currently approved under Type Certificate No. A2NM, are swept-wing, conventional tail, twin-engine, turbo-fan-powered, single aisle, medium-sized transport category airplanes.

The applicable regulations to airplanes currently approved under Type Certificate No. A2NM do not require seats to meet the more stringent flammability standards required of large, non-metallic panels in the cabin interior. At the time the applicable rules were written, seats were designed with a metal frame covered by fabric, not with large, non-metallic panels. Seats also met the then-recently-adopted standards for flammability of seat cushions. With the seat design being mostly fabric and metal, the contribution to a fire in the cabin had been minimized and was not considered a threat. For these reasons, seats did not need to be tested to heat release and smoke emission requirements.

Seat designs have now evolved to occasionally include non-traditional, large, non-metallic panels. Taken in total, the surface area of these panels is on the same order as the sidewall and overhead stowage bin interior panels. To provide the level of passenger protection intended by the airworthiness standards, these non-traditional, large, non-metallic panels in the cabin must meet the standards of Title 14, Code of Federal Regulations (14 CFR), part 25, Appendix F, parts IV and V, heat release and smoke emission requirements.

Type Certification Basis

Under the provisions of § 21.101, Flight Structures, Inc. must show that the Boeing Model 757 series airplanes, as changed, continue to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. A2NM or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the ''original type certification basis.'' The regulations incorporated by reference in Type Certificate No. A2NM are as follows:

For Boeing Model 757–200 series airplanes—part 25, as amended by Amendment 25–1 through Amendment 25–45. In addition, an equivalent safety finding exists with respect to § 25.853(c), Compartment interiors.

For Boeing Model 757–300 series airplanes—part 25, as amended by Amendment 25–1 through Amendment 25–85 with the exception listed: Section 25.853(d)(3), Compartment interiors, at Amendment 25–72.

If the Administrator finds that the applicable airworthiness regulations (i.e., 14 CFR part 25) do not contain adequate or appropriate safety standards for the Boeing Model 757 series airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same novel or unusual design feature, the special conditions would also apply to the other model.

In addition to the applicable airworthiness regulations and special conditions, the Boeing Model 757 series airplanes must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.101.

Novel or Unusual Design Features

The Boeing Model 757 series airplanes will incorporate the following novel or unusual design features: These models offer interior arrangements that include passenger seats that incorporate non-traditional, large, non-metallic panels in lieu of the traditional metal frame covered by fabric. The flammability properties of these panels have been shown to significantly affect the survivability of the cabin in the case of fire. These seats are considered a novel design for transport category airplanes that include Amendment 25–61 and Amendment 25–66 in the certification basis, and were not considered when those airworthiness standards were established.

The existing regulations do not provide adequate or appropriate safety

standards for seat designs that incorporate non-traditional, large, non-metallic panels in their designs. In order to provide a level of safety that is equivalent to that afforded to the balance of the cabin, additional airworthiness standards, in the form of special conditions, are necessary. These special conditions supplement § 25.853. The requirements contained in these special conditions consist of applying the identical test conditions required of all other large panels in the cabin, to seats with non-traditional, large, non-metallic panels.

A non-traditional, large, non-metallic panel, in this case, is defined as a panel with exposed-surface areas greater than 1.5 square feet installed per seat place. The panel may consist of either a single component or multiple components in a concentrated area. Examples of parts of the seat where these non-traditional panels are installed include, but are not limited to seat backs, bottoms and leg/foot rests, kick panels, back shells, credenzas and associated furniture. Examples of traditional exempted parts of the seat include: arm caps, armrest close-outs such as end bays and armrest-styled center consoles, food trays, video monitors, and shrouds.

Clarification of ''Exposed''

''Exposed'' is considered to include panels that are directly exposed to the passenger cabin in the traditional sense, and panels that are enveloped, such as by a dress cover. Traditional fabrics or leathers currently used on seats are excluded from these special conditions. These materials must still comply with § 25.853(a) and § 25.853(c) if used as a covering for a seat cushion, or § 25.853(a) if installed elsewhere on the seat. Non-traditional, large, non-metallic panels covered with traditional fabrics or leathers will be tested without their coverings or covering attachments.

Discussion

In the early 1980s, the FAA conducted extensive research on the effects of post-crash flammability in the passenger cabin. As a result of this research and service experience, the FAA adopted new standards for interior surfaces associated with large surface area parts. Specifically, the rules require measurement of heat release and smoke emission (part 25, Appendix F, parts IV and V) for the affected parts. Heat release has been shown to have a direct correlation with post-crash fire survival time. Materials that comply with the standards (i.e., § 25.853 titled ''Compartment interiors'' as amended by Amendment 25–61 and Amendment 25–66) extend survival time by approximately two minutes over materials that do not comply.

At the time these standards were written, the potential application of the requirements of heat release and smoke emission to seats was explored. The seat frame itself was not a concern because it was primarily made of aluminum and there were only small amounts of non-metallic materials. It was determined that the overall effect on survivability was negligible, whether or not the food trays met the heat release and smoke requirements. The requirements therefore did not address seats. The preambles to both the Notice of Proposed Rule Making, Notice No. 85–10 (50 FR 15038, April 16, 1985) and the Final Rule at Amendment 25–61 (51 FR 26206, July 21, 1986), specifically note that seats were excluded ''because the recently-adopted standards for flammability of seat cushions will greatly inhibit involvement of the seats.''

Subsequently, the Final Rule at Amendment 25–83 (60 FR 6615, March 6, 1995) clarified the definition of minimum panel size: ''It is not possible to cite a specific size that will apply in all installations; however, as a general rule, components with exposed-surface areas of one square foot or less may be considered small enough that they do not have to meet the new standards. Components with exposed-surface areas greater than two square feet may be considered large enough that they do have to meet the new standards. Those with exposed-surface areas greater than one square foot, but less than two square feet, must be considered in conjunction with the areas of the cabin in which they are installed before a determination could be made.''

In the late 1990s, the FAA issued Policy Memorandum 97–112–39, Guidance for Flammability Testing of Seat/Console Installations, October 17, 1997. That memo was issued when it became clear that seat designs were evolving to include large, non-metallic panels with surface areas that would impact survivability during a cabin fire event, comparable to partitions or galleys. The memo noted that large surface area panels must comply with heat release and smoke emission requirements, even if they were attached to a seat.

If the FAA had not issued such policy, seat designs could have been viewed as a loophole to the airworthiness standards that would result in an unacceptable decrease in survivability during a cabin fire event.

In October 2004, an issue was raised regarding the appropriate flammability standards for passenger seats that incorporated non-traditional, large, non-metallic panels in lieu of the traditional metal covered by fabric. The Seattle Aircraft Certification Office and Transport Standards Staff reviewed this design and determined that it represented the kind and quantity of material that should be required to pass the heat release and smoke emissions requirements. We have determined that special conditions would be promulgated to apply the standards defined in § 25.853(d) to seats with large, non-metallic panels in their design.

Applicability

As discussed above, these special conditions are applicable to the Boeing Model 757 series airplanes. Should Flight Structures, Inc. apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate No. A2NM to incorporate the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on the Boeing Model 757 series of airplanes. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the

Administrator, the following special conditions are issued as part of the type certification basis for Boeing Model 757 series airplanes modified by Flight Structures, Inc.

Seats With Non-Traditional, Large, Non-Metallic Panels

1. Except as provided in paragraph 3 of these special conditions, compliance with 14 CFR part 25, Appendix F, parts IV and V, heat release and smoke emission, is required for seats that incorporate non-traditional, large, non-metallic panels that may either be a single component or multiple components in a concentrated area in their design.

2. The applicant may designate up to and including 1.5 square feet of non-traditional, non-metallic panel material per seat place that does not have to comply with special condition Number 1, above. A triple seat assembly may have a total of 4.5 square feet excluded on any portion of the assembly (e.g., outboard seat place 1 square foot, middle 1 square foot, and inboard 2.5 square feet).

3. Seats do not have to meet the test requirements of 14 CFR part 25, Appendix F, parts IV and V, when installed in compartments that are not otherwise required to meet these requirements. Examples include:

a. Airplanes with passenger capacities of 19 or less,

b. Airplanes that do not have § 25.853, Amendment 25–61 or later, in their certification basis and do not need to comply with the requirements of 14 CFR 121.312, and

c. Airplanes exempted from § 25.853, Amendment 25–61 or later.

Issued in Renton, Washington, on November, 5, 2012.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–27370 Filed 11–8–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0806; Directorate Identifier 2012–NM–022–AD; Amendment 39–17243; AD 2012–22–07]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Bombardier, Inc. Model DHC–8–400, –401, and –402 airplanes. This AD was prompted by reports of an in-service incident where the propeller de-icing system became unavailable due to burnt/chafed wires within the alternating current contactor box (ACCB). This AD requires inspection for chafing, damage, and loose wiring within an ACCB and repair if necessary; and requires rework and re-identification of the wiring installation within each ACCB. We are issuing this AD to detect and correct damaged, chafed, or loose wiring within an ACCB, which could affect the operation of the windshield heater, ice detector, angle of attack (AOA) vane heater, pilot probe heater, engine intake heater, or propeller de-icing system, and subsequently adversely affect the airplane's flight characteristics in icing conditions.

DATES: This AD becomes effective December 14, 2012.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 14, 2012.

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

FOR FURTHER INFORMATION CONTACT: Assata Dessaline, Aerospace Engineer, Avionics and Flight Test Branch, ANE–172, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228–7301; fax (516) 794–5531.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on August 16, 2012 (77 FR 49394). That NPRM proposed to correct an unsafe condition for the specified products. The Mandatory Continuing Airworthiness Information (MCAI) states:

> There has been one (1) reported in-service incident where the propeller de-icing system became unavailable due to burnt/chafed wires within the Alternating Current Contactor Box (ACCB). There has also been a number of additional minor events of wires found chafed within ACCBs.
>
> An investigation revealed that inadequate clearance between the wires and metallic structure within the ACCB could cause chafed wires.
>
> Damaged, chafed or loose wiring within an ACCB could affect the operation of the windshield heater, ice detector, angle of attack (AOA) vane heater, pitot probe heater, engine intake heater or propeller de-icing system. Loss of one of these systems could adversely affect the aeroplane's flight characteristics in icing conditions.
>
> This [Transport Canada Civil Aviation (TCCA)] Airworthiness Directive (AD) mandates the [visual] inspection [for damaged, chafed, and loose wiring within an ACCB and replace if necessary] and rectification [rework] of the wiring installation within each ACCB.

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

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM (77 FR 49394, August 16, 2012) or on the determination of the cost to the public.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM (77 FR 49394, August 16, 2012) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (77 FR 49394, August 16, 2012).

Costs of Compliance

We estimate that this AD will affect 83 products of U.S. registry. We also estimate that it will take about 7 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $49,385, or $595 per product.

In addition, we estimate that any necessary follow-on actions would take about 2 work-hours and require parts costing $0, 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 AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM (77 FR 49394, August 16, 2012), the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2012–22–07 Bombardier, Inc.: Amendment 39–17243. Docket No. FAA–2012–0806; Directorate Identifier 2012–NM–022–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective December 14, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. Model DHC–8–400, –401, and –402 airplanes, certificated in any category, serial numbers 4001 and subsequent.

(d) Subject

Air Transport Association (ATA) of America Code 24: Electrical Power.

(e) Reason

This AD was prompted by reports of an in-service incident where the propeller de-icing system became unavailable due to burnt/chafed wires within the alternating current contactor box (ACCB) due to inadequate clearance. We are issuing this AD to detect and correct damaged, chafed, or loose wiring within an ACCB, which could affect the operation of the windshield heater, ice detector, angle of attack (AOA) vane heater, pilot probe heater, engine intake heater, or propeller de-icing system, and subsequently adversely affect the airplane's flight characteristics in icing conditions.

(f) Compliance

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

(g) Inspection

For airplanes having serial numbers 4001 through 4354 inclusive, and 4356 through 4366 inclusive: Within 6,000 flight hours or 36 months after the effective date of this AD, whichever occurs first: Do a general visual inspection for chafing, damage, and insulation damage, and rework the wiring within the ACCB, in accordance with the Accomplishment Instructions of the applicable Bombardier service bulletin specified in paragraphs (g)(1) through (g)(4) of this AD. If any chafing, damage, or insulation damage is found, before further flight, replace the damaged wiring, in accordance with the Accomplishment Instructions of the applicable Bombardier service bulletin specified in paragraphs (g)(1) through (g)(4) of this AD.

(1) Bombardier Service Bulletin 84–24–47, Revision A, dated September 14, 2011.
(2) Bombardier Service Bulletin 84–24–48, Revision A, dated September 14, 2011.
(3) Bombardier Service Bulletin 84–24–49, Revision A, dated September 14, 2011.
(4) Bombardier Service Bulletin 84–24–50, Revision A, dated September 14, 2011.

(h) Parts Installation Prohibition

As of the effective date of this AD, no person may install an ACCB having the combination of part numbers (P/N) and series specified in paragraphs (h)(1), (h)(2), (h)(3), and (h)(4) of this AD on any airplane.

(1) P/N 1152130–6, series 1, 2, and 4.
(2) P/N 1152148–6, series 1, 2, 4, and 5.
(3) P/N 1152090–6, series 1, 2, and 4.
(4) P/N 1152124–6, series 1, 2, 4, and 5.

(i) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using the applicable service bulletin specified in paragraphs (i)(1) through (i)(4) of this AD, which are not incorporated by reference in this AD.

(1) Bombardier Service Bulletin 84–24–47, dated April 26, 2011.
(2) Bombardier Service Bulletin 84–24–48, dated April 26, 2011.
(3) Bombardier Service Bulletin 84–24–49, dated April 26, 2011.
(4) Bombardier Service Bulletin 84–24–50, dated April 26, 2011.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE–170, 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 ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

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

(k) Related Information

(1) Refer to MCAI Canadian Airworthiness Directive CF–2012–03, dated January 11, 2012, and the service information specified in paragraphs (k)(1)(i) through (k)(1)(iv) of this AD, for related information.

(i) Bombardier Service Bulletin 84–24–47, Revision A, dated September 14, 2011.

(ii) Bombardier Service Bulletin 84–24–48, Revision A, dated September 14, 2011.

(iii) Bombardier Service Bulletin 84–24–49, Revision A, dated September 14, 2011.

(iv) Bombardier Service Bulletin 84–24–50, Revision A, dated September 14, 2011.

(2) For service information identified in this AD, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone 416–375–4000; fax 416–375–4539; email *thd.qseries@aero.bombardier.com;* Internet *http://www.bombardier.com.*

(l) Material Incorporated by Reference

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

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

(i) Bombardier Service Bulletin 84–24–47, Revision A, dated September 14, 2011.

(ii) Bombardier Service Bulletin 84–24–48, Revision A, dated September 14, 2011.

(iii) Bombardier Service Bulletin 84–24–49, Revision A, dated September 14, 2011.

(iv) Bombardier Service Bulletin 84–24–50, Revision A, dated September 14, 2011.

(3) For service information identified in this AD, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone 416–375–4000; fax 416–375–4539; email *thd.qseries@aero.bombardier.com;* Internet *http://www.bombardier.com.*

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

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

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

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–26774 Filed 11–8–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0518; Directorate Identifier 2010–NM–150–AD; Amendment 39–17231; AD 2012–21–15]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called A300–600 series airplanes); and Model A310 series airplanes. This AD was prompted by events of excessive rudder pedal inputs and consequent high loads on the vertical stabilizer on several airplanes. This AD requires either incorporating a design change to the rudder control system and/or other systems, or installing a stop rudder inputs warning (SRIW) modification. We are issuing this AD to prevent loads on the vertical stabilizer that exceed ultimate design loads, which could cause failure of the vertical stabilizer and consequent reduced controllability of the airplane.

DATES: This AD is effective December 14, 2012.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of December 14, 2012.

ADDRESSES: For the service information identified in this AD, contact Airbus SAS—EAW (Airworthiness Office), 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

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

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

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM published in the **Federal Register** on May 19, 2011 (76 FR 28914). That NPRM proposed to require incorporating a design change to the rudder control system and/or other systems to address the unsafe condition.

Relevant Service Information

Since we issued the NPRM (76 FR 28914, May 19, 2011), Airbus has issued the following service information:

- Airbus Mandatory Service Bulletin A300–22–6055, Revision 01, including Appendix 01, dated May 31, 2012
- Airbus Service Bulletin A300–22–6054, including Appendix 01, dated June 20, 2012
- Airbus Service Bulletin A300–22–6056, dated April 25, 2012
- Airbus Service Bulletin A300–31–6140, dated May 4, 2012
- Airbus Mandatory Service Bulletin A310–22–2064, Revision 01, including Appendix 01, dated May 31, 2012
- Airbus Service Bulletin A310–22–2063, including Appendix 01, dated June 20, 2012
- Airbus Service Bulletin A310–22–2065, dated April 25, 2012
- Airbus Service Bulletin A310–31–2144, dated May 4, 2012

These service bulletins describe procedures related to the SRIW modification. The procedures include installing a SRIW device, activating the SRIW device, upgrading the flight control computer to introduce the SRIW logic, and upgrading the flight warning computer. We have revised paragraph (g) in this final rule to allow accomplishment of this modification as an optional method of compliance with the requirements of the AD.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the proposal (76 FR 28914, May 19, 2011) and the FAA's response to each comment.

Support for the NPRM (76 FR 28914, May 19, 2011)

The National Transportation Safety Board (NTSB) and Air Line Pilots Association, International (ALPA), support the intent of the NPRM (76 FR 28914, May 19, 2011).

Requests To Withdraw NPRM (76 FR 28914, May 19, 2011): Unjustifiable Burden on Operators

UPS and FedEx requested that we withdraw the NPRM (76 FR 28914, May 19, 2011).

UPS stated that, in light of its existing operational and monitoring processes, the cost of the NPRM (76 FR 28914, May 19, 2011) would be a severe and unnecessary burden relative to its benefit. UPS stated that its flightcrews operate the airplanes in a manner that would not warrant the need for the proposed systems. UPS described its A300 flight training program, flight operations quality assurance (FOQA) program, and manual changes that were prompted by the incidents, and added that its training and awareness programs have been enhanced to specifically address the inherent high-speed sensitivity or response of the A300 rudder control system. UPS concluded that its flight training program emphasizes proper use of the rudder for which the rudder has been certified, and its robust FOQA program coupled with a review of maximum lateral loading from actual flights demonstrates that UPS flightcrews do not induce heavy side loading with improper rudder use. In addition, UPS stated that the FAA has already taken numerous actions to address this safety issue.

FedEx stated that its current flightcrew training practices have ensured elimination of excessive rudder pedal inputs on FedEx's Model A300–600 and A310 series airplanes. FedEx further detailed that it has monitored and recorded events of lateral G exceedences at FedEx as a result of FAA AD 2002–06–09, Amendment 39–12686 (67 FR 13259, March 22, 2002; corrected at 67 FR 51459, August 8, 2002), and all such events have been a result of something other than pilot rudder pedal input.

Although the FAA agrees with the importance of enhanced training and operational awareness of Model A300 and A310 rudder pedal sensitivity, we disagree to withdraw the NPRM (76 FR 28914, May 19, 2011). The National Transportation Safety Board (NTSB) found that the rudder pedal's sensitivity contributed to the American Airlines flight 587 accident, and, during a recent upset on an airplane with a similar system, the pilot made excessive pedal input, thinking he was actually correcting an airplane malfunction. Even with significant emphasis on training and rudder pedal sensitivity awareness, however, there have been additional full rudder pedal reversal occurrences on airplanes with similar rudder control systems. We have concluded that training alone is inadequate, and we have determined that a modification such as the pedal travel limiter unit (PTLU) or other design modification is necessary to address the unsafe condition. We have not changed the final rule regarding this issue. Based on the best information available on possible flightcrew training and possible design modifications, we have identified the need to incorporate a design change that will further address this unsafe condition. In addition, the FAA has tasked a joint authority-industry group to recommend criteria that might be used to evaluate other models. Upon acceptance of appropriate criteria, the FAA will begin to assess other in-service airplanes. Currently, the group is scheduled to complete its work in late 2013. See the FAA's response to the comments under ''Request to Expand Applicability'' in this final rule.

Request To Emphasize Training

In addition to supporting design enhancements to prevent inadvertent rudder over control, ALPA stated there should continue to be emphasis on the appropriate use of rudder in training programs.

The FAA agrees with the commenter that training programs are beneficial. Since the American Airlines Flight 587 accident, the FAA has emphasized training with letters to all affected operators notifying them of concerns regarding the need for industry-wide pilot knowledge and training on proper use of rudder pedals, in addition to the potential consequences of some maneuvers that might exceed the structural limits of the vertical tail. The FAA also tasked a working group to help develop specific training programs for rudder usage on all transport category airplanes. The FAA has also added language in section 25.1583(a)(3) of the Federal Aviation Regulations (14 CFR 25.1583(a)(3)) to warn against control reversals. Training will continue to be emphasized in the future; however, the intent of this AD is to require a design change be made to the airplane to correct the unsafe condition. We have not changed this final rule regarding this issue.

Request for Alternative Solution

Airbus suggested that, in lieu of the PTLU design modification discussed in the NPRM (76 FR 28914, May 19, 2011), we revise the NPRM to add another way to comply—by installing a warning light on the glareshield directly in front of each pilot and an associated ''stop rudder inputs'' aural warning, in addition to revising the airplane flight manual and reinforced flightcrew training. Airbus noted that flightcrew failure to use proper techniques was a contributing factor to the excessive rudder pedal inputs.

According to Airbus, its warning system will deter pilots from continuing the application of rapid alternating and large rudder pedal inputs, and is a more suitable solution than the PTLU modification proposed by the FAA.

We acknowledge Airbus's suggested solution, which was unavailable for consideration at the time we issued the NPRM (76 FR 28914, May 19, 2011). Following the receipt of the Airbus comments, the FAA has evaluated the Airbus alternative and found the ''stop rudder inputs'' warning (SRIW) modification combined with suitable flightcrew training programs provides an acceptable mitigation for the unsafe condition. As stated previously, we agree to change this final rule to allow the SRIW modification as an optional method of compliance with the requirements of the AD. In addition, since we issued the NPRM, the European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2012–0088, dated June 25, 2012, to require installation of the SRIW modification on Model A300–600 and A310 series airplanes to address this unsafe condition.

Requests for Alternative Compliance Method

Francis Gentile requested that we revise the NPRM (76 FR 28914, May 19, 2011) to include, as one way to comply with the NPRM, the option to tape a yaw string onto the front windows to give the pilot maximum feedback against excessive yaw and pilot-induced oscillation.

We disagree with this request. The unsafe condition presents itself with dynamic yaw excursions linked to rudder pedal reversals. Yaw indicators already present on the flight deck have

not proven effective in previous rudder pedal reversal events.

Mr. Gentile also suggested adhering a pointed cone on each rudder pedal to give the pilot the progressive feedback sensation of force applied to the pedal and possibly cause pain in the ball of the foot or a twisting ankle to deter the pilot from making inputs or at least alert the pilot to stop making such an input. The commenter pointed out that this solution might be less expensive than the proposed modification. The commenter noted that the cone might also interfere with other pedal functions such as braking.

We do not agree with this comment. The commenter has provided an unproven design suggestion. There is no evidence that such devices would be effective at preventing the unsafe condition. The rudder pedals are used normally for taxiing and flying the airplane. Adding cone devices to the pedals may interfere with normal pedal usage. There are certain safety-critical conditions where it is necessary for the pilot to apply rapid hard pedal inputs. Anything that interferes with the pilot's ability to make necessary inputs could reduce safety. Such devices might also defeat the purpose of the pedal adjustment feature that allows shorter or taller pilots to use the pedal, and affect appropriate steering and braking. Under the provisions of paragraph (h) of this AD, however, we will consider requests for approval of different compliance methods if sufficient data are submitted to substantiate that the change would provide an acceptable level of safety.

We have not changed the AD regarding these issues.

Request To Expand Applicability

Airbus questioned the basis for the NPRM (76 FR 28914, May 19, 2011)—that rudder pedal sensitivity is limited to Model A300–600 and A310 series airplanes. Airbus added that rapid alternating and large pilot rudder inputs while enroute are inappropriate and have the potential to be unsafe for a wider fleet of large transport airplanes. Airbus identified several resources supporting this position.

We infer that Airbus wants us to expand the applicability of the NPRM (76 FR 28914, May 19, 2011), or otherwise consider similar rulemaking to extend to other airplane models and airplanes produced by other manufacturers. While the FAA has not determined that an unsafe condition exists on other airplanes, we are considering a number of factors on other airplanes, including pedal reversals, pedal sensitivity, and airplane dynamics and fin loads. NTSB Safety Recommendation A–04–56 recommends developing a revised standard to ensure safe handling qualities in the yaw axis throughout the flight envelope, including limits for rudder pedal sensitivity. Currently an FAA aviation rulemaking advisory committee (ARAC) has been assigned to evaluate this safety recommendation. Pending the ARAC recommendation, the FAA will determine whether other airplanes have a similar unsafe condition that needs to be addressed by rulemaking or airworthiness actions. We have not changed the final rule regarding this issue.

Request To Remove Model A310–200 Airplanes From Applicability

Airbus requested that we revise the applicability of the NPRM (76 FR 28914, May 19, 2011) to remove Model A310–200 airplanes because their remaining service life is short.

We disagree with the request. Service life projections vary among operators and are difficult to accurately determine. Airbus did not provide any specific service life projections. In addition, the utilization rate of these airplanes is low, which can preserve and extend their life. We therefore do not consider this request to have adequate justification. We have not changed the final rule regarding this issue.

Request To Revise Compliance Time: Account for PTLU Development Time

FedEx requested that we extend the proposed compliance time to account for development time for the PTLU.

We disagree with the request. We have determined that the unsafe condition warrants corrective action within the specified time frame. If developing the PTLU and incorporating the mandated changes require additional time, the FAA may consider revising the AD to extend the compliance time, or provide such relief through approval of an AMOC to extend the compliance time of the AD according to the provisions of paragraph (h) of this AD. We have not changed the final rule regarding this issue.

Request To Revise Compliance Time: Allow for New Maintenance Procedures

FedEx requested that we revise the compliance time in the NPRM (76 FR 28914, May 19, 2011) to allow time to incorporate new maintenance procedures to accommodate the proposed modification. Based on past experience, FedEx considered the proposed 48-month compliance time unrealistic to account for changes in maintenance programs. FedEx also requested that we extend the proposed compliance time to 72 months to allow time to revise the master minimum equipment list (MMEL) to support dispatch reliability of the newly installed system. UPS stated that at least 6 years would be needed to install the PTLU on its fleet.

We disagree with the FedEx proposal. In determining the appropriate compliance time for this AD, we considered many factors, including those related to maintenance program adjustments. Further, once the PTLU is developed and ready for incorporation on the fleet, operators may request MMEL relief via an AMOC request to the AD. We determined that the compliance time, as proposed, will maintain the necessary level of safety and allow adequate time for operators to modify their maintenance program. We have not changed the final rule regarding this issue.

Request To Extend Compliance Time: Account for Design Service Goals

Airbus requested that we revise the proposed compliance time to consider the Airbus design service goals (DSGs) for the affected airplanes. Airbus provided a proposed grace period for any airplane close to its DSG value near the end of the compliance time, until the airplane's certificate of airworthiness is withdrawn.

We disagree with the request. This AD includes all airplanes that have the defined unsafe condition regardless if the airplane is currently in operation, or has been removed from service. As Airbus has described the operators may choose to further invest in the airplanes and operate them in what Airbus calls the extended service goals (ESG). This AD does not prevent an airplane from being operated beyond the DSG so a grace period for any airplane close to its DSG does not maintain an adequate level of safety. Under the provisions of paragraph (h) of this final rule, however, we will consider requests to approve an extension of the compliance time if sufficient data are submitted to substantiate that the extension would also provide an acceptable level of safety. We have not changed the final rule regarding this issue.

Concern for Length of Time To Develop and Mandate Fix

Two commenters expressed concern about the length of time it has taken to develop and mandate a fix for the unsafe condition.

The NTSB, although encouraged by the various actions being considered to address the unsafe condition, was concerned about the lack of a definitive

fix for the rudder system. Since the exact details of the PTLU fix have not yet been available, the NTSB could not determine the benefit of this system. The NTSB was also concerned about the amount of time spent to make the design change available to operators.

Geoffrey Barrance also questioned this timeframe, and asked whether we have new information about the need to mandate a modification of the rudder system.

The FAA understands the NTSB concern about the lack of definitive PTLU design information provided with the NPRM (76 FR 28914, May 19, 2011), and the concern about the amount of time that has transpired to make a design change available to operators. As stated in the NPRM, there were no service instructions available at that time to address the unsafe condition. However, the FAA determined that taking additional time to develop service information before beginning the corrective action notification process was not in the public's interest. Since the date of the NPRM publication, Airbus has developed a design change that is a more cost-effective solution than the originally planned PTLU, which has also received design approval by the EASA and the FAA.

Request To Clarify Modification Approval Timeframe

Geoffrey Barrance acknowledged the FAA's possible reluctance to limit the corrective action to a single technical approach, but questioned why it would take 3 years to mandate installation of the PTLU.

We have established a compliance time of 4 years to implement the required design change, including an estimated 3-year timeframe for developing and approving a modification that ensures that parts and installation instructions are available. The FAA is confident that a modification will be available in a timely manner and that the compliance time, as proposed, will leave adequate time for operators to implement the changes required by this AD. We have not changed the final rule regarding this issue.

Request To Clarify Background in NPRM (76 FR 28914, May 19, 2011)

Based on its request for an alternative solution to the unsafe condition, Airbus requested changes to the Discussion section of the NPRM (76 FR 28914, May 19, 2011).

Where the NPRM (76 FR 28914, May 19, 2011) referred to events of ''excessive rudder pedal inputs'' that resulted in high vertical stabilizer loads, Airbus suggested that we recharacterize the events as ''excessive rapid alternating and large pilot rudder pedal inputs.'' Airbus described the reported conditions that support this finding.

Where the NPRM (76 FR 28914, May 19, 2011) describes the PTLU as one option under consideration for the modification to the rudder control system, Airbus suggested that we also state that the PTLU has no effect on crew awareness that rapid alternating and larger rudder inputs addressed in section 25.1583 of the Federal Aviation Regulations (14 CFR 25.1583) are always inappropriate. Airbus stated that if a flightcrew were to perform such inputs, the loads created would be lower for an airplane fitted with a PTLU than one without a PTLU. But the flightcrew would still have the potential to add to the loads in the same direction induced on the vertical stabilizer by an increasing sideslip. Airbus concluded that high loads to the vertical stabilizer will occur anyway if the pilot continues to use the inappropriate piloting technique, but a given level of high loads and the associated hazard will be reached a few seconds later for an airplane fitted with a PTLU.

We agree that the requested changes might clarify the background information of the NPRM (76 FR 28914, May 19, 2011). The Discussion section, however, is not restated in a final rule, so we have not changed the final rule regarding this issue.

Request To Include Additional Background Information

Francis Gentile requested that we add a journal article to the AD docket. This article indicated the need for design improvements to relieve the limited adaptive capability of pilots.

We acknowledge the commenter's request, but the article was not part of the AD development process and would serve no purpose in the AD docket. In light of potential proprietary issues and the appropriateness of posting this type of article in the AD docket, we have not changed the final rule regarding this issue.

Request To Provide Information on Evaluation of Rudder Pedal Sensitivity

ALPA requested an evaluation of rudder pedal sensitivity and means to prevent inadvertent over control.

The FAA has already tasked the ARAC to consider general rulemaking in 14 CFR part 25 to address pedal sensitivity as well as several other considerations to ensure that pilot-commanded pedal reversals are safe or precluded, or that the system design reduces the likelihood of pedal reversals. We have not changed the final rule regarding this issue.

Request for Information

The NTSB requested information on Airbus's development of a flight deck warning light that does not incorporate any mechanical changes to the rudder system. The NTSB is concerned that a warning light alone will not rectify the unsafe condition.

The SRIW warning modification consists of a prominent warning light and a loud verbal warning directing the pilot to cease inputs to the rudder. After reviewing the design, analyses, and simulator demonstrations, the FAA has concluded that these alerts, taken together, are compelling, timely, and will prevent the flightcrew from continuing the inappropriate rudder inputs prior to exceeding the ultimate design loads that could result in failure of the vertical stabilizer. The FAA has determined that the SRIW modification, combined with suitable flightcrew training programs, provides an acceptable mitigation for the unsafe condition.

As explained previously, we have changed the final rule to include the SRIW modification as one approved method for complying with this AD.

Request To Revise Cost Estimate

Airbus noted that the NPRM (76 FR 28914, May 19, 2011) included estimated costs only for the PTLU installation. Airbus requested that we revise the NPRM to include the estimated costs to install an alert warning system. UPS asserted that the NPRM underestimated the costs of the proposed modification, which would involve upgrading computers and installing warning light consoles, switching relays, and associated interconnect wiring.

We agree to revise the cost estimate. Cost information for the alert warning system was not available when we issued the NPRM (76 FR 28914, May 19, 2011). As one of the modifications accepted by the FAA, it should be included. We have revised the Costs of Compliance section accordingly in this final rule.

Request To Change Air Transport Association (ATA) Code

Airbus requested that we revise paragraph (d) of the NPRM (76 FR 28914, May 19, 2011) to add ATA Code 31, Instruments, to reflect Airbus's proposal to install a crew warning as one way to comply with the NPRM.

We agree with the request and rationale. We have changed paragraph (d) in this final rule accordingly.

Questions About Safety Recommendations (SRs)

Mr. Barrance asked whether the NPRM (76 FR 28914, May 19, 2011) addressed NTSB SRs A–04–56 and A–04–57, and whether failure to refer to SR A–04–58 was an omission.

An FAA ARAC is considering general rulemaking to address rudder pedal sensitivity, including factors beyond those specified in this AD. This AD is in response to SRs A–04–058, A–04–044, and A–04–063. We have not changed the final rule regarding this issue.

Conclusion

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

Costs of Compliance

We estimate that this AD will affect 215 airplanes of U.S. registry.

The unsafe condition may be addressed by installing a PTLU or alert warning system, although these may not be the only acceptable methods. The following table provides the estimated costs for U.S. operators to comply with this AD, based on preliminary information provided by the manufacturer.

ESTIMATED COSTS

Installation	Work hours	Average labor rate per hour	Parts	Cost per product
PTLU	100	$85	$190,000	$198,500
Alert warning system for products with a flight warning computer standard developed from year 2000 and onwards	32	85	70,000	72,720
Alert warning system for remaining airplanes	32	85	105,000	107,720

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2012–21–15 Airbus: Amendment 39–17231; Docket No. FAA–2011–0518; Directorate Identifier 2010–NM–150–AD.

(a) Effective Date

This AD is effective December 14, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes; Model A300 B4–605R and B4–622R airplanes; Model A300 F4–605R and F4–622R airplanes; Model A300 C4–605R Variant F airplanes; and Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes; certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls; and 31, Instruments.

(e) Unsafe Condition

This AD was prompted by events of excessive alternating rudder pedal inputs and consequent loads on the vertical stabilizer that exceed ultimate design loads. Such events could lead to failure of the vertical stabilizer and consequent reduced controllability of the airplane.

(f) Compliance

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

(g) Modification

Within 48 months after the effective date of this AD, do the actions specified in either paragraph (g)(1) or (g)(2) of this AD to address the unsafe condition identified in paragraph (e) of this AD.

(1) Incorporate a design change to the rudder control system and/or other systems, in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA.

(2) Install a stop rudder inputs warning (SRIW) modification by doing the applicable actions specified in paragraph (g)(2)(i) or (g)(2)(ii) of this AD, as applicable.

(i) For Model A300–600 series airplanes: Do the applicable actions specified in paragraphs (g)(2)(i)(A) and (g)(2)(i)(B) of this AD.

(A) Install a SRIW device, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–22–6054, including Appendix 01, dated June 20, 2012. Before or concurrently with the SRIW installation, do the actions specified in paragraphs (g)(2)(i)(A)*(1)* and (g)(2)(i)(A)*(2)* of this AD.

(1) Upgrade the flight control computer (FCC) to introduce the SRIW logic, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–22–6056, dated April 25, 2012.

(2) Upgrade the flight warning computer (FWC) to introduce the SRIW aural capability, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–31–6140, dated May 4, 2012.

(B) Activate the SRIW device, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A300–22–6055, Revision 01, including Appendix 01, dated May 31, 2012.

(ii) For Model A310 series airplanes: Do the actions specified in paragraphs (g)(2)(ii)(A) and (g)(2)(ii)(B) of this AD.

(A) Install a SRIW device, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A310–22–2063, including Appendix 01, dated June 20, 2012. Before or concurrently with the SRIW installation, do the actions specified in paragraphs (g)(2)(ii)(A)*(1)* and (g)(2)(ii)(A)*(2)* of this AD.

(1) Upgrade the FCC to introduce the SRIW logic, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A310–22–2065, dated April 25, 2012.

(2) Upgrade the FWC to introduce the SRIW aural capability, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A310–31–2144, dated May 4, 2012.

(B) Activate the SRIW device, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A310–22–2064, Revision 01, including Appendix 01, dated May 31, 2012.

(h) Alternative Methods of Compliance (AMOCs)

(1) 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 Manager, ANM–116, send it to the attention of the person identified in the Related Information section of this AD.

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

(i) Related Information

(1) For related information, refer to MCAI European Aviation Safety Agency Airworthiness Directive 2012–0088, dated June 25, 2012, and the service bulletins identified in paragraphs (i)(1)(i) through (i)(1)(viii) of this AD, for related information.

(i) Airbus Mandatory Service Bulletin A300–22–6055, Revision 01, including Appendix 01, dated May 31, 2012.

(ii) Airbus Mandatory Service Bulletin A310–22–2064, Revision 01, including Appendix 01, dated May 31, 2012.

(iii) Airbus Service Bulletin A300–22–6054, including Appendix 01, dated June 20, 2012.

(iv) Airbus Service Bulletin A300–22–6056, dated April 25, 2012.

(v) Airbus Service Bulletin A300–31–6140, dated May 4, 2012.

(vi) Airbus Service Bulletin A310–22–2063, including Appendix 01, dated June 20, 2012.

(vii) Airbus Service Bulletin A310–22–2065, dated April 25, 2012.

(viii) Airbus Service Bulletin A310–31–2144, dated May 4, 2012.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–2125; fax 425–227–1149.

(j) Material Incorporated by Reference

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

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

(i) Airbus Mandatory Service Bulletin A300–22–6055, Revision 01, including Appendix 01, dated May 31, 2012.

(ii) Airbus Mandatory Service Bulletin A310–22–2064, Revision 01, including Appendix 01, dated May 31, 2012.

(iii) Airbus Service Bulletin A300–22–6054, including Appendix 01, dated June 20, 2012.

(iv) Airbus Service Bulletin A300–22–6056, dated April 25, 2012.

(v) Airbus Service Bulletin A300–31–6140, dated May 4, 2012.

(vi) Airbus Service Bulletin A310–22–2063, including Appendix 01, dated June 20, 2012.

(vii) Airbus Service Bulletin A310–22–2065, dated April 25, 2012.

(viii) Airbus Service Bulletin A310–31–2144, dated May 4, 2012.

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

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

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

Issued in Renton, Washington, on October 12, 2012.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–26963 Filed 11–8–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0502; Directorate Identifier 2010–SW–097–AD; Amendment 39–17242; AD 2012–22–06]

RIN 2120–AA64

Airworthiness Directives; Aeronautical Accessories, Inc., High Landing Gear Forward Crosstube Assembly

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for Aeronautical Accessories, Inc. (AAI) high landing gear forward crosstube assemblies (crosstubes) installed on Agusta S.p.A. (Agusta) Model AB412 and AB412EP; and Bell Helicopter Textron, Inc. (Bell) Model 205A, 205A–1, 205B, 212, 412, 412CF, and 412EP helicopters during production or based on a supplemental type certificate (STC). This AD requires counting and recording the total number of landings for the crosstubes, and inspecting the crosstubes and replacing them if a crack or other damage exists. This AD was prompted by two reports from the field of failed crosstubes. The actions are intended to prevent failure of a crosstube, collapse of the landing gear, and subsequent loss of control of the helicopter.

DATES: This AD is effective December 14, 2012.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of December 14, 2012.

ADDRESSES: For service information identified in this AD, contact Aeronautical Accessories, Inc., P.O. Box 3689, Bristol, TN 37625–3689, telephone (423) 538–5151 or (800) 251–7094, fax (423) 538–8469, or at *http://www.aero-access.com.* You may review a copy of the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth Texas 76137.

Examining the AD Docket: You may examine the AD docket on the Internet

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

FOR FURTHER INFORMATION CONTACT: Michael Kohner, Aviation Safety Engineer, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone (817) 222–5170; email *7-avs-asw-170@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On May 11, 2012, at 77 FR 27663, the **Federal Register** published our notice of proposed rulemaking (NPRM), which proposed to amend 14 CFR part 39 to include an AD that would apply to AAI crosstubes installed on Agusta Model AB412 and AB412EP, and Bell Model 205A, 205A–1, 205B, 212, 412, 412CF, and 412EP helicopters during production or based on an STC. That NPRM proposed to require creating a component history card or equivalent record and counting and recording the total number of landings for the crosstubes. It also proposed to require inspecting the crosstubes and replacing them if a crack or other damage exists. The proposed requirements were intended to prevent failure of a crosstube, collapse of the landing gear, and subsequent loss of control of the helicopter.

The NPRM was prompted by two reports from the field of crosstube failures. AAI issued Alert Service Bulletin AA–08055, Revision B, dated August 12, 2009 (ASB) to provide procedures for repetitively inspecting the high forward crosstubes to detect this condition.

Comments

We gave the public the opportunity to participate in developing this AD, but we received no comments on the NPRM (77 FR 27663, May 11, 2012).

FAA's Determination

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

Related Service Information

We reviewed the AAI ASB, which specifies establishing a takeoff/landing history, recurrent visual and fluorescent penetrant inspections of the crosstubes, and dimensional inspections of the skid gear. We have also reviewed AAI Instructions for Continued Airworthiness (ICA) for Crosstubes, Report No. AA–01136, Revision K, dated February 15, 2012, which contains the information necessary for inspection and maintenance of each crosstube installed on the Agusta and Bell helicopters.

Costs of Compliance

We estimate that this AD will affect 115 helicopters of U.S. Registry and that operators will incur the following costs to comply with this AD:

- Creating a historical record and determining the number of landings will require a half work hour at an average labor rate of $85 per hour for a cost per helicopter of about $42 and a cost to the U.S. operator fleet of $4,830 per inspection cycle.
- Preparing and inspecting the crosstube will require 8.5 work hours at an average labor rate of $85 per hour for a cost per helicopter of about $722 and a cost to the U.S. operator fleet of $83,030 per inspection cycle.
- Performing the dimensional inspection of the skid gear will require 1 work hour at an average labor rate of $85 per hour for a cost per helicopter of $85 and a cost to the U.S. operator fleet of $9,775 per inspection cycle.
- Fluorescent penetrant inspecting the crosstube will require 24 work hours at an average labor rate of $85 per hour for a cost per helicopter of $2,040 and a cost to the U.S. operator fleet of $234,600 per inspection cycle.
- If required, replacing a crosstube with an airworthy crosstube will require 10 work hours at an average labor rate of $85, required parts will cost $9,315, for a cost per helicopter of $10,165.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2012–22–06 Aeronautical Accessories, Inc. (AAI): Amendment 39–17242; Docket No. FAA–2012–0502; Directorate Identifier 2010–SW–097–AD.

(a) Applicability

This AD applies to high landing gear forward crosstube assembly (crosstube), part

number (P/N) 212–321–103, installed on Agusta S.p.A. Model AB412 and AB412EP and Bell Helicopter Textron, Inc. Model 205A, 205A–1, 205B, 212, 412, 412CF, and 412EP helicopters, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as failure of the landing gear crosstube, which could result in collapse of the landing gear and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective December 14, 2012.

(d) Compliance

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

(e) Required Actions

(1) Within 50 hours time-in-service (TIS) after the effective date of this AD:

(i) Create a component history card or equivalent record for the crosstube by following the Accomplishment Instructions, Part A, paragraph 1., of AAI Alert Service Bulletin No. AA–08055, Revision B, dated August 12, 2009 (ASB).

(ii) Determine and record on the component history card or equivalent record the total number of landings for the crosstube. If the landing information is unavailable, estimate the number by multiplying the airframe hours TIS by 10. Continue to count and record the number of landings for the crosstube. For the purposes of this AD, a landing would be counted anytime the helicopter lifts off into the air and then lands again with any further reduction of the collective after the landing gear touches the ground.

(2) Within 50 hours TIS after the effective date of this AD or before reaching a total of 7,500 landings on any crosstube, whichever occurs later:

(i) Prepare the crosstube inspection areas as described in the Accomplishment Instructions, Part B, paragraphs 1. through 5. and Figure 1, of the ASB.

(ii) Using a 10X or higher power magnifying glass and a bright light, visually inspect the prepared areas of the crosstube for a crack. If there is a crack, before further flight, replace the crosstube with an airworthy crosstube.

(iii) If there is no crack, following the inspection, prime and paint the inspection areas by following the Accomplishment Instructions, Part B, paragraphs 7. and 8., of the ASB. If there is any corrosion or other damage, perform the replacement or repair required in paragraph (e)(5)(iv) of this AD before priming and painting the inspection areas.

(3) Thereafter, at intervals not to exceed 200 landings, clean the crosstube inspection areas by following the Accomplishment Instructions, Part C, paragraph 1., of the ASB. Using a 10X or higher power magnifying glass and a bright light, visually inspect the clear-coated areas of the crosstube for a crack. If there is a crack, before further flight, replace the crosstube with an airworthy crosstube.

(4) Within 30 days after the effective date of this AD or before reaching a total of 10,000 landings on any crosstube, whichever occurs later, and thereafter at intervals not to exceed 2,500 landings or 12 months, whichever occurs first, determine the horizontal deflection of the crosstube from the centerline of the helicopter (BL 0.0) to the outside of the skid tubes by following the Accomplishment Instructions, Part D, paragraphs 1. and 2., of the ASB. If the crosstube measures outside any of the limits depicted in Figure 2 of the ASB, before further flight, replace the crosstube with an airworthy crosstube.

(5) Within 3 months after the effective date of this AD or before reaching a total of 12,500 landings on any crosstube, whichever occurs later, and thereafter at intervals not to exceed 5,000 landings:

(i) Remove and disassemble the landing gear assembly and crosstube to prepare for a fluorescent penetrant inspection (FPI) by following the Accomplishment Instructions, Part E.1, paragraphs 1. through 6., of the ASB.

(ii) Clean and prepare the crosstube by removing the sealant and paint as described in the Accomplishment Instructions, Part E.2, paragraphs 1. through 3. and Figure 3, of the ASB.

(iii) Perform an FPI of the crosstube in the areas depicted in Figure 3 of the ASB for a crack, any corrosion, a nick, scratch, dent, or any other damage by following the Accomplishment Instructions, Part E.3, paragraph 1., of the ASB. If there is a crack, before further flight, replace the crosstube with an airworthy crosstube.

(iv) If there is any corrosion or a nick, scratch, dent, or any other damage, before further flight, repair the crosstube to an airworthy configuration if the damage is within the maximum repair damage limits or replace the crosstube with an airworthy crosstube. Chapter 3.5 Repair, Table 1. and Figure 3 of the AAI Instructions for Continued Airworthiness for Crosstubes, Report No. AA–01136, Revision K, dated February 15, 2012, contains the maximum repair damage limits and repair procedures.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Rotorcraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Michael Kohner, Aviation Safety Engineer, Rotorcraft Certification Office, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone (817) 222–5170; email *7-avs-asw-170@faa.gov.*

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

(g) Subject

Joint Aircraft Service Component (JASC) Code: 3213: Main Landing Gear Strut/Axle/Truck.

(h) Material Incorporated by Reference

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

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

(i) Aeronautical Accessories Inc. Alert Service Bulletin No. AA–08055, Revision B, dated August 12, 2009.

(ii) Aeronautical Accessories Inc. Instructions for Continued Airworthiness for Crosstubes, Report No. AA–01136, Revision K, dated February 15, 2012.

(3) For service information identified in this AD, contact Aeronautical Accessories, Inc., P.O. Box 3689, Bristol, TN 37625–3689, telephone (423) 538–5151 or (800) 251–7094, fax (423) 538–8469, or at *http://www.aero-access.com.*

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

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

Issued in Fort Worth, Texas, on October 24, 2012.

Lance T. Gant,

Acting Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2012–26901 Filed 11–8–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0428; Directorate Identifier 2011–NM–078–AD; Amendment 39–17248; AD 2012–22–12]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus Model A330–243, –243F, –341, –342, and –343 airplanes. This AD was prompted by reports of cracking of air intake cowls on Rolls-Royce Trent engines, worn and detached attachment

links, and fractured thermal anti-ice (TAI) piccolo tubes. This AD requires inspecting piccolo tubes, piccolo tube mount links, the aft side of the forward bulkhead, and outer boundary angles (OBA) for cracks, fractures, and broken links, and corrective actions if necessary. We are issuing this AD to prevent degraded structural integrity of the engine nose cowl in case of forward bulkhead damage in conjunction with a broken piccolo tube, and damage to the engine due to operation in icing conditions with reduced TAI performance.

DATES: This AD becomes effective December 14, 2012.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 14, 2012.

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

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

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on May 8, 2012 (77 FR 26998). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

> During shop visit, several primary assembly structures of A330 aeroplanes Trent 700 [engine] air intake cowl have been found with cracks in the forward bulkhead web, web stiffeners and outer boundary angles. Several attachment links have been found severely worn, and some had become detached. In 2 cases, the Thermal Anti Ice (TAI) Piccolo tube was found fractured. Investigations are still ongoing to determine the root cause(s).
>
> If not detected and corrected, a broken Piccolo tube in conjunction with forward bulkhead damage could ultimately lead to in flight detachment of the outer barrel, which would constitute an unsafe condition.
>
> For the reasons described above, this [European Aviation Safety Agency (EASA)] AD requires to perform inspections of RR [Rolls-Royce] Trent 700 [engine] nose cowls and, depending on findings, to do the applicable corrective action(s). These inspections include internal inspection of Piccolo tube, detailed inspection of Piccolo tube mount links, [boroscope] inspection of aft side of forward bulkhead and outer boundary angle [for cracks, fractures, and broken links].

We are issuing this AD to prevent degraded structural integrity of the engine nose cowl in case of forward bulkhead damage in conjunction with a broken piccolo tube and damage to the engine due to operation in icing conditions with reduced TAI performance. The corrective action is replacing the affected engine air intake cowl with a new or serviceable cowl. You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We considered the comments received.

Request To Delete Completion of Reporting Form

US Airways requested that we delete the requirement to complete Appendix 01 of Airbus Mandatory Service Bulletin A330–71–3025, dated January 10, 2011, which is the form for reporting inspection results to Airbus. US Airways stated that accomplishing this reporting is burdensome and does not improve the safety aspects of the inlet cowl inspections.

We agree because reporting is voluntary. Airbus has concurred that EASA AD 2011–0062, dated April 4, 2011, does not require reporting of the inspection findings and that it is Airbus's intent that reporting should be done on a voluntary basis. We have changed the final rule throughout to exclude Appendix 01 when referring to Airbus Mandatory Service Bulletin A330–71–3025, dated January 10, 2011.

Request To Change Piccolo Tube Link Inspection

US Airways requested that the piccolo tube link inspection be completely independent for each inlet cowl, and that a conservative approach could be incorporated in the NPRM (77 FR 26998, May 8, 2012) to allow only one broken piccolo tube link on an inlet cowl if the cowl remains in service on an airplane. US Airways stated that more than one broken piccolo tube link would mandate removal of the cowl prior to further flight. US Airways explained that the inspection results tie the serviceability of cowl being inspected to the condition of the inlet cowl installed on the other engine of the airplane. US Airways asserted that this will require a difficult and unnecessarily complicated management plan by an operator. US Airways reasoned that the serviceability of the inlet cowl being inspected should be determined independently of the inlet cowl installed on the other engine, and that Table 3 ''Detailed Inspection of the Broken Piccolo Tubes Links'' of Paragraph 1.E., ''Compliance,'' of Airbus Mandatory Service Bulletin A330–71–3025, dated January 10, 2011, contains 20 different scenarios related to the number of broken piccolo tube links in both the left and right inlet cowls and flight cycles achieved on each inlet cowl. US Airways stated that the left and right engines and nacelles are completely separate and designed to individually provide continued propulsion to the airplane in the event of failure of one engine; and that this is the basis of the FAA extended operations (ETOPS) rules.

We disagree with changing the piccolo tube link inspection requirements, and allowing one piccolo tube link broken on each inlet cowl. The criteria and corrective actions specified in Airbus Mandatory Service Bulletin A330–71–3025, dated January 10, 2011, represent the conditions for the safe operation of the airplane. Only one piccolo tube link broken on the airplane is allowed. The commenter did not provide sufficient data to substantiate that its request would provide an acceptable level of safety. Once we issue this AD, any person may request approval of an alternate methods of compliance (AMOC) under the provisions of paragraph (k) of this AD. We have not changed the AD in this regard.

Request To Change OBA and Forward Bulkhead Inspection Criteria

US Airways recommended a change in the OBA and forward bulkhead inspection criteria, as follows.

- Cracks up to 9 inches in length on the OBA would be acceptable.
- Cracks up to 2 inches in length on the forward bulkhead would be acceptable.
- Re-inspection of the OBA and forward bulkhead would be required at subsequent intervals not to exceed 2,500 flight cycles.
- Replace the inlet cowl for any OBA crack of 22 inches or greater or any forward bulkhead crack of 13 inches or greater, would be required prior to further flight.
- Replace the inlet cowl for an OBA crack greater than 15 inches, but less than 22 inches, or any forward bulkhead crack greater than 9 inches, but less than 13 inches, within 100 flight cycles.

We disagree because Airbus Mandatory Service Bulletin A330–71–3025, dated January 10, 2011, which references Rolls-Royce Service Bulletin RB.211–71–AG416, dated September 3, 2010, provides the inspection criteria and allowable conditions for the safe operation of the airplane. The commenter did not present sufficient data to substantiate that the crack lengths in its first and second recommendations would provide an acceptable level of safety. Actions suggested by the commenter in its third, fourth, and fifth recommendations are already reflected in paragraphs (i)(1)(ii), (i)(2)(i), and (i)(2)(ii) of this AD. However, operators may request approval of an AMOC under the provisions of paragraph (k) of this AD if sufficient data are submitted to substantiate that the change would provide a acceptable level of safety. We have not changed the AD in this regard.

Request To Change Engine Inlet Cowl Inspection

US Airways recommended a simpler re-inspection management plan of inspecting any engine inlet cowl that has achieved more than 5,000 flight cycles since new at repeat intervals not to exceed 2,500 flight cycles. US Airways stated that the engine inlet cowl inspection should follow Airbus Mandatory Service Bulletin A330–71–3025, dated January 10, 2011; and Rolls-Royce Service Bulletin RB.211–71–AG416, dated September 3, 2010; regarding the inspection schedule of the piccolo tube, the piccolo tube links, the OBA, and the forward bulkhead.

We disagree because Airbus Mandatory Service Bulletin A330–71–3025, dated January 10, 2011, which references Rolls-Royce Service Bulletin RB.211–71–AG416, dated September 3, 2010, specifies the repetitive inspection intervals for the safe operation of the airplane, which depend on the crack size. If the crack is within allowable limits, the inspection interval may be greater or less than 2,500 flight cycles as recommended by the commenter. Insufficient justification was submitted to substantiate a 2,500-flight-cycle inspection interval. However, under the provisions of paragraph (k) of this AD we will consider requests for an AMOC if sufficient data is submitted to justify an extended inspection interval for certain limits. We have not changed the AD in this regard.

Request To Change Wording in Paragraphs (h)(2) and (h)(3) of the NPRM (77 FR 26998, May 8, 2012)

Airbus requested that we change the word ''engine'' to ''aircraft'' in paragraph (h)(2) of the NPRM (77 FR 26998, May 8, 2012).

US Airways requested that we clarify the instructions in paragraph (h)(3) of the NPRM (77 FR 26998, May 8, 2012) by revising ''* * * and the opposite intake cowl of the same engine has * * *,'' to state ''* * * and the intake cowl of the opposite engine has * * *.''

We agree to clarify paragraphs (h)(2) and (h)(3) of this AD. We changed the word ''engine'' to ''airplane'' in paragraphs (h)(2) and (h)(3) of the AD, since each engine has one inlet cowl.

Request To Change Unsafe Condition Statement

Airbus requested that we remove the information that a broken piccolo tube could lead to in-flight damage of the engine and reduced TAI performance from the unsafe condition statement in the NPRM (77 FR 26998, May 8, 2012).

We agree with the commenter's requested wording change of the unsafe condition statement in this AD. In addition, we have revised the unsafe condition statement in this AD to match the unsafe condition statement defined in Airbus Mandatory Service Bulletin A330–71–3025, dated January 10, 2011. We have changed the Summary and Discussion sections, and paragraph (e) of the AD.

Request To Change Repetitive Inspection Interval

Airbus requested that we lower the repetitive inspection interval for the OBA and forward bulkhead inspections from 450 flight cycles to 250 flight cycles, and from 400 flight cycles to 200 flight cycles respectively. The commenter stated that these lower inspection intervals will be introduced in the forthcoming revisions of the Airbus and Rolls-Royce service information.

We disagree to change the repetitive inspection intervals in this AD. We have determined that the compliance times required by this AD adequately address the identified unsafe condition. However, if additional data are presented that would justify a shorter compliance time, we might consider further rulemaking on this issue. New revisions of the service information referenced in this AD have not been released. We have not changed the AD in this regard.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM (77 FR 26998, May 8, 2012) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (77 FR 26998, May 8, 2012).

Costs of Compliance

Based on the service information, we estimate that this AD affects about 14 products of U.S. registry. We also estimate that it takes about 10 work-hours per engine to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of the AD on U.S. operators to be $11,900 per engine, or $850 per engine.

In addition, we estimate that any necessary follow-on actions would take about 16 work-hours per engine for a cost of $1,360 per engine. We have received no definitive data that would enable us to provide material cost estimates for the on-condition actions specified in this AD. We have no way of determining the number of products that might 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 AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

3. Will not affect intrastate aviation in Alaska; and

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM (77 FR 26998, May 8, 2012), the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2012–22–12 Airbus: Amendment 39–17248. Docket No. FAA–2012–0428; Directorate Identifier 2011–NM–078–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective December 14, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Model A330–243, –243F, –341, –342, and –343 airplanes, certificated in any category, all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 71, Powerplant.

(e) Reason

This AD was prompted by reports of cracking of air intake cowls on Rolls-Royce Trent engines, worn and detached attachment links, and fractured thermal anti-ice (TAI) piccolo tubes. We are issuing this AD to prevent degraded structural integrity of the engine nose cowl in case of forward bulkhead damage in conjunction with a broken piccolo tube, and damage to the engine due to operation in icing conditions with reduced TAI performance.

(f) Compliance

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

(g) Piccolo Tube Inspection

At the applicable time specified in paragraph (g)(1) or (g)(2) of this AD, do a boroscope inspection of each air intake cowl assembly of each engine to detect cracked or fractured piccolo tubes, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011. If any cracked or fractured piccolo tube is found: Before further flight, replace the affected engine air intake cowl with a new or serviceable engine air intake cowl, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011.

(1) For any engine air intake cowl that has accumulated fewer than 5,000 flight cycles since its first installation on an airplane as of the effective date of this AD: Inspect within 24 months after the engine air intake cowl has accumulated 5,000 total flight cycles.

(2) For any engine air intake cowl that has accumulated 5,000 or more flight cycles since its first installation on an airplane as of the effective date of this AD: Inspect within 24 months after the effective date of this AD.

(h) Piccolo Link Inspection

If the inspection findings of paragraph (g) of this AD indicate no cracked or fractured piccolo tube: Before further flight, do a boroscope inspection of the piccolo tube links to detect broken links, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011. If no broken links are found: Before further flight, do the actions required by paragraph (i) of this AD.

(1) If four or more broken piccolo tube links are found: Before further flight, replace the affected engine air intake cowl with a new or serviceable engine air intake cowl, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011.

(2) If three or fewer broken piccolo tube links are found, and the opposite engine air intake cowl of the same airplane has accumulated 5,000 flight cycles or less since the engine air intake cowl was first installed on an airplane: Before further flight, do the actions in Figure A–FBBAA-Sheet 03, Flow Chart, of Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011, as required by paragraph (i) of this AD.

(3) If three or fewer broken piccolo tube links are found, and the opposite engine air intake cowl of the same airplane has accumulated more than 5,000 flight cycles since the engine air intake cowl was first installed on an airplane: Before further flight, do a boroscope inspection of the piccolo tube links of the opposite engine air intake cowl side to detect broken links, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011.

(i) If the inspection findings of the piccolo tube links of the opposite engine air intake cowl side indicate no broken piccolo tube links: Before further flight, do the actions required by paragraph (i) of this AD.

(ii) If the inspection findings of the piccolo tube links of the opposite engine air intake cowl side indicate one or more broken piccolo tube links: Before further flight, do the actions specified in Note 01 of Figure A–FBBAA-Sheet 02, Flow Chart, of Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011, at the time specified in Note 01 of Figure A–FBBAA-Sheet 02, Flow Chart, of Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011, except for the instructions to ''See Sheet 03.'' Where Note 01 of Figure A–FBBAA-Sheet 02, Flow Chart, of Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011, specifies to ''See Sheet 03'' to do a detailed inspection of the OBA and bulkhead, as specified in Rolls-Royce Service Bulletin RB.211–71–AG416, excluding Appendix 1, dated September 3, 2010: This AD requires the detailed inspection specified in Figure A–FBBAA-Sheet 03, Flow Chart, of Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011, to be done in accordance with paragraph (i) of this AD.

(i) Repetitive Outer Boundary Angle and Forward Bulkhead Inspection

If the results of the inspection required by paragraph (h) of this AD indicate no broken piccolo tube links, or if the requirements in paragraph (h)(2) or (h)(3)(ii) of this AD specify to do the actions in Figure A–FBBAA-Sheet 03, Flow Chart, of Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011: Before further flight, do a boroscope inspection of the OBA and forward bulkhead to detect cracks or fractures, in accordance with the Accomplishment Instructions of Airbus

Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011; and the Accomplishment Instructions of Rolls-Royce Service Bulletin RB.211–71–AG416, excluding Appendix 1, dated September 3, 2010.

(1) If the findings of the inspection are within the allowable damage limits, as specified in the Accomplishment Instructions of Rolls-Royce Service Bulletin RB.211–71–AG416, excluding Appendix 1, dated September 3, 2010: Do the actions in paragraphs (i)(1)(i) and (i)(1)(ii) of this AD.

(i) Repeat the inspection of the OBA and forward bulkhead thereafter at the repeat interval specified in Part 3.B. of the Accomplishment Instructions of Rolls-Royce Service Bulletin RB.211–71–AG416, excluding Appendix 1, dated September 3, 2010.

(ii) Repeat the inspections specified in paragraphs (g) and (h) of this AD thereafter at intervals not to exceed 2,500 flight cycles.

(2) If the findings of the inspection are not within the allowable damage limits, as specified in the Accomplishment Instructions of Rolls-Royce Service Bulletin RB.211–71–AG416, excluding Appendix 1, dated September 3, 2010: Do the actions in paragraphs (i)(2)(i) or (i)(2)(ii) of this AD, as applicable.

(i) If any OBA crack is 22 inches or greater, or any forward bulkhead crack is 13 inches or greater: Before further flight, replace the affected engine air intake cowl with a new or serviceable engine air intake cowl, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011.

(ii) If any OBA crack is 15 inches or greater, but less than 22 inches, or any forward bulkhead crack is 9 inches or greater, but less than 13 inches: Within 100 flight cycles, replace the affected engine air intake cowl with a new or serviceable engine air intake cowl, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011.

(j) Repetitive Inspections for Replaced Engine Air Intake Cowls

If any engine air intake cowl is replaced in accordance with the requirements of this AD with an engine air intake cowl that has less than 5,000 flight cycles since the engine air intake cowl was first installed on an airplane: Repeat the inspection required by paragraph (g) of this AD thereafter at the compliance time specified in paragraph (g)(1) of this AD.

(1) If any engine air intake cowl is replaced in accordance with the requirements of this AD with an engine air intake cowl with 5,000 flight cycles or more since the engine air intake cowl was first installed on an airplane: Repeat the inspections required by paragraphs (g) and (h) of this AD thereafter at intervals not to exceed 2,500 flight cycles.

(2) If any engine air intake cowl is replaced in accordance with the requirements of this AD with an engine air intake cowl with 5,000 flight cycles or more since the engine air intake cowl was first installed on an airplane: Repeat the inspections required by paragraph (i) of this AD thereafter at the intervals specified in the Accomplishment Instructions of Rolls-Royce Service Bulletin RB.211–71–AG416, excluding Appendix 1, dated September 3, 2010.

(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: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone (425) 227–1138; fax (425) 227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *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.

(l) Related Information

Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2011–0062, dated April 4, 2011, and the service information specified in paragraphs (l)(1) and (l)(2) of this AD, for related information.

(1) Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011.

(2) Rolls-Royce Service Bulletin RB.211–71–AG416, excluding Appendix 1, dated September 3, 2010.

(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 the AD specifies otherwise.

(i) Airbus Mandatory Service Bulletin A330–71–3025, excluding Appendices 01 and 02, dated January 10, 2011.

(ii) Rolls-Royce Service Bulletin RB.211–71–AG416, excluding Appendix 1, dated September 3, 2010.

(3) For Airbus service information identified in this AD, contact Airbus SAS—Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *airworthiness.A330-A340@airbus.com;* Internet *http://www.airbus.com.*

(4) For Rolls-Royce service information identified in this AD, contact Rolls-Royce Plc, Technical Publications, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; telephone 44 (0) 1332 245882; fax 44 (0) 1332 249936; Internet *http://www.Rolls-Royce.com.*

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

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

Issued in Renton, Washington, on October 26, 2012.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–26892 Filed 11–8–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0679; Directorate Identifier 2012–NM–063–AD; Amendment 39–17246; AD 2012–22–10]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc. Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, Model CL–600–2D15 (Regional Jet Series 705) airplanes, Model CL–600–2D24 (Regional Jet Series 900) airplanes, and Model CL–600–2E25 (Regional Jet Series 1000) airplanes. This AD was prompted by a report that certain wing-to-fuselage attachment nuts do not conform to the certification design requirements for dual locking features. This AD requires repetitive inspections to determine that cotter pins are installed at affected wing-to-fuselage attachment joints and replacement if necessary. We are issuing this AD to prevent loss of wing-to-fuselage attachment joints, which could result in the loss of the wing.

DATES: This AD becomes effective December 14, 2012.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 14, 2012.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey Zimmer, Aerospace Engineer, Airframe & Mechanical Systems Branch, ANE–171, New York Aircraft Certification Office (ACO), FAA, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228–7306; fax (516) 794–5531.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on July 11, 2012 (77 FR 40826). That NPRM proposed to correct an unsafe condition for the specified products. The Mandatory Continuing Airworthiness Information (MCAI) states:

> The manufacturer has determined that wing-to-fuselage attachment nuts, part number (P/N) SH670–35635–1, SH670–35440–951, SH670–35440–3, SH670–35635–1 and 95136D–2412, installed at six attachment joint locations, do not conform to the certification design requirements for dual locking features. The nuts are not of the self-locking type as required and do not provide the frictional thread interference required to prevent the nut from backing off the bolt. As a result, only a single locking device, the cotter pin, is provided at these critical joints. In the case where a nut becomes loose, in combination with a missing or broken cotter pin, the attachment bolt at the wing-to-fuselage joint could migrate and fall out. Loss of two attachment joints could potentially result in the loss of the wing.
>
> This [Transport Canada Civil Aviation] Airworthiness Directive (AD) mandates a [repetitive] detailed visual inspection (DVI) of each affected wing-to-fuselage attachment joint to ensure that a cotter pin is installed.

The required actions also include replacing any missing cotter pin. You may obtain further information by examining the MCAI in the AD docket.

Comments

We gave the public the opportunity to participate in developing this AD. We have considered the comment received.

Request for Credit for Previous Actions

Mesa Airlines requested that paragraph (i) of the NPRM (77 FR 40826, July 11, 2012), regarding credit for the previous actions, be revised to include credit for Bombardier Maintenance Review Board Report 57–10–305, Task 000–53–170–501, Detailed Inspection of the Wing-to-Fuselage Attachment Fittings—FS708.00, FS752.00, and FS797.00 at LBL45.0 and RBL45.0, as compliance for the initial inspection specified in paragraph (g) of the NPRM.

We disagree with the request to give credit for the initial inspection by accomplishing the task specified by the commenter. The intent of this AD is to ensure cotter pin installation, and while Task 000–53–170–501 inspects for corrosion and general condition of the wing attachment fittings, it does not specify inspecting the cotter pins. Therefore, the cotter pins could be missed during the inspection in Task 000–53–170–501. We have not changed the AD in this regard.

Conclusion

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

- Are consistent with the intent that was proposed in the NPRM (77 FR 40826, July 11, 2012) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (77 FR 40826, July 11, 2012).

Costs of Compliance

We estimate that this AD will affect 366 products of U.S. registry. We also estimate that it will take about 5 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $155,550, or $425 per product.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD. 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 AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM (77 FR 40826, July 11, 2012), the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator,

the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2012–22–10 Bombardier, Inc.: Amendment 39–17246. Docket No. FAA–2012–0679; Directorate Identifier 2012–NM–063–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective December 14, 2012.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, serial numbers 10002 through 10999 inclusive; Model CL–600–2D15 (Regional Jet Series 705) and CL–600–2D24 (Regional Jet Series 900) airplanes, serial numbers 15001 through 15990 inclusive; and Model CL–600–2E25 (Regional Jet Series 1000) airplanes, serial numbers 19001 through 19990 inclusive; certificated in any category.

(d) Subject

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

(e) Reason

This AD was prompted by a report that certain wing-to-fuselage attachment nuts do not conform to the certification design requirements for dual locking features. We are issuing this AD to prevent loss of wing-to-fuselage attachment joints, which could result in the loss of the wing.

(f) Compliance

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

(g) Repetitive Detailed Inspection

Within 3,000 flight hours or 18 months after the effective date of this AD, whichever occurs first: Perform a detailed inspection of each affected wing-to-fuselage attachment joint, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 670BA–53–042, Revision A, dated April 27, 2012. Repeat the inspection thereafter at intervals not to exceed 6,600 flight hours.

Note 1 to paragraph (g) of this AD: The compliance time in this AD differs from the recommended compliance time specified in Bombardier Service Bulletin 670BA–53–042, Revision A, dated April 27, 2012.

(h) Corrective Action

If any cotter pin is found missing during any inspection required by paragraph (g) of this AD: Before further flight, replace any missing cotter pin using a method approved by either the Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA; or Transport Canada Civil Aviation (or its delegated agent).

(i) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 670BA–53–042, dated December 21, 2011, which is not incorporated by reference in this AD.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO, ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone (516) 228–7300; fax (516) 794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

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

(k) Related Information

(1) Refer to MCAI Canadian Airworthiness Directive CF–2012–10, dated March 12, 2012; and Bombardier Service Bulletin 670BA–53–042, Revision A, dated April 27, 2012; for related information.

(2) For Bombardier service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.*

(l) Material Incorporated by Reference

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

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

(i) Bombardier Service Bulletin 670BA–53–042, Revision A, dated April 27, 2012.

(ii) Reserved.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.*

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

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

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

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–26961 Filed 11–8–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 400

[Docket No. FAA–2012–0318; Amdt. No. 400–4]

RIN 2120–AK16

Voluntary Licensing of Amateur Rocket Operations; Withdrawal

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct Final rule, withdrawal.

SUMMARY: The FAA is withdrawing a previously published direct final rule that would have allowed launch operators that conduct certain amateur rocket launches to voluntarily apply for a commercial space transportation license or experimental permit. The FAA is withdrawing this action because of the adverse comments it received.

DATES: The direct final rule published on August 22, 2012, at 77 FR 50584 is withdrawn, effective November 8, 2012.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact Shirley McBride, Senior Transportation Industry Analyst, Office of Commercial Space Transportation, Regulations and Analysis Division, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–7470; facsimile (202) 267–5463;

email *Shirley.McBride@faa.gov*. For legal questions concerning this action, contact Laura Montgomery, Senior Attorney for Commercial Space Transportation, Office of the Chief Counsel, Regulations Division, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–3150; facsimile (202) 267–7971; email *laura.montgomery@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

On August 22, 2012, the FAA published a direct final rule that would have amended the scope of its chapter III regulations to give operators of Class 3 advanced high-power rockets the option of applying for a chapter III launch license or permit, or continuing to operate under 14 CFR chapter I, part 101. The direct final rule would have been strictly voluntary. Only those operators that wished to apply under chapter III for a license needed to do so. However, once an operator accepted an FAA license or permit, part 101 would no longer have applied, and the operator would have been governed by the provisions of chapter III for those rockets.

The Commercial Space Launch Act provides that the United States should encourage private sector launches, reentries, and associated services. The FAA initiated the direct final rule primarily to support those launch operators that, under contract with NASA, were required by NASA to obtain an FAA launch license. Because the rule was strictly voluntary, the FAA believed there was good cause to issue it as a direct final rule.

Reason for Withdrawal

The FAA is withdrawing the direct final rule because the agency received several adverse comments. In brief, the commenters raised issues concerning the potential cost to small businesses and the government, both in terms of the resources necessary for preparing and evaluating applications and in terms of the conditional payment of excess claims commonly referred to as ''indemnification.'' Others expressed doubts about whether amateur rockets could ever meet chapter III requirements, whether applying those requirements to smaller vehicles made sense or was necessary, and whether safety issues were created.

Conclusion

Withdrawal of Amendment No. 400–4 does not preclude the FAA from a rulemaking on the subject in the future or committing the agency to any future course of action.

The FAA withdraws Amendment No. 400–4 published at 77 FR 50584 on August 22, 2012.

Issued in Washington, DC, on November 6, 2012.

Michael P. Huerta,

Acting Administrator.

[FR Doc. 2012–27503 Filed 11–7–12; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1926

[Docket ID–OSHA–2012–0025]

RIN 1218–AC75

Revising the Exemption for Digger Derricks in the Cranes and Derricks in Construction Standard

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

ACTION: Direct final rule.

SUMMARY: OSHA is broadening the exemption for digger derricks in its standard for cranes and derricks. OSHA issued a final standard updating the requirements for cranes and derricks on August 9, 2010, and the Edison Electric Institute (EEI) petitioned for review of the standard in the United States Court of Appeals. After petitioning, EEI provided OSHA with new information regarding digger derricks. OSHA reviewed the additional information and the rulemaking record, and decided to broaden the exemption for digger derricks used in the electric-utility industry by means of this direct final rule.

DATES: This direct final rule will become effective on February 7, 2013, unless OSHA receives significant adverse comment to this direct final rule by December 10, 2012. All submissions, whether transmitted, mailed, or delivered, must bear a postmark or provide other evidence of the submission date.

ADDRESSES: Submit comments (including comments to the information-collection (paperwork) determination described under the section titled AGENCY DETERMINATIONS), hearing requests, and other information and materials, identified by Docket No. OSHA–2012–0025, by any of the following methods:

Electronically: Submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: OSHA allows facsimile transmission of comments that are 10 pages or fewer in length (including attachments). Fax these documents to the OSHA Docket Office at (202) 693–1648; OSHA does not require hard copies of these documents. Instead of transmitting facsimile copies of attachments that supplement these documents (*e.g.,* studies, journal articles), commenters must submit these attachments to the OSHA Docket Office, Technical Data Center, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210. These attachments must clearly identify the sender's name, the date, and the docket number (OSHA–2012–0025), so that the Docket Office can attach them to the appropriate document.

Regular or express mail, hand delivery, or messenger (courier) service: Submit comments and any additional information or material to the OSHA Docket Office, Docket No. OSHA–2012–0025 or RIN No. 1218–AC75, Technical Data Center, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210; telephone: (202) 693–2350. (OSHA's TTY number is (877) 889–5627.) Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by express mail, hand delivery, and messenger service. The Docket Office will accept deliveries (express mail, hand delivery, and messenger service) during the Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m. ET.

Docket: To read or download comments or other information or material in the docket, go to *http://www.regulations.gov* or to the OSHA Docket Office at the address above. Documents in the docket are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not available publicly to read or download through this Web site. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT: *General information and press inquiries:* Mr. Frank Meilinger, Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington,

DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

Technical inquiries: Mr. Garvin Branch, Directorate of Construction, Room N–3468, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2020; fax: (202) 693–1689; email: *branch.garvin@dol.gov.*

For copies of this ***Federal Register*** *notice, news releases, and other relevant document:* Electronic copies of these documents are available at OSHA's Web page at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Request for Comment
II. Direct Final Rulemaking
III. Discussion of the Digger-Derrick Exemption in 29 CFR 1926, Subpart CC
A. Background
B. Changes to the Text of the Exemption in 29 CFR 1926.1400(c)(4)
C. Discussion of Conforming Revisions to 29 CFR 1926, Subpart V (Power Transmission and Distribution)
IV. Agency Determinations
A. Significant Risk
B. Final Economic Analysis and Final Regulatory Flexibility Analysis
C. Technological Feasibility
D. Paperwork Reduction Act of 1995
E. Federalism
F. State Plan States
G. Unfunded Mandates Reform Act
H. Consultation and Coordination With Indian Tribal Governments
List of Subjects in 29 CFR Part 1926
Authority and Signature
Amendments to Standards

I. Request for Comment

OSHA requests comments on all issues related to this direct final rule, including economic, paperwork, or other regulatory impacts of this rule on the regulated community. If OSHA receives no significant adverse comment, OSHA will publish a **Federal Register** document confirming the effective date of this direct final rule and withdrawing the companion proposed rule published in the ''Proposed Rules'' section of today's **Federal Register**. Such confirmation may include minor stylistic or technical changes to the document. For the purpose of judicial review, OSHA views the date of confirmation of the effective date of this direct final rule as the date of promulgation.

II. Direct Final Rulemaking

In direct final rulemaking, an agency publishes a direct final rule in the **Federal Register** with a statement that the rule will go into effect unless the agency receives significant adverse comment within a specified period. The agency may publish an identical proposed rule at the same time. If the agency receives no significant adverse comment in response to the direct final rule, the rule goes into effect. OSHA typically confirms the effective date of a direct final rule through a separate **Federal Register** notice. If the agency receives a significant adverse comment, the agency withdraws the direct final rule and treats such comment as a response to the proposed rule. An agency typically uses direct final rulemaking when an agency anticipates that a rule will not be controversial.

For purposes of this direct final rule, a significant adverse comment is one that explains why the amendments to OSHA's digger-derrick exemption would be inappropriate. In determining whether a comment necessitates withdrawal of the direct final rule, OSHA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. OSHA will not consider a comment recommending an additional amendment to be a significant adverse comment unless the comment states why the direct final rule would be ineffective without the addition. Furthermore, OSHA will not consider a comment requesting any narrowing of the existing digger-derrick exemption to be a significant adverse comment because narrowing the existing exemption is beyond the scope of this rulemaking. Moreover, a comment requesting an expansion of the exemption to encompass activities not related to digger-derrick use by electric utilities also would be beyond the scope of this rulemaking, and OSHA will not consider such a comment to be a significant adverse comment unless the commenter explains why the provisions of the direct final rule, as these provisions apply to digger derricks, would be ineffective without the expansion.

In addition to publishing this direct final rule, OSHA is publishing a companion proposed rule in the ''Proposed Rules'' section of today's **Federal Register**. The comment period for the proposed rule runs concurrently with that of the direct final rule. OSHA also will treat comments received on the companion proposed rule as comments regarding the direct final rule. Likewise, OSHA will consider significant adverse comment submitted to the direct final rule as comment to the companion proposed rule. Therefore, if OSHA receives a significant adverse comment on either this direct final rule or the proposed rule, it will publish a timely withdrawal of this direct final rule and proceed with the companion proposed rule. In the event that OSHA withdraws the direct final rule because of significant adverse comment, OSHA will consider all timely comments received in response to the direct final rule when it continues with the proposed rule. After carefully considering all comments to the direct final rule and the proposal, OSHA will decide whether to publish a new final rule. OSHA determined that the subject of this rulemaking is suitable for direct final rulemaking. OSHA originally included the digger-derrick exemption in the proposed Cranes and Derricks in Construction standard as a result of negotiated rulemaking involving stakeholders from many affected sectors. The existing rule for Cranes and Derricks in Construction, subpart CC of 29 CFR 1926, exempts the majority of digger derricks used in the telecommunications and electric-utility industries from the requirements of that subpart. Because the revision specified in this direct final rule extends the exemption to a small number of digger derricks used in the electric-utility industry, and does not impose any new costs or duties, OSHA does not expect objections from the public to this rulemaking action.

III. Discussion of the Digger-Derrick Exemption in 29 CFR 1926, Subpart CC

A. Background of the Digger-Derrick Exemption

A ''digger derrick'' or ''radial boom derrick'' is a specialized type of equipment designed to install utility poles. A digger derrick typically is equipped with augers to drill holes for the poles and with a hydraulic boom to lift the poles and set them in the holes. Employers also use the booms to lift objects other than poles; accordingly, electric utilities, telecommunication companies, and their contractors use booms both to place objects on utility poles and for general lifting purposes at worksites (Docket ID OSHA–2007–0066–0139.1). When OSHA promulgated subpart V (Power Transmission and Distribution) in 1972, it excluded digger derricks from certain requirements of 29 CFR 1926, subpart N, the predecessor to the current 29 CFR 1926, subpart CC, standard.

OSHA developed the proposed standard for cranes and derricks in construction through a negotiated rulemaking involving stakeholders from many affected sectors. The proposed standard included a limited exemption for digger derricks (73 FR 59714, 59916 (Oct. 9, 2008)). After the publication of the proposed rule, OSHA received many

comments criticizing the scope of the exemption because the scope applied to digger derricks designed for the electric-utility industry, and then only when used to dig holes for utility work. Commenters noted that customary use of the digger derrick also involved placing a pole in the hole and attaching transformers and other items to the pole. Commenters complained that the exemption would be largely meaningless unless it also encompassed these functions. Several representatives of the telecommunications industry noted that the industry used digger derricks routinely for similar purposes, and requested that OSHA expand the digger-derrick exemption to encompass telecommunications work in addition to electric-utility work (Docket ID OSHA–2007–0066–0234 and OSHA–2007–0066–0129.1).

When OSHA issued the final Cranes and Derricks in Construction rule, it noted concerns about the scope of the exemption, and broadened the scope of the exemption (see 75 FR 47906, 47924–47926, and 48136 (Aug. 9, 2010)). Current subpart CC, therefore, exempts digger derricks used by both the electric-utility and the telecommunications industries, and encompasses all pole work in these industries, including placing utility poles in the ground and attaching transformers and other equipment to the poles (see 29 CFR 1400(c)(4)). In that exemption, OSHA clarifies that digger derricks in construction that are exempt from subpart CC must still comply with the applicable worker protections in the OSHA standards governing electric-utility and telecommunications work at §§ 1910.268 and 1910.269. The existing exemption in § 1926.1400(c) states that the subpart does not cover digger derricks when used for augering holes for poles carrying electric and telecommunication lines, placing and removing the poles, and for handling associated materials to be installed on or removed from the poles. Digger derricks used in work subject to 29 CFR part 1926, subpart V, must comply with 29 CFR 1910.269. Digger derricks used in construction work for telecommunication service (as defined at 29 CFR 1910.268(s)(40)) must comply with 29 CFR 1910.268.

When the activities are exempt from subpart CC of 29 CFR 1926, they must still comply with all other applicable construction standards, such as 29 CFR 1926, subpart O (Motor Vehicles, Mechanized Equipment, and Marine Operations), and subpart V.[1]

On October 6, 2010, Edison Electrical Institute petitioned for review of the Cranes and Derricks in Construction standard in the U.S. Court of Appeals for the District of Columbia. During subsequent discussions with OSHA, EEI provided new information to OSHA regarding the use of digger derricks in the electric-utility industry and the resulting impact on the utilities' operations under the current digger-derrick exemption in subpart CC. According to EEI, the exemption from subpart CC covers roughly 95 percent of work conducted by digger derricks in the electric-utility industry (see OSHA–2012–0025–0004 for EEI Dec. 7, 2010, letter, page 2). The majority of the work under the remaining five percent is work that is closely related to the exempted work. *Id.* For example, when electric utilities use digger derricks to perform construction work involving pole installations, the same digger-derrick crew that performs the pole work typically installs pad-mount transformers on the ground as part of the same power system as the poles. While the pole work is exempt under 29 CFR 1926.1400(c)(4), the placement of the pad-mount transformer on the ground is not.

Furthermore, in comparison to currently exempted pole work, OSHA believes most (if not all) of the remaining five percent of work is at least as safe. Weight measurements provided by EEI demonstrate that transformers placed on a pad on the ground are roughly the same weight as, or in some cases lighter than, the weight of the transformers lifted onto the poles, or the poles themselves (see OSHA–2012–0025–0003 for EEI handout, ''Typical Weights'' chart).[2] In addition, electric utilities typically place distribution transformers in a right of way along front property lines, close to a roadway, or along rear property lines, irrespective of whether the transformers are pole- or pad-mounted. In those cases, the lifting radius of a digger derrick placing a transformer on a pad is similar to the lifting radius of a digger derrick placing a transformer on a pole. Consequently, the lifting forces on a digger derrick should be approximately the same regardless of whether the transformer is pole- or pad-mounted (see, e.g., OSHA–2012–0025–0003). Finally, the approximate height of the transformer relative to the employee installing the transformer is the same for the two types of transformers. An employee installing a pad-mounted transformer is on the ground, near the pad, whereas an employee installing a pole-mounted transformer is either on the pole, or in an aerial lift, near the mounting point for the transformer. In either case, the transformer would be around the same height as the employee.

Because the same workers generally perform both types of work, utility employers must, when the standard becomes fully effective in November 2014, incur the cost of meeting all other requirements in subpart CC, including the operator-certification requirements, for those workers to perform the five percent of the work not currently exempted. The result could be a sizable cost (about $21.6 million annually) for an activity that does not appear significantly more dangerous than the type of activity that OSHA already exempted. (See Section IV.B. (Final Economic Analysis and Final Regulatory Flexibility Act Analysis) in this preamble for a summary of these costs.) OSHA did not consider this result when it promulgated the standard.

OSHA acknowledges the arguments that there are minimal safety benefits attributable to imposing the standard's requirements on the remaining five percent of non-exempted work; moreover, the exempted digger-derrick operations are still subject to the protections afforded to workers by OSHA's electric-utility and telecommunications standards (§ 1910.269, subpart V of 29 CFR 1926, and § 1910.268, respectively). OSHA

[1] For telecommunications work, compliance with the provisions of § 1910.268 is a condition of the exemption in § 1926.400(c)(4). The scope limitations in § 1910.268(a) (such as the language stating that it does not apply to construction) are irrelevant to application of the exemption. If an employer uses a digger derrick for telecommunications construction work and does not comply with the provisions in § 1910.268, then that employer fails to qualify for the exemption in § 1926.400(c)(4). As a result, that employer must comply with all of the requirements in subpart CC of part 1926, including the operator-certification requirements in § 1926.1427. If the employer fails to comply with subpart CC, and cannot demonstrate that it complied with § 1910.268 for telecommunications work, or § 1910.269 for electric-utility work, then OSHA will cite the employer under subpart CC (not § 1910.268 or § 1910.269). If the employer demonstrates that it complies with the exemption in subpart CC, but does not comply with the separate requirements in subpart O applicable to all motorized vehicles in construction, then OSHA will cite the employer under subpart O. Note that this explanation does not suggest that OSHA is restricting its enforcement discretion on whether to issue citations at all.

[2] EEI's chart does not show weights for concrete and plastic transformer pads, and EEI did not indicate that utilities use digger derricks to place those pads. If utilities do use digger derricks to lift pads, EEI's presentation indicates that digger derricks lift the transformers separately. Because the surface area of these pads is comparable to the transformers on them, and because these pads are generally only a few hundred millimeters thick, OSHA does not believe that the pads weigh any more than transformers or poles.

also notes that the largest labor organization for workers in the electric-utility industry, the International Brotherhood of Electrical Workers, participated in settlement discussions, corroborated the general validity of the information provided by EEI, and actively supported EEI's request for an expanded digger-derrick exemption. In light of these factors, OSHA is removing the burdens on employers for the remaining five percent of non-exempted work, and revising the digger-derrick exemption to include all digger derricks used in construction work subject to 29 CFR 1926, subpart V. Based on its estimates in the Final Economic Analysis in the 2010 final rule, the Agency determined that expanding the exemption for digger derricks will enable employers in NAICS 221120 to avoid compliance costs of about $15.9 million per year, while employers in NAICS 221110 will avoid about $5.7 million per year, for a total cost savings of about $21.6 million annually.

When the Agency promulgated the final Cranes and Derricks in Construction rule, OSHA's primary concern about extending the digger-derrick exemption beyond pole work was that such an extension would provide employers with an incentive to use digger derricks on construction sites to perform construction tasks normally handled by cranes—tasks that are beyond the original design capabilities of a digger derrick. In discussing this concern, OSHA stated, ''[T]he general lifting work done at those other worksites would be subject to this standard if done by other types of lifting equipment, and the same standards should apply as apply to that equipment * * *.'' (75 FR 47925). OSHA acknowledges that revising the exemption would extend the digger-derrick exemption to include some work at substations. However, EEI indicated that the employers in the electric-utility industry limit such uses to assembly or arrangement of substation components, and that these employers use other types of cranes instead of digger derricks to perform lifting and installation work at substations (see OSHA–2012–0025–0005 for Jan. 2011 EEI letter). If OSHA finds that, should this direct final rule become a final rule, employers are using digger derricks increasingly for other tasks, the Agency may revisit this issue and adjust the exemption accordingly. The Agency also recognizes that, because the exemption only applies to work subject to the electrical-power and telecommunications standards, employers cannot use digger derricks within this exemption to perform unrelated tasks such as the construction of a building or the foundation or structural components of a substation before the installation of electric power-transmission or power-distribution equipment. A digger derrick used for this type of construction will still be subject to the requirements in 29 CFR 1926, subpart CC, and operators will have to be certified in accordance with § 1926.1427.

B. Changes to the Text of the Exemption in 29 CFR 1926.1400(c)(4)

OSHA is revising the exemption in 29 CFR 1926.1400(c)(4) to include within the exemption ''any other work subject to subpart V of 29 CFR part 1926.'' This revision expands the exemption to remove from coverage under subpart CC of 29 CFR 1926 the types of non-pole, digger-derrick work described by EEI. OSHA is not expanding the exemption for pole work performed by employers in the telecommunications industry because no party raised or requested such an exemption in the litigation; therefore, this issue is outside the scope of this rulemaking.

The Agency also is making several minor clarifications to the text of the exemption. First, OSHA is making a minor grammatical clarification by replacing ''and'' with ''or'' in the phrase ''poles carrying electric *or* telecommunication lines'' (emphasis added). This revision will ensure that the regulated community does not misconstrue the exemption as limited to poles that carry both electric and telecommunications lines. This clarification is consistent with OSHA's explanation in the preamble of the Cranes and Derricks in Construction final rule (see 75 FR 47925).

Second, OSHA is adding the phrase ''to be eligible for this exclusion'' at the beginning of the sentence requiring compliance with § 1910.268 and subpart V of 29 CFR 1926, respectively. This revision limits the exemption to the use of digger derricks that comply with the requirements in subpart V or § 1910.268; if an employer uses a digger derrick for subpart V or telecommunications work without complying with all of the requirements in subpart V or § 1910.268, then the work is not exempt, and the employer must comply with all of the requirements of subpart CC of 29 CFR 1926. This clarification is consistent with OSHA's explanation of the exemption in the preamble of the final rule (see 75 FR 47925–47926).

Third, OSHA is replacing the reference to § 1910.269 with a reference to 29 CFR 1926, subpart V. The current exemption in § 1926.1400(c)(4) requires employers using digger derricks for work covered by subpart V to comply with the requirements in § 1910.269. However, in the 2010 final rule for Cranes and Derricks in Construction, OSHA also revised 29 CFR 1926.952(c)(2) of subpart V to require digger derricks used for the purposes exempted from subpart CC to comply with § 1910.269. Thus, although the revised exemption in this direct final rule specifies compliance with subpart V instead of § 1910.269, there is no substantive revision to digger derricks used for augering holes and handling associated materials. The primary purpose for this revision is to harmonize the § 1926.1400(c)(4) exemption with 29 CFR 1926.952(c)(2) to ensure that non-pole digger-derrick work covered by subpart V receives the same protections as pole work covered by subpart V.

C. Discussion of Conforming Revisions to 29 CFR 1926, Subpart V

As part of this harmonizing process, OSHA also is revising the corresponding provision in subpart V that requires compliance with § 1910.269 for all digger-derrick work exempted from subpart CC, including §§ 1910.269(p) (Mechanical equipment), 1910.269(a)(2) (Training), and 1910.269(l) (Working on or near exposed energized parts) (see new 29 CFR 1926.952(c)(2)). When OSHA promulgated subpart CC of 29 CFR 1926 in 2010, the Agency also revised § 1926.952(c)(2) in subpart V of its construction standards (75 FR 48135). The revision mirrored the terminology in the digger-derrick exemption in § 1926.1400(c)(4), and required employers using digger derricks so exempted to comply with § 1910.269 (Electric power generation, transmission, and distribution). In making this revision, the Agency noted that it added specific minimum clearance-distance requirements, which are applicable to subpart V work, to the cranes and derricks in construction rules at subpart CC, and explained that it revised § 1926.952(c) to require digger derricks to comply with § 1910.269 to provide ''comparable safety requirements'' (75 FR 47921).

As revised, paragraph § 1926.952(c)(2) requires employers using digger derricks for subpart V work and, thus, not subject to the requirements of subpart CC of 29 CFR 1926, to comply with the requirements in § 1910.269. OHSA also is clarifying that paragraph (c)(2) applies in addition to, not in place of, the general requirement in § 1926.952(c) that all equipment (including digger derricks) must comply with subpart O of 29 CFR 1926. As noted in the preamble to the subpart CC final rule, OSHA

currently is developing a rule that will amend subpart V to avoid inconsistencies between subpart V of the construction standards and § 1910.269 (see 70 FR 34822 (June 15, 2005)). Pending completion of that rulemaking, digger derricks excluded from subpart CC of 29 CFR 1926 will be subject to the same requirements regardless of whether employers use them for work covered by subpart V or work covered by § 1910.269, and regardless of whether employers use them for pole work or other subpart V work.

IV. Agency Determinations

A. Significant Risk

The purpose of the Occupational Safety and Health Act of 1970 (OSH Act; 29 U.S.C. 651 *et al.*) is ''to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources'' (29 U.S.C. 651(b)). To achieve this goal, Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards (29 U.S.C. 654(b), 655(b)). An occupational safety or health standard is a standard that ''requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment'' (29 U.S.C. 652(8)). A standard is reasonably necessary or appropriate within the meaning of Section 652(8) if it substantially reduces or eliminates significant risk (see *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607 (1980)).

This direct final rule does not impose any additional requirements on employers. Because OSHA previously determined that the Cranes and Derricks in Construction standard substantially reduces a significant risk (see 75 FR 47913), it is unnecessary for the Agency to make additional findings on risk for the purposes of this minor amendment to the digger-derrick exemption (see, *e.g., Public Citizen Health Research Group* v. *Tyson,* 796 F.2d 1479, 1502 n.16 (DC Cir. 1986) (rejecting the argument that OSHA must ''find that each and every aspect of its standard eliminates a significant risk'').

B. Final Economic Analysis and Final Regulatory Flexibility Act Analysis

When it issued the final rule for Cranes and Derricks in Construction, OSHA prepared a Final Economic Analysis (FEA) as required by the Occupational Safety and Health Act of 1970 (''OSH Act''; 29 U.S.C. 651 *et seq.*) and Executive Orders 12866 and 13563. OSHA also published a final regulatory flexibility analysis as required by the Regulatory Flexibility Act (5 U.S.C. 601–612).

In the FEA for the final rule (OSHA–2007–0066–0422), the Agency estimated that there were about 10,000 crane operators in NAICS 221110 Electric Power Generation, and about 20,000 crane operators in NAICS 221120 Electric Power Transmission, Control, and Distribution. OSHA based these figures on estimates of the number of construction work crews in these industries from its subpart V FEA, with an allowance (to assure maximum flexibility) that there be three trained crane operators for every work crew. Based on submissions to the record, OSHA estimated that 85 percent of these 30,000 operators (25,500) worked on digger derricks, while 15 percent of the operators operated truck-mounted cranes, or boom trucks; therefore, a total of 25,500 digger-derrick operators would require operator certification.

In its FEA for the final rule, OSHA estimated that the total costs for NAICS 221110 would be $6.7 million ($4 million for operator certification), and the total costs for NAICS 221120 would be $18.7 million annually ($8.7 million for operator certification) (see FEA Table B–9 in the Aug. 9, 2010, FR notice). Fully exempting digger derricks from the scope of the standard also eliminates costs for other activities besides operator certification, such as inspections and power-line safety. In the original FEA, the two main cost components for an industry were the number of crane operators and the number of jobs involving cranes. The original FEA estimated that digger derricks represented 85 percent of operators, and 85 percent of jobs involving cranes. OSHA, therefore, estimates that digger derricks account for 85 percent of the costs attributed to NAICS 221110 and NAICS 221120. Applying this 85 percent factor to the total costs for the industries yields costs for digger derricks of $5.7 million per year in NAICS 221110 and $15.9 million per year in NAICS 221120, for a total of $21.6 million per year.[3]

This direct final rule will eliminate nearly all of the estimated $21.6 million per year in costs associated with digger derricks. These estimated cost savings may be slightly overstated because OSHA noted in its FEA that the cost assumptions might not represent the most efficient way to meet the requirements of the rule. However, OSHA wanted to assure the regulated community that, even with somewhat overstated cost estimates, the rule would still be economically feasible.

In its original FEA (OSHA–2007–0066–0422), OSHA reported an average of 0.5 crane-related fatalities per year in SIC codes NAICS 221110 and NAICS 221120. However, the original FEA did not indicate that any of these fatalities involved digger derricks or other equipment covered by the standard. Moreover, in light of the information provided by EEI, there is no indication that the additional five percent of digger-derrick activity exempted through this rulemaking poses any hazard greater than the hazard posed by the digger-derrick activities OSHA already exempted in the 2010 final rule.

Because this direct final rule estimates cost savings of $21.6 million per year, this direct final rule is not economically significant within the meaning of Executive Order 12866 (58 FR 51735). The rule does not impose additional costs on any private-sector or public-sector entity, and does not meet any of the criteria for an economically significant or major rule specified by Executive Order 12866 and the relevant statutes. This rule is not a ''major rule'' under Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*).

OSHA developed this direct final rule consistent with the provisions of Executive Orders 12866 and 13563. Accordingly, this direct final rule follows closely the principle of EO 13563 that agencies should use new data developed after completion of a rulemaking (retrospective analysis) to determine if a regulation ''should be modified, streamlined, expanded, or repealed.'' In this case, review of data submitted after completion of the initial rulemaking provided OSHA with the opportunity to streamline a rule by dropping its application to digger derricks, thereby saving the industry an estimated $21.6 million per year. As

[3] Based on the size of digger derricks and EEI's descriptions of digger-derrick activities, OSHA understands that the vast majority of digger-derrick use for construction activity in the electric-utility industry will involve transmission and distribution work subject to subpart V of 29 CFR 1926. Employers categorized under NAICS 221120 generally conduct electric-transmission and -distribution work. However, OSHA is including digger derricks under NAICS 221110, which is the SIC code for power generation, because some employers may be under that SIC code because their primary work is in that area, but those employers also may engage in transmission work covered by subpart V. Because the record does not indicate that employers use digger derricks for power-generation construction activities, OSHA assumes that the use of digger derricks under NAICS 221110 is for subpart V work.

described previously, this action removes duties and costs for the electric-utility industry, and does not impose any new duties on any employer. Because small entities will have reduced costs as a result of this direct final rule, the Agency certifies that the final standard would not impose significant economic costs on a substantial number of small entities.

C. Technological Feasibility

A standard is technologically feasible when the protective measures it requires already exist, when available technology can bring the protective measures into existence, or when that technology is reasonably likely to develop (see *American Textile Mfrs. Institute* v. *OSHA,* 452 U.S. 490, 513 (1981) (ATMI); *American Iron and Steel Institute* v. *OSHA,* 939 F.2d 975, 980 (DC Cir. 1991) (AISI)). This direct final rule does not require any additional protective measures. In the original FEA, OSHA found the standard to be technologically feasible (75 FR 48079). OSHA concludes that this revision is feasible as well because it reduces or removes current requirements on employers.

D. Paperwork Reduction Act of 1995

When OSHA issued the final rule on August 9, 2010, the Agency submitted an Information Collection Request (ICR) to OMB titled *Cranes and Derricks in Construction (29 CFR Part 1926 Subpart CC).* On November 1, 2010, OMB approved the ICR under OMB Control Number 1218–0261, with an expiration date of November 30, 2013. Subsequently, in December 2010, OSHA discontinued the *Cranes and Derricks Standard for Construction (29 CFR 1926.550)* ICR (OMB Control Number 1218–0113) because the new ICR superseded this ICR. In addition, OSHA retitled the new ICR to *Cranes and Derricks in Construction (29 CFR Part 1926, Subpart CC and Subpart DD).*

This direct final rule, which expands the digger-derrick exemption, does not require any additional collection of information or alter the substantive requirements detailed in the 2010 ICR. The only impact on the collection of information will be a reduction in the number of entities collecting information. Accordingly, OSHA does not believe it is necessary to submit a new ICR to OMB. OSHA will identify any reduction in burden hours when it renews the ICR.

Interested parties may comment on OSHA's determination that this direct final rule contains no additional paperwork requirements by sending their written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for OSHA, Office of Management and Budget, Room 10235, 726 Jackson Place NW., Washington, DC 20503. The Agency also encourages commenters to submit their comments on this paperwork determination to OSHA, along with their other comments on this direct final rule, within the specified comment period.

OSHA notes that a federal agency cannot conduct or sponsor a collection of information unless it is approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* and the agency also displays a currently valid OMB control number for the collection of information, and that the public need not respond to a collection of information requirement unless the agency displays a currently valid OMB control number. Also, notwithstanding any other provisions of law, no person shall be subject to a penalty for failing to comply with a collection of information requirement if the requirement does not display a currently valid OMB control number.

E. Federalism

OSHA reviewed this direct final rule in accordance with the Executive Order on Federalism (Executive Order 13132 (64 FR 43255 (Aug. 10, 1999))), which requires that Federal agencies, to the extent possible, refrain from limiting state policy options, consult with states prior to taking any actions that would restrict state policy options, and take such actions only when clear constitutional authority exists and the problem is national in scope. Executive Order 13132 provides for preemption of state law only with the expressed consent of Congress. Federal agencies must limit any such preemption to the extent possible.

Under Section 18 of the OSH Act, Congress expressly provides that states may adopt, with federal approval, a plan for the development and enforcement of occupational safety and health standards. The OSH Act refers to states that obtain federal approval for such a plan as ''State Plan States'' (29 U.S.C. 667). Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the federal standards. Subject to these requirements, State Plan States are free to develop and enforce under state law their own requirements for safety and health standards.

OSHA previously concluded that its promulgation of subpart CC complies with Executive Order 13132 (75 FR 48128 and 48129). Because the current rulemaking does not impose any additional burdens, that analysis applies to the revision of the digger-derrick exemption. Therefore, this direct final rule complies with Executive Order 13132. In states without OSHA-approved state plans, any standard developed from this direct final rule would impact state policy options in the same manner as every standard promulgated by OSHA. In states with OSHA-approved state plans, this rulemaking does not limit state policy options.

F. State Plan States

When federal OSHA promulgates a new standard or more stringent amendment to an existing standard, the 27 states and U.S. territories with their own OSHA-approved occupational safety and health plans must amend their standards to reflect the new standard or amendment, or show OSHA why such action is unnecessary, *e.g.,* because an existing state standard covering this area is at least as effective in protecting employees as the new federal standard or amendment (29 CFR 1953.5(a)). The state standard must be at least as effective in protecting employees as the final federal rule. State Plan States must issue the standard within six months of the promulgation date of the final federal rule. When OSHA promulgates a new standard or amendment that does not impose additional or more stringent requirements than an existing standard, State Plan States are not required to amend their standards, although OSHA may encourage them to do so.

The 27 states and U.S. territories with OSHA-approved occupational safety and health plans are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. Connecticut, Illinois, New Jersey, New York, and the Virgin Islands have OSHA-approved State Plans that apply to state and local government employees only.

The amendments made in this direct final rule do not impose any new requirements on employers. Accordingly, State Plan States are not required to amend their standards to incorporate the expanded exemption specified in this direct final rule, but they may do so if they so choose.

G. Unfunded Mandates Reform Act

When OSHA issued the final rule for Cranes and Derricks in Construction (75

FR 48130), it reviewed the rule according to the Unfunded Mandates Reform Act of 1995 (UMRA; 2 U.S.C. 1501 *et seq.*) and Executive Order 13132 (64 FR 43255 (Aug. 10, 1999)), and concluded that the final rule did not meet the definition of a ''Federal intergovernmental mandate'' under the UMRA. OSHA's standards do not apply to state or local governments except in states that have voluntarily adopted state plans. OSHA further noted that the rule imposed costs of over $100 million per year on the private sector and, therefore, required review under the UMRA for those costs; the Agency determined that its Final Economic Analysis met that requirement. *Id.*

As discussed above in Section IV.B. (Final Economic Analysis and Final Regulatory Flexibility Act Analysis) of this preamble, this direct final rule reduces expenditures by private-sector employers. For the purposes of the UMRA, OSHA certifies that this direct final rule does not mandate that state, local, or tribal governments adopt new, unfunded regulatory obligations, or increase expenditures by the private sector of more than $100 million in any year.

H. Consultation and Coordination With Indian Tribal Governments

OSHA reviewed this direct final rule in accordance with Executive Order 13175 (65 FR 67249 (Nov. 9, 2000)), and determined that it does not have ''tribal implications'' as defined in that order. This direct final rule does not have substantial direct effects 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.

List of Subjects in 29 CFR Part 1926

Cranes and derricks, Construction industry, Occupational safety and health.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC 20210, authorized the preparation of this notice. OSHA is issuing this direct final rule under the following authorities: 29 U.S.C. 653, 655, 657; 40 U.S.C. 3701 *et seq.;* 5 U.S.C. 553; Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012); and 29 CFR part 1911.

Signed at Washington, DC, on October 9, 2012.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Amendments to Standards

For the reasons stated in the preamble of this direct final rule, OSHA is amending 29 CFR part 1926 as follows:

PART 1926—[AMENDED]

Subpart V—Power Transmission and Distribution.

■ 1. Revise the authority citation for subpart V to read as follows:

Authority: 40 U.S.C. 3701; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order Nos. 12–71 (36 FR 8754); 8–76 (41 FR 25059); 9–83 (48 FR 35736), 1–90 (55 FR 9033), 5–2007 (72 FR 31159), or 1–2012 (77 FR 3912), as applicable. Section 1926.951 also is issued under 29 CFR part 1911.

■ 2. Amend § 1926.952 by revising paragraph (c)(2) to read as follows:

§ 1926.952 Mechanical equipment.

* * * * *

(c). * * *

(2) Use of digger derricks must comply with § 1910.269 (in addition to 29 CFR 1926, subpart O) whenever such use is excluded from 29 CFR 1926, subpart CC, in accordance with § 1926.1400(c)(4).

* * * * *

Subpart CC—Cranes and Derricks in Construction.

■ 3. Revise the authority citation for subpart CC to read as follows:

Authority: 40 U.S.C. 3701; 29 U.S.C. 653, 655, 657; and Secretary of Labor's Order No. 5–2007 (72 FR 31159) or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

■ 4. Amend § 1926.1400 by revising paragraph (c)(4) to read as follows:

§ 1926.1400 Scope.

* * * * *

(c) * * *

(4) Digger derricks when used for augering holes for poles carrying electric or telecommunication lines, placing and removing the poles, and for handling associated materials for installation on, or removal from, the poles, or when used for any other work subject to subpart V of this part. To be eligible for this exclusion, digger-derrick use in work subject to subpart V of this part must comply with all of the provisions of that subpart, and digger-derrick use in construction work for telecommunication service (as defined at § 1910.268(s)(40)) must comply with all of the provisions of § 1910.268.

* * * * *

[FR Doc. 2012–27210 Filed 11–8–12; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 552

Yemen Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (''OFAC'') is issuing regulations to implement Executive Order 13611 of May 16, 2012 (''Blocking Property of Persons Threatening the Peace, Security, or Stability of Yemen''). OFAC intends to supplement this part 552 with a more comprehensive set of regulations, which may include additional interpretive and definitional guidance and additional general licenses and statements of licensing policy.

DATES: *Effective Date:* November 9, 2012.

FOR FURTHER INFORMATION CONTACT: Assistant Director for Sanctions Compliance & Evaluation, tel.: 202/622–2490, Assistant Director for Licensing, tel.: 202/622–2480, Assistant Director for Policy, tel.: 202/622–4855, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202/622–2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*www.treasury.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs also is available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Background

On May 16, 2012, the President issued Executive Order 13611 (77 FR 29533, May 18, 2012) (''E.O. 13611''), invoking the authority of, *inter alia,* the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) and the National Emergencies Act (50 U.S.C. 1601 *et seq.*).

The Department of the Treasury's Office of Foreign Assets Control (''OFAC'') is issuing the Yemen

Sanctions Regulations, 31 CFR part 552 (the ''Regulations''), to implement E.O. 13611, pursuant to authorities delegated to the Secretary of the Treasury in E.O. 13611. A copy of E.O. 13611 appears in Appendix A to this part.

The Regulations are being published in abbreviated form at this time for the purpose of providing immediate guidance to the public. OFAC intends to supplement this part 552 with a more comprehensive set of regulations, which may include additional interpretive and definitional guidance and additional general licenses and statements of licensing policy. The appendix to the Regulations will be removed when OFAC supplements this part with a more comprehensive set of regulations.

Public Participation

Because the Regulations involve a foreign affairs function, the provisions of Executive Order 12866 of September 30, 1993, and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to the Regulations are contained in 31 CFR part 501 (the ''Reporting, Procedures and Penalties Regulations''). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

List of Subjects in 31 CFR Part 552

Administrative practice and procedure, Banking, Banks, Blocking of assets, Brokers, Credit, Foreign Trade, Investments, Loans, Securities, Services, Yemen.

For the reasons set forth in the preamble, the Department of the Treasury's Office of Foreign Assets Control adds part 552 to 31 CFR chapter V to read as follows:

PART 552—YEMEN SANCTIONS REGULATIONS

Subpart A—Relation of This Part to Other Laws and Regulations

Sec.
552.101 Relation of this part to other laws and regulations.

Subpart B—Prohibitions

552.201 Prohibited transactions.
552.202 Effect of transfers violating the provisions of this part.
552.203 Holding of funds in interest-bearing accounts; investment and reinvestment.

Subpart C—General Definitions

552.301 Blocked account; blocked property.
552.302 Effective date.
552.303 Entity.
552.304 Interest.
552.305 Licenses; general and specific.
552.306 Person.
552.307 Property; property interest.
552.308 Transfer.
552.309 United States.
552.310 U.S. financial institution.
552.311 United States person; U.S. person.

Subpart D—Interpretations

§ 552.401 [Reserved]
552.402 Effect of amendment.
552.403 Termination and acquisition of an interest in blocked property.
552.404 Transactions ordinarily incident to a licensed transaction.
552.405 Setoffs prohibited.
552.406 Entities owned by a person whose property and interests in property are blocked.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

552.501 General and specific licensing procedures.
552.502 [Reserved]
552.503 Exclusion from licenses.
552.504 Payments and transfers to blocked accounts in U.S. financial institutions.
552.505 Entries in certain accounts for normal service charges authorized.
552.506 Provision of certain legal services authorized.
552.507 Authorization of emergency medical services.

Subpart F—[Reserved]

Subpart G—[Reserved]

Subpart H—Procedures

552.801 [Reserved]
552.802 Delegation by the Secretary of the Treasury.

Subpart I—Paperwork Reduction Act

552.901 Paperwork Reduction Act notice.

APPENDIX A TO PART 552—Executive Order 13611 of May 16, 2012

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 110–96, 121 Stat. 1011 (50 U.S.C. 1705 note); E.O. 13611, 77 FR 29533, May 18, 2012.

Subpart A—Relation of This Part to Other Laws and Regulations

§ 552.101 Relation of this part to other laws and regulations.

This part is separate from, and independent of, the other parts of this chapter, with the exception of part 501 of this chapter, the recordkeeping and reporting requirements and license application and other procedures of which apply to this part. Actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. Differing foreign policy and national security circumstances may result in differing interpretations of similar language among the parts of this chapter. No license or authorization contained in or issued pursuant to those other parts authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to any other provision of law or regulation authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to this part relieves the involved parties from complying with any other applicable laws or regulations.

Note to § 552.101: This part has been published in abbreviated form for the purpose of providing immediate guidance to the public. OFAC intends to supplement this part with a more comprehensive set of regulations, which may include additional interpretive and definitional guidance and additional general licenses and statements of licensing policy.

Subpart B—Prohibitions

§ 552.201 Prohibited transactions.

All transactions prohibited pursuant to Executive Order 13611 of May 16, 2012, are also prohibited pursuant to this part.

Note 1 to § 552.201: The names of persons designated pursuant to Executive Order 13611, whose property and interests in property therefore are blocked pursuant to this section, are published in the **Federal Register** and incorporated into the Office of Foreign Assets Control's Specially Designated Nationals and Blocked Persons List (''SDN List'') with the identifier ''[YEMEN].'' The SDN List is accessible through the following page on the Office of Foreign Assets Control's Web site: *www.treasury.gov/sdn*. Additional information pertaining to the SDN List can be found in Appendix A to this chapter. *See* § 552.406 concerning entities that may not be listed on the SDN List but whose property and interests in property are nevertheless blocked pursuant to this section.

Note 2 to § 552.201: The International Emergency Economic Powers Act (50 U.S.C. 1701–1706), in Section 203 (50 U.S.C. 1702), authorizes the blocking of property and interests in property of a person during the pendency of an investigation. The names of persons whose property and interests in property are blocked pending investigation pursuant to this section also are published in the **Federal Register** and incorporated into

the SDN List with the identifier ''[BPI–YEMEN].''

Note 3 to § 552.201: Sections 501.806 and 501.807 of this chapter describe the procedures to be followed by persons seeking, respectively, the unblocking of funds that they believe were blocked due to mistaken identity, or administrative reconsideration of their status as persons whose property and interests in property are blocked pursuant to this section.

§ 552.202 Effect of transfers violating the provisions of this part.

(a) Any transfer after the effective date that is in violation of any provision of this part or of any regulation, order, directive, ruling, instruction, or license issued pursuant to this part, and that involves any property or interest in property blocked pursuant to § 552.201, is null and void and shall not be the basis for the assertion or recognition of any interest in or right, remedy, power, or privilege with respect to such property or property interests.

(b) No transfer before the effective date shall be the basis for the assertion or recognition of any right, remedy, power, or privilege with respect to, or any interest in, any property or interest in property blocked pursuant to § 552.201, unless the person who holds or maintains such property, prior to that date, had written notice of the transfer or by any written evidence had recognized such transfer.

(c) Unless otherwise provided, an appropriate license or other authorization issued by the Office of Foreign Assets Control before, during, or after a transfer shall validate such transfer or make it enforceable to the same extent that it would be valid or enforceable but for the provisions of the International Emergency Economic Powers Act, Executive Order 13611, this part, and any regulation, order, directive, ruling, instruction, or license issued pursuant to this part.

(d) Transfers of property that otherwise would be null and void or unenforceable by virtue of the provisions of this section shall not be deemed to be null and void or unenforceable as to any person with whom such property is or was held or maintained (and as to such person only) in cases in which such person is able to establish to the satisfaction of the Office of Foreign Assets Control each of the following:

(1) Such transfer did not represent a willful violation of the provisions of this part by the person with whom such property is or was held or maintained (and as to such person only);

(2) The person with whom such property is or was held or maintained did not have reasonable cause to know or suspect, in view of all the facts and circumstances known or available to such person, that such transfer required a license or authorization issued pursuant to this part and was not so licensed or authorized, or, if a license or authorization did purport to cover the transfer, that such license or authorization had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained; and

(3) The person with whom such property is or was held or maintained filed with the Office of Foreign Assets Control a report setting forth in full the circumstances relating to such transfer promptly upon discovery that:

(i) Such transfer was in violation of the provisions of this part or any regulation, ruling, instruction, license, or other directive or authorization issued pursuant to this part;

(ii) Such transfer was not licensed or authorized by the Office of Foreign Assets Control; or

(iii) If a license did purport to cover the transfer, such license had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained.

Note to paragraph (d) of § 552.202: The filing of a report in accordance with the provisions of paragraph (d)(3) of this section shall not be deemed evidence that the terms of paragraphs (d)(1) and (d)(2) of this section have been satisfied.

(e) Unless licensed pursuant to this part, any attachment, judgment, decree, lien, execution, garnishment, or other judicial process is null and void with respect to any property in which, on or since the effective date, there existed an interest of a person whose property and interests in property are blocked pursuant to § 552.201.

§ 552.203 Holding of funds in interest-bearing accounts; investment and reinvestment.

(a) Except as provided in paragraphs (e) or (f) of this section, or as otherwise directed by the Office of Foreign Assets Control, any U.S. person holding funds, such as currency, bank deposits, or liquidated financial obligations, subject to § 552.201 shall hold or place such funds in a blocked interest-bearing account located in the United States.

(b)(1) For purposes of this section, the term *blocked interest-bearing account* means a blocked account:

(i) In a federally-insured U.S. bank, thrift institution, or credit union, provided the funds are earning interest at rates that are commercially reasonable; or

(ii) With a broker or dealer registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), provided the funds are invested in a money market fund or in U.S. Treasury bills.

(2) Funds held or placed in a blocked account pursuant to paragraph (a) of this section may not be invested in instruments the maturity of which exceeds 180 days.

(c) For purposes of this section, a rate is commercially reasonable if it is the rate currently offered to other depositors on deposits or instruments of comparable size and maturity.

(d) For purposes of this section, if interest is credited to a separate blocked account or subaccount, the name of the account party on each account must be the same.

(e) Blocked funds held in instruments the maturity of which exceeds 180 days at the time the funds become subject to § 552.201 may continue to be held until maturity in the original instrument, provided any interest, earnings, or other proceeds derived therefrom are paid into a blocked interest-bearing account in accordance with paragraphs (a) or (f) of this section.

(f) Blocked funds held in accounts or instruments outside the United States at the time the funds become subject to § 552.201 may continue to be held in the same type of accounts or instruments, provided the funds earn interest at rates that are commercially reasonable.

(g) This section does not create an affirmative obligation for the holder of blocked tangible property, such as chattels or real estate, or of other blocked property, such as debt or equity securities, to sell or liquidate such property. However, the Office of Foreign Assets Control may issue licenses permitting or directing such sales or liquidation in appropriate cases.

(h) Funds subject to this section may not be held, invested, or reinvested in a manner that provides immediate financial or economic benefit or access to any person whose property and interests in property are blocked pursuant to § 552.201, nor may their holder cooperate in or facilitate the pledging or other attempted use as collateral of blocked funds or other assets.

Subpart C—General Definitions

§ 552.301 Blocked account; blocked property.

The terms *blocked account* and *blocked property* shall mean any account or property subject to the prohibitions in § 552.201 held in the

name of a person whose property and interests in property are blocked pursuant to § 552.201, or in which such person has an interest, and with respect to which payments, transfers, exportations, withdrawals, or other dealings may not be made or effected except pursuant to an authorization or license from the Office of Foreign Assets Control expressly authorizing such action.

Note to § 552.301: See § 552.406 concerning the blocked status of property and interests in property of an entity that is 50 percent or more owned by a person whose property and interests in property are blocked pursuant to § 552.201.

§ 552.302 Effective date.

The term *effective date* refers to the effective date of the applicable prohibitions and directives contained in this part, and, with respect to a person whose property and interests in property are blocked pursuant to § 552.201, is the earlier of the date of actual or constructive notice that such person's property and interests in property are blocked.

§ 552.303 Entity.

The term *entity* means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization.

§ 552.304 Interest.

Except as otherwise provided in this part, the term *interest,* when used with respect to property (*e.g.,* ''an interest in property''), means an interest of any nature whatsoever, direct or indirect.

§ 552.305 Licenses; general and specific.

(a) Except as otherwise specified, the term *license* means any license or authorization contained in or issued pursuant to this part.

(b) The term *general license* means any license or authorization the terms of which are set forth in subpart E of this part.

(c) The term *specific license* means any license or authorization not set forth in subpart E of this part but issued pursuant to this part.

Note to § 552.305: *See* § 501.801 of this chapter on licensing procedures.

§ 552.306 Person.

The term *person* means an individual or entity.

§ 552.307 Property; property interest.

The terms *property* and *property interest* include, but are not limited to, money, checks, drafts, bullion, bank deposits, savings accounts, debts, indebtedness, obligations, notes, guarantees, debentures, stocks, bonds, coupons, any other financial instruments, bankers acceptances, mortgages, pledges, liens or other rights in the nature of security, warehouse receipts, bills of lading, trust receipts, bills of sale, any other evidences of title, ownership or indebtedness, letters of credit and any documents relating to any rights or obligations thereunder, powers of attorney, goods, wares, merchandise, chattels, stocks on hand, ships, goods on ships, real estate mortgages, deeds of trust, vendors' sales agreements, land contracts, leaseholds, ground rents, real estate and any other interest therein, options, negotiable instruments, trade acceptances, royalties, book accounts, accounts payable, judgments, patents, trademarks or copyrights, insurance policies, safe deposit boxes and their contents, annuities, pooling agreements, services of any nature whatsoever, contracts of any nature whatsoever, and any other property, real, personal, or mixed, tangible or intangible, or interest or interests therein, present, future, or contingent.

§ 552.308 Transfer.

The term *transfer* means any actual or purported act or transaction, whether or not evidenced by writing, and whether or not done or performed within the United States, the purpose, intent, or effect of which is to create, surrender, release, convey, transfer, or alter, directly or indirectly, any right, remedy, power, privilege, or interest with respect to any property. Without limitation on the foregoing, it shall include the making, execution, or delivery of any assignment, power, conveyance, check, declaration, deed, deed of trust, power of attorney, power of appointment, bill of sale, mortgage, receipt, agreement, contract, certificate, gift, sale, affidavit, or statement; the making of any payment; the setting off of any obligation or credit; the appointment of any agent, trustee, or fiduciary; the creation or transfer of any lien; the issuance, docketing, or filing of, or levy of or under, any judgment, decree, attachment, injunction, execution, or other judicial or administrative process or order, or the service of any garnishment; the acquisition of any interest of any nature whatsoever by reason of a judgment or decree of any foreign country; the fulfillment of any condition; the exercise of any power of appointment, power of attorney, or other power; or the acquisition, disposition, transportation, importation, exportation, or withdrawal of any security.

§ 552.309 United States.

The term *United States* means the United States, its territories and possessions, and all areas under the jurisdiction or authority thereof.

§ 552.310 U.S. financial institution.

The term *U.S. financial institution* means any U.S. entity (including its foreign branches) that is engaged in the business of accepting deposits, making, granting, transferring, holding, or brokering loans or credits, or purchasing or selling foreign exchange, securities, or commodity futures or options, or procuring purchasers and sellers thereof, as principal or agent. It includes but is not limited to depository institutions, banks, savings banks, trust companies, securities brokers and dealers, commodity futures and options brokers and dealers, forward contract and foreign exchange merchants, securities and commodities exchanges, clearing corporations, investment companies, employee benefit plans, and U.S. holding companies, U.S. affiliates, or U.S. subsidiaries of any of the foregoing. This term includes those branches, offices, and agencies of foreign financial institutions that are located in the United States, but not such institutions' foreign branches, offices, or agencies.

§ 552.311 United States person; U.S. person.

The term *United States person* or *U.S. person* means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States.

Subpart D—Interpretations

§ 552.401 [Reserved]

§ 552.402 Effect of amendment.

Unless otherwise specifically provided, any amendment, modification, or revocation of any provision in or appendix to this part or chapter or of any order, regulation, ruling, instruction, or license issued by the Office of Foreign Assets Control does not affect any act done or omitted, or any civil or criminal proceeding commenced or pending, prior to such amendment, modification, or revocation. All penalties, forfeitures, and liabilities under any such order, regulation, ruling, instruction, or license continue and may be enforced as if such amendment, modification, or revocation had not been made.

§ 552.403 Termination and acquisition of an interest in blocked property.

(a) Whenever a transaction licensed or authorized by or pursuant to this part results in the transfer of property (including any property interest) away from a person, such property shall no longer be deemed to be property blocked pursuant to § 552.201, unless there exists in the property another interest that is blocked pursuant to § 552.201, the transfer of which has not been effected pursuant to license or other authorization.

(b) Unless otherwise specifically provided in a license or authorization issued pursuant to this part, if property (including any property interest) is transferred or attempted to be transferred to a person whose property and interests in property are blocked pursuant to § 552.201, such property shall be deemed to be property in which that person has an interest and therefore blocked.

§ 552.404 Transactions ordinarily incident to a licensed transaction.

Any transaction ordinarily incident to a licensed transaction and necessary to give effect thereto is also authorized, except:

(a) An ordinarily incident transaction, not explicitly authorized within the terms of the license, by or with a person whose property and interests in property are blocked pursuant to § 552.201; or

(b) An ordinarily incident transaction, not explicitly authorized within the terms of the license, involving a debit to a blocked account or a transfer of blocked property.

§ 552.405 Setoffs prohibited.

A setoff against blocked property (including a blocked account), whether by a U.S. bank or other U.S. person, is a prohibited transfer under § 552.201 if effected after the effective date.

§ 552.406 Entities owned by a person whose property and interests in property are blocked.

A person whose property and interests in property are blocked pursuant to § 552.201 has an interest in all property and interests in property of an entity in which it owns, directly or indirectly, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 552.201, regardless of whether the entity itself is designated pursuant to Executive Order 13611.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

§ 552.501 General and specific licensing procedures.

For provisions relating to licensing procedures, see part 501, subpart E of this chapter. Licensing actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. General licenses and statements of licensing policy relating to this part also may be available through the Yemen sanctions page on OFAC's Web site: *www.treasury.gov/ofac.*

§ 552.502 [Reserved]

§ 552.503 Exclusion from licenses.

The Office of Foreign Assets Control reserves the right to exclude any person, property, transaction, or class thereof from the operation of any license or from the privileges conferred by any license. The Office of Foreign Assets Control also reserves the right to restrict the applicability of any license to particular persons, property, transactions, or classes thereof. Such actions are binding upon actual or constructive notice of the exclusions or restrictions.

§ 552.504 Payments and transfers to blocked accounts in U.S. financial institutions.

Any payment of funds or transfer of credit in which a person whose property and interests in property are blocked pursuant to § 552.201 has any interest that comes within the possession or control of a U.S. financial institution must be blocked in an account on the books of that financial institution. A transfer of funds or credit by a U.S. financial institution between blocked accounts in its branches or offices is authorized, provided that no transfer is made from an account within the United States to an account held outside the United States, and further provided that a transfer from a blocked account may be made only to another blocked account held in the same name.

Note to § 552.504: *See* § 501.603 of this chapter for mandatory reporting requirements regarding financial transfers. *See also* § 552.203 concerning the obligation to hold blocked funds in interest-bearing accounts.

§ 552.505 Entries in certain accounts for normal service charges authorized.

(a) A U.S. financial institution is authorized to debit any blocked account held at that financial institution in payment or reimbursement for normal service charges owed it by the owner of that blocked account.

(b) As used in this section, the term *normal service charges* shall include charges in payment or reimbursement for interest due; cable, telegraph, internet, or telephone charges; postage costs; custody fees; small adjustment charges to correct bookkeeping errors; and, but not by way of limitation, minimum balance charges, notary and protest fees, and charges for reference books, photocopies, credit reports, transcripts of statements, registered mail, insurance, stationery and supplies, and other similar items.

§ 552.506 Provision of certain legal services authorized.

(a) The provision of the following legal services to or on behalf of persons whose property and interests in property are blocked pursuant to § 552.201 is authorized, provided that all receipts of payment of professional fees and reimbursement of incurred expenses must be specifically licensed:

(1) Provision of legal advice and counseling on the requirements of and compliance with the laws of the United States or any jurisdiction within the United States, provided that such advice and counseling are not provided to facilitate transactions in violation of this part;

(2) Representation of persons named as defendants in or otherwise made parties to domestic U.S. legal, arbitration, or administrative proceedings;

(3) Initiation and conduct of legal, arbitration, or administrative proceedings before any U.S. federal, state, or local court or agency;

(4) Representation of persons before any U.S. federal, state, or local court or agency with respect to the imposition, administration, or enforcement of U.S. sanctions against such persons; and

(5) Provision of legal services in any other context in which prevailing U.S. law requires access to legal counsel at public expense.

(b) The provision of any other legal services to persons whose property and interests in property are blocked pursuant to § 552.201, not otherwise authorized in this part, requires the issuance of a specific license.

(c) Entry into a settlement agreement or the enforcement of any lien, judgment, arbitral award, decree, or other order through execution, garnishment, or other judicial process purporting to transfer or otherwise alter or affect property or interests in property blocked pursuant to § 552.201 is prohibited unless licensed pursuant to this part.

§ 552.507 Authorization of emergency medical services.

The provision of nonscheduled emergency medical services in the United States to persons whose property and interests in property are blocked pursuant to § 552.201 is authorized, provided that all receipt of payment for such services must be specifically licensed.

Subpart F—[Reserved]

Subpart G—[Reserved]

Subpart H—Procedures

§ 552.801 [Reserved]

§ 552.802 Delegation by the Secretary of the Treasury.

Any action that the Secretary of the Treasury is authorized to take pursuant to Executive Order 13611 of May 16, 2012 (77 FR 29533, May 18, 2012), and any further Executive orders relating to the national emergency declared therein, may be taken by the Director of the Office of Foreign Assets Control or by any other person to whom the Secretary of the Treasury has delegated authority so to act.

Subpart I—Paperwork Reduction Act

§ 552.901 Paperwork Reduction Act notice.

For approval by the Office of Management and Budget (''OMB'') under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) of information collections relating to recordkeeping and reporting requirements, licensing procedures (including those pursuant to statements of licensing policy), and other procedures, *see* § 501.901 of this chapter. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

Appendix A to Part 552—Executive Order 13611

Executive Order 13611 of May 16, 2012

Blocking Property of Persons Threatening the Peace, Security, or Stability of Yemen

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*) (NEA), and section 301 of title 3, United States Code, I, BARACK OBAMA, President of the United States of America, find that the actions and policies of certain members of the Government of Yemen and others threaten Yemen's peace, security, and stability, including by obstructing the implementation of the agreement of November 23, 2011, between the Government of Yemen and those in opposition to it, which provides for a peaceful transition of power that meets the legitimate demands and aspirations of the Yemeni people for change, and by obstructing the political process in Yemen. I further find that these actions constitute an unusual and extraordinary threat to the national security and foreign policy of the United States, and I hereby declare a national emergency to deal with that threat. I hereby order:

Section 1. All property and interests in property that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person, including any foreign branch, of the following persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in: any person determined by the Secretary of the Treasury, in consultation with the Secretary of State, to:

(a) have engaged in acts that directly or indirectly threaten the peace, security, or stability of Yemen, such as acts that obstruct the implementation of the agreement of November 23, 2011, between the Government of Yemen and those in opposition to it, which provides for a peaceful transition of power in Yemen, or that obstruct the political process in Yemen;

(b) be a political or military leader of an entity that has engaged in the acts described in subsection (a) of this section;

(c) have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, the acts described in subsection (a) of this section or any person whose property and interests in property are blocked pursuant to this order; or

(d) be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to this order.

Sec. 2. I hereby determine that the making of donations of the type of articles specified in section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)) by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to section 1 of this order would seriously impair my ability to deal with the national emergency declared in this order, and I hereby prohibit such donations as provided by section 1 of this order.

Sec. 3. The prohibitions in section 1 of this order include but are not limited to:

(a) the making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to this order; and

(b) the receipt of any contribution or provision of funds, goods, or services from any such person.

Sec. 4. The prohibitions in section 1 of this order apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted prior to the effective date of this order.

Sec. 5. Nothing in section 1 of this order shall prohibit transactions for the conduct of the official business of the United States Government by employees, grantees, or contractors thereof.

Sec. 6. (a) Any transaction that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in this order is prohibited.

(b) Any conspiracy formed to violate any of the prohibitions set forth in this order is prohibited.

Sec. 7. For the purposes of this order:

(a) the term ''person'' means an individual or entity;

(b) the term ''entity'' means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization; and

(c) the term ''United States person'' means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States.

Sec. 8. For those persons whose property and interests in property are blocked pursuant to this order who might have a constitutional presence in the United States, I find that because of the ability to transfer funds or other assets instantaneously, prior notice to such persons of measures to be taken pursuant to this order would render those measures ineffectual. I therefore determine that for these measures to be effective in addressing the national emergency declared in this order, there need be no prior notice of a listing or determination made pursuant to section 1 of this order.

Sec. 9. The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to take such actions, including the promulgation of rules and regulations, and to employ all powers granted to the President by IEEPA as may be necessary to carry out the purposes of this order. The Secretary of the Treasury may redelegate any of these functions to other officers and agencies of the United States Government consistent with applicable law. All agencies of the United States Government are hereby directed to take all appropriate measures within their authority to carry out the provisions of this order.

Sec. 10. The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to submit the recurring and final reports to the Congress on the national emergency declared in this order, consistent with section 401(c) of the NEA (50 U.S.C. 1641(c)) and section 204(c) of IEEPA (50 U.S.C. 1703(c)).

Sec. 11. 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.

Barack Obama
THE WHITE HOUSE,
May 16, 2012.

Dated: November 2, 2012.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

Approved: November 2, 2012.

David S. Cohen,

Under Secretary, Office of Terrorism and Financial Intelligence, Department of the Treasury.

[FR Doc. 2012–27352 Filed 11–8–12; 8:45 am]

BILLING CODE 4810–AL–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0755; FRL–9366–3]

Dinotefuran; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of dinotefuran in or on pome fruits and stone fruits. This action is in response to EPA's granting of emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on pome fruits and stone fruits. This regulation establishes a maximum permissible level for residues of dinotefuran in or on these commodities. The time-limited tolerances expire on December 31, 2015.

This regulation also makes the systematic chemical name for dinotefuran consistent within the section and with EPA's policy on chemical nomenclature.

DATES: This regulation is effective November 9, 2012. Objections and requests for hearings must be received on or before January 8, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0755, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Andrea Conrath, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–9356; email address: *conrath.andrea@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0755 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 8, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0755, by one of the following methods:

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

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

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6), 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for combined residues of dinotefuran, (RS)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine, including its metabolites and degradates, in or on pome fruits and stone fruits at 1.0 part per million (ppm). These time-limited tolerances expire on December 31, 2015.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having

received any petition from an outside party.

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemptions for Dinotefuran on Pome Fruits and Stone Fruits and FFDCA Tolerances

Several States requested emergency exemptions claiming that the abrupt increase and spread of damaging populations of the Brown Marmorated Stink Bug (BMSB) resulted in an urgent and non-routine pest control situation. The available insecticides for BMSB control are either ineffective, adversely impact integrated pest management programs, and/or have use limitations that make them unsuitable for season-long control of BMSB. The States asserted that without the use of dinotefuran as an additional pest management tool for pome and stone fruit orchards, uncontrolled infestations of BMSB are likely to result in economic losses in excess of 20%. After having reviewed the submissions, EPA determined that an emergency condition exists for these States, and that the criteria for approval of the emergency exemptions were met. EPA authorized specific exemptions under FIFRA section 18 for the use of dinotefuran on pome fruits and stone fruits for control of the BMSB in Delaware, Maryland, New Jersey, North Carolina, Pennsylvania, Virginia, and West Virginia.

Consistent with the need to move quickly on the emergency exemptions in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2015, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on pome fruits and stone fruits after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether dinotefuran meets FIFRA's registration requirements for use on pome fruits and stone fruits or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these time-limited tolerance decisions serve as a basis for registration of dinotefuran by a State for special local needs under FIFRA section 24(c). Nor do these tolerances by themselves serve as the authority for persons in any State other than Delaware, Maryland, New Jersey, North Carolina, Pennsylvania Virginia, and West Virginia to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemptions for dinotefuran, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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

As part of its evaluation of the emergency exemption applications, EPA assessed the potential risks presented by residues of dinotefuran in or on pome fruits and stone fruits. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18.

EPA has evaluated the use of dinotefuran on pome fruits and stone fruits, as well as various other crops, and recently established tolerances for similar use patterns, in the **Federal Register** issue of September 12, 2012 (77 FR 56133) (FRL–9359–6) in association with requests for tolerances to support registrations of dinotefuran under section 3 of FIFRA.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for dinotefuran including exposure resulting from the tolerances established by this action.

In the September 12, 2012 **Federal Register** issue, EPA published a final rule establishing tolerances for residues of dinotefuran in 40 CFR 180.603(a) in or on berry, low growing, except strawberry, subgroup 13–07H; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13–07F; onion, bulb, subgroup 3–07A; onion, green, subgroup 3–07B; peach; tea, dried; vegetable, tuberous and corm, subgroup 1C; and watercress. A summary of the toxicological endpoints for dinotefuran used for human risk assessment is discussed in Units III.A. and B. of the September 12, 2012 final rule.

The human health risk assessment used to support the September 12, 2012 final rule (''Dinotefuran: Human Health Risk Assessment for Proposed Section 3 Uses on Tuberous and Corm Vegetables Subgroup 1C, Onion Subgroup 3–07A, Onion Subgroup 3–07B, Small Fruit Subgroup 13–07F, Berry Subgroup 13–07H, Peach, and Watercress, And a Tolerance on Imported Tea''), took into account the assumption that dinotefuran would be used on pome fruits and stone fruits pursuant to emergency exemptions.

Therefore the aggregate risks for dinotefuran for this action are not changed from those discussed in the September 12, 2012 final rule.

In its aggregate assessment of exposures and risks associated with dinotefuran, EPA concluded the following: That the acute dietary exposure from food and water to dinotefuran will occupy 5.8% of the acute population adjusted dose (aPAD) for children 1–2 years old, the population group receiving the greatest exposure; that chronic exposure to dinotefuran from food and water will utilize 2.6% of the chronic population adjusted dose (cPAD) for children 1–2 years old, the population group

receiving the greatest exposure; and that the combined short-term risk from food, water, and residential exposures result in an aggregate margin of exposure (MOE) of 3,000 for children 1–2 years old from hand to mouth exposure from treated turf, the scenario with the highest exposure. Because EPA's level of concern for dinotefuran is a MOE of 100 or below, the MOEs are not of concern. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, dinotefuran is not expected to pose a cancer risk to humans.

Therefore, EPA concluded that there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to dinotefuran residues. Refer to the September 12, 2012 final rule, available at *http://www.regulations.gov,* for a summary of the aggregate risk assessments and determination of safety. A more detailed discussion of the aggregate risk assessments and determination of safety may be found at *http://www.regulations.gov* in the document titled ''Revised: Dinotefuran: Human Health Risk Assessment for Proposed Section 3 Uses on Tuberous and Corm Vegetables Subgroup 1C, Onion Subgroup 3–07A, Onion Subgroup 3–07B, Small Fruit Subgroup 13–07F, Berry Subgroup 13–07H, Peach, and Watercress, And a Tolerance on Imported Tea'' in docket ID number EPA–HQ–OPP–2011–0433.

EPA relies upon those risk assessments and the findings made in the **Federal Register** document in support of this action.

V. Other Considerations

A. Analytical Enforcement Methodology

There are several analytical methods available for determination of residues of dinotefuran and its metabolites. For determination of dinotefuran and its metabolites, DN, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and UF, 1-methyl-3-(tetrahydro-3-furylmethyl)urea, a high performance liquid chromatography/tandem mass spectrometry (HPLC/MS/MS) method is available. For the determination of residues of dinotefuran only, an HPLC/ultraviolet (UV) detection method is available. For the determination of only the metabolites (DN and UF), HPLC/MS and HPLC/MS/MS methods are available. These methods are adequate to enforce the tolerance expression.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

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

There are currently no Codex, Canadian or Mexican MRLs established for dinotefuran.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of dinotefuran, (RS)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine, including its metabolites and degradates, in or on fruit, pome, group 11 and fruit, stone, group 12 at 1.0 ppm. These tolerances expire on December 31, 2015.

EPA is also revising 40 CFR 180.603(b) to use the same systematic chemical name for dinotefuran as is presently used in 40 CFR 180.603(a), for purposes of consistency within the section and with EPA's policy regarding chemical nomenclature.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

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

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

VIII. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: November 1, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.603, revise paragraph (b) to read as follows:

§ 180.603 Dinotefuran; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of dinotefuran, (*RS*)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine, including its metabolites and degradates, in or on the commodities in the following table, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified in the table is to be determined by measuring only the sum of dinotefuran and its metabolites DN, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and UF, 1-methyl-3-(tetrahydro-3-furylmethyl)urea, calculated as the stoichiometric equivalent of dinotefuran, in or on the commodities listed in the table. The tolerances expire and are revoked on the dates specified in the table.

Commodity	Parts per million	Expiration/revocation date
Fruit, pome, group 11	1.0	12/31/15
Fruit, stone, group 12	1.0	12/31/15
Rice, grain	2.8	12/31/12

* * * * *

[FR Doc. 2012–27403 Filed 11–8–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 206

[Docket ID FEMA–2012–0004]

RIN 1660–AA75

Debris Removal: Eligibility of Force Account Labor Straight-Time Costs Under the Public Assistance Program for Hurricane Sandy

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Interim final rule.

SUMMARY: The Fiscal Year 2007 Department of Homeland Security Appropriations Act authorized a Public Assistance Pilot Program intended to reduce the costs to the Federal government of providing assistance to States and local governments; increase flexibility in the administration of assistance; and expedite the provision of assistance under the Robert T. Stafford Disaster Relief and Emergency Assistance Act. Due to the current pressing need for efficient and timely recovery from a catastrophic disaster event, Hurricane Sandy, which has cast widespread debris over a major portion of the eastern seaboard of the United States, this rule implements one of the debris-related Public Assistance Pilot procedures: it allows for the reimbursement of the straight- or regular time salaries and benefits of the employees of Public Assistance applicants who perform disaster-related debris and wreckage removal work for any major disaster or emergency declared by the President on or after October 27, 2012, in response to Hurricane Sandy.

DATES: This interim final rule is effective November 9, 2012, and applicable October 27, 2012. Comments must be submitted by January 8, 2013.

ADDRESSES: You may submit comments, identified by Docket ID FEMA–2012–0004, by one of the following methods:

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

Mail/Hand Delivery/Courier: Regulatory Affairs Division, Office of Chief Counsel, Federal Emergency Management Agency, Room 835, 500 C Street, SW., Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: William Roche, Director, Public Assistance Division, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472–3100, (phone) 202–212–2340; or (email) *William.Roche@dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. The Public Assistance Program

1. General

Each year, the United States is struck by natural disasters, which may include events such as storms, earthquakes, volcanic eruptions, and landslides, as well as events that occur from various other causes, such as fires, floods, and explosions. When a locality is, or will be, overwhelmed by the magnitude of the damage from any such event, the community turns to the State for help. If it is evident that the situation is or will be beyond the combined capabilities of local and State resources, the Governor may request that the President declare that an emergency or major disaster exists in the State, under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), 42 U.S.C. 5121–5207.

If the President declares an emergency or major disaster and authorizes Public Assistance, FEMA may award Public Assistance grants to assist State and local governments (including Indian Tribal governments) and certain private nonprofit (PNP) organizations as defined in subpart H of 44 CFR part 206 (collectively referred to as ''applicants,'' ''grantees,'' or ''subgrantees''). Public Assistance grants assist State, Tribal, and local governments with the response to and recovery from the declared event. Specifically, the Public Assistance program provides assistance for debris removal, emergency protective measures, and permanent restoration of public infrastructure. FEMA refers to debris removal and emergency protective measures as ''emergency work.'' FEMA also categorizes these types of work as Category A (debris removal) and Category B (emergency protective measures). Category B includes debris removal costs that are incurred as emergency protective measures, such as

clearing debris to establish immediate emergency access. Permanent restoration of infrastructure, which FEMA refers to as ''permanent work,'' includes several categories, including Roads and Bridges (Category C), Water Control Facilities (Category D), Buildings and Equipment (Category E), Utilities (Category F), and Parks, Recreational Facilities, and Other Items (Category G). This rulemaking applies to debris removal activities only (Categories A and B).

2. Debris Removal

Sections 403(a)(3)(A), 407 and 502(a)(5) of the Stafford Act authorize FEMA to provide assistance to eligible applicants to remove debris from public and private property following a Presidential major disaster or emergency declaration, when in the public interest. *See* 42 U.S.C. 5170b(a)(3)(A), 5173, and 5192. Removal must be necessary to eliminate immediate threats to lives, public health and safety, eliminate immediate threats of significant damage to improved public or private property, or ensure the economic recovery of the affected community-at-large. *See* 44 CFR 206.224. The debris must be the direct result of the disaster and located in the disaster area, and the applicant must have the legal responsibility to remove the debris. To ensure these requirements are met, FEMA has issued extensive guidance on oversight processes and procedures to monitor debris removal activities.

In the immediate aftermath of an event, the removal of debris is a critical aspect of a community's economic recovery and return to normalcy. Debris blocks roadways prohibiting the passage of police, fire, and medical teams. Debris slows repairs and reconstruction of essential buildings and homes. It also may cause health and safety problems if left to fall on passersby, grow mold, or foster insect infestation.

Between January 1, 1999, and December 1, 2010, FEMA obligated an annual average of 3,940 Project Worksheets (PWs) and $675,534,796 for Category A, Debris Removal for major disasters and emergency declarations. This figure does not include Category B debris removal work, including work to remove debris blocking emergency response; therefore, the total amount of debris removal funded during this time period is even higher.

B. The Public Assistance Pilot Program

The Fiscal Year (FY) 2007 Department of Homeland Security Appropriations Act (Appropriations Act), Public Law 109–295, authorized FEMA to conduct a Public Assistance Pilot Program to reduce the costs to the Federal government of providing debris-related assistance to States and local governments, increase flexibility in the administration of assistance, and expedite the provision of assistance under sections 403(a)(3)(A), 502(a)(5), and 407 of the Stafford Act. FEMA implemented four of the six Pilot procedures authorized by the Appropriations Act for the administration of Public Assistance grants. The four initiatives that FEMA offered as part of the Pilot were: grants based on estimates (for Category A and C–G large projects up to $500,000); an increased Federal cost share for debris removal projects for applicants with a FEMA-approved debris management plan; reimbursement of straight-time wages for applicant force account labor performing disaster related debris removal work; and a debris recycling initiative. The Appropriations Act also gave FEMA the authority to waive regulations and policies to implement the Public Assistance Pilot Program. It allowed State and local governments to participate in the Public Assistance Pilot Program on a voluntary basis. Public Assistance applicants were not required to use the Pilot procedures, but could elect to use one or more of the Pilot procedures for one or more of its projects. The Appropriations Act did not authorize the participation of private non-profit applicants in the Pilot Program. FEMA was prohibited from approving any Pilot projects after December 31, 2008, and was required to submit a report to Congress regarding the effectiveness of the Pilot Program. On May 20, 2009, FEMA submitted the report, entitled ''FEMA Public Assistance Pilot Program Fiscal Year 2009 Report to Congress.''

This rule implements one of the debris-related Pilot Program procedures, Force Account Labor, for disaster-related debris and wreckage removal work for any major disaster or emergency declared by the President on or after October 27, 2012, in response to Hurricane Sandy.

Under the current Public Assistance program, FEMA only pays overtime for an applicant's own labor forces and equipment, referred to as ''force account labor,'' performing debris removal work. The regular time (also called ''straight-time'') salaries and benefits of permanently employed personnel are not eligible in calculating allowable costs. *See* 44 CFR 206.228(a)(2). However, FEMA reimburses reasonable costs associated with a debris contract, including the cost of contract workers' regular time as well as overtime. This creates an incentive for applicants to contract for debris removal work, even after relatively small events which could have been handled in part, or entirely, by an applicant's employees. For over a decade, State and local applicants have requested reimbursement for straight-time salaries for their force account labor who are pulled away from their normal day-to-day work to perform debris removal operations. In response to these requests and under the Force Account Labor procedure of the Pilot Program, FEMA reimbursed the straight-time salaries and benefits of the applicant's employees who performed disaster-related debris and wreckage removal work. FEMA's objective in reimbursing force account labor was to provide applicants the opportunity and incentive to use their own employees for debris removal activities in situations where applicants determine that is the most appropriate method to perform the work. In addition, FEMA wanted to evaluate whether debris removal operations and monitoring performed by force account labor was less costly and more efficient than contractor operations.

Feedback received on the Public Assistance Pilot Program indicated that the Force Account Labor procedure resulted in administrative benefits. States and FEMA Regional Offices reported that grant applicants who utilized this procedure relied less on contractors, which resulted in fewer complaints and negotiation over costs and scopes of work and thus eliminated delays in accomplishing the work. FEMA also found that the Force Account Labor procedure provided applicants an incentive to monitor debris removal activities of contractors with its regular employees, rather than enter into contracts to perform the work. Indeed, ninety percent of all applicants participating in the Public Assistance Pilot Program requested reimbursement for straight- or regular time salary and benefits for their permanent employees who performed at least some of the monitoring or debris removal activities. This large participation rate, coupled with reporting from the States and FEMA Regions, shows that reimbursing straight-time for an applicant's regular employees who performed debris removal work provided an incentive for applicants to complete debris removal work themselves rather than entering into contracts to perform the work.

The Force Account Labor procedure of the Public Assistance Pilot Program also resulted in cost and time savings. Funding straight- or regular time force account labor costs provided applicants an incentive to manage debris

operations more effectively and decreased the number of contractors required to both perform debris operations and monitor debris removal contractors. Not only did it reduce contractor costs, but it also allowed applicants to stop paying for contract equipment, and use their own equipment for debris operations. Funding the straight-time of an applicant's employees also provided additional flexibility to local governments, allowing them to use a combination of contracting and force account labor for debris removal work.

In addition, because applicants started debris operations more expeditiously, and reduced or eliminated delays related to procuring and mobilizing contractors, the force account provision of the Pilot Program resulted in faster obligation of funding from FEMA. FEMA obligated funds for debris removal projects that used the Force Account Labor procedure in 60 percent less time than for those that used contractors for debris removal projects.

II. Discussion of the Rule

This rule implements the Force Account Labor procedure of the Public Assistance Pilot Program for debris removal work related to Hurricane Sandy, a catastrophic disaster event of unprecedented magnitude and severity. The geographic depth of this storm is exceptional, covering major portions of the Mid-Atlantic and Northeast, and bringing devastation to much of the Eastern seaboard. In response to this event, FEMA is promulgating this rule to accelerate the nation's recovery by maximizing the use of force account labor. A 2011 Department of Homeland Security Inspector General Report recommended that FEMA implement the force account labor procedure in some form, especially for an event of this magnitude, which would assist in reducing the occurrence of waste, fraud, and abuse.

This rule revises 44 CFR 206.228(a)(2) to allow the reimbursement of straight- or regular-time salaries and benefits of a grantee's or subgrantee's permanently employed personnel for debris removal work due to Hurricane Sandy performed under the Stafford Act's Major Disaster Assistance Programs (sections 403 and 502) or Emergency Assistance Programs (section 407). In order to receive reimbursement, force account labor employees must work exclusively on Hurricane Sandy debris removal. They cannot combine Hurricane Sandy debris removal with their normal work-related tasks or any other tasks, including tasks related to emergencies or major disasters declared by the President before October 27, 2012. Finally, reimbursement is restricted to 30 consecutive calendar days. These provisions will provide an incentive to applicants to maximize the use of their force account labor, thus lessening the need to secure and oversee contract labor, and encouraging them to allot 100 percent of the work time of their regular staff to Hurricane Sandy debris removal, thereby contributing to a quicker and more efficient recovery.

Eligible activities include disaster-related debris and wreckage removal work for any major disaster or emergency declared by the President on or after October 27, 2012, in response to Hurricane Sandy under Category A, Debris Removal, and/or Category B, Emergency Protective Measures. Emergency work is that work which must be performed to reduce or eliminate an immediate threat to life, protect public health and safety, and to protect improved property that is threatened as a result of the disaster. *See* 44 CFR 206.225. Debris removal work, whether labeled as Category A or Category B, must be in the public interest. *See* 44 CFR 206.224. In practice, FEMA treats debris removal work the same whether it is under Category A or under Category B. Therefore, this rule makes straight-or regular-time salaries and benefits for an eligible applicant's force account labor eligible in calculating the cost of eligible Category A and/or Category B debris removal work. This rule does not allow for the reimbursement of straight- or regular time salaries and benefits of a grantee's or subgrantee's permanently employed personnel for any other emergency protective measures under Category B.

Non-Substantive Changes.

This rule adds a reference to ''grantee'' in paragraph (a)(2) of section 206.228; it currently only refers to ''subgrantees.'' The eligibility of force account labor costs outlined in 44 CFR 206.228(a)(2) applies to grantees as well as subgrantees. The State, in most cases, acts as the grantee for the Public Assistance Program. Applicants who are successful in obtaining Public Assistance are identified as ''subgrantees.'' Since State, Tribal, and local government agencies are eligible applicants for Public Assistance, States may act as the grantee, as well as the subgrantee. While most work is performed by the subgrantees, it is possible that grantees could perform eligible debris removal and/or permanent work, and therefore incur straight-time force account labor costs for those activities. To be more accurate, this rule adds ''grantee'' to paragraph (a)(2) of section 206.228. The rule also establishes a cross reference to the exception for host state evacuation and sheltering in 44 CFR 206.202.

III. Administrative Procedure Act

FEMA has good cause to publish this interim final rule without notice and comment under 5 U.S.C. 553(b)(3)(B), as it would be impracticable, unnecessary and contrary to the public interest. The impacts of Hurricane Sandy illustrate the need for promulgating this rule as quickly as possible. Between October 28, 2012 and October 31, 2012, Hurricane Sandy produced widespread wind, storm surge, flood, and snow damage to the Mid-Atlantic and Northeast regions of the United States. Before Hurricane Sandy had even made landfall the President issued emergency declarations for nine States, authorizing Federal resources to assist those States with their preparations for the historic storm. Hurricane force winds were experienced along portions of the coasts from Virginia to Massachusetts. On October 29, 2012, Hurricane Sandy made landfall as a post-tropical cyclone with maximum sustained winds of 85 miles per hour, which corresponds to a strong Category 1 hurricane on the Saffir Simpson Scale. Landfall occurred very close with high tide in many areas, resulting in substantial storm surge including almost 14 feet in New York City, and the Holland and Brooklyn-Battery tunnels remain closed due to flooding as of October 30, 2012. Thus far, Sandy is responsible for 30 fatalities in the United States, with search and rescue operations still ongoing.

Efficient and effective debris operations are arguably the single most important step toward community recovery following a major disaster—the ability of residents to return and live in a safe and healthy environment depends on the quality of the debris response. Since 2000, the Public Assistance Program awarded over $8 billion in grant funding—nearly 20 percent of all Public Assistance grants obligated during the period—to reimburse eligible applicants for debris removal. In addition, over $3 billion has been expended on Direct Federal Assistance related to debris removal. While the full scope of the damage from Sandy has yet to be determined, United States Army Corps of Engineering modeling estimates that a Category 1 hurricane making landfall in approximately the same area as Sandy could result in an excess of 27.3 million cubic yards of debris, spread across nine states and the District of Columbia.

Removing the current disincentive to applicants using their own employees

for debris removal operations will encourage applicants to use their own labor forces to perform debris work that may be done more quickly, more efficiently, and at less cost than going through a procurement process and bringing in debris removal contractors.

This rule implements a procedure that has already been thoroughly tested through a Pilot Program in which any eligible State or local government was welcome to participate. Over 4,000 applicants chose to participate, and FEMA's analysis of the Pilot program indicated that it was very beneficial to those applicants. State and local governments that participated in the Pilot program were highly supportive of this procedure. In addition, the Department of Homeland Security's Office of Inspector General has recommended that this procedure be implemented in some form.

Due to the widespread, significant impact of disasters like Hurricane Sandy, and given that the procedure implemented by this interim final rule was extensively tested during the Public Assistance Pilot Program, FEMA has determined that it would be impracticable, unnecessary, and contrary to the public interest to delay putting the provisions of this interim final rule in place until a public notice and comment process has been completed. We find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We will accept public comments on this interim final rule for 60 days.

We are also dispensing with the Administrative Procedure Act requirement that a new rule not take effect until 30 days after it is issued. Instead, this rule is effective October 27, 2012, to allow the maximum benefit for Hurricane Sandy debris removal operations. Immediate effectiveness is authorized because this is a substantive rule granting an exception to the prohibition on reimbursing Public Assistance applicants for their straight-time force account labor costs associated with debris removal in response a major disaster or emergency. In addition, for the reasons set forth above, there is good cause to make the procedure implemented by this rule effective immediately.

IV. Regulatory Analysis

A. National Environmental Policy Act (NEPA)

CEQ regulations provide for Federal agencies to establish categories of actions that do not individually or cumulatively have a significant impact on the human environment which do not require an environmental assessment or environmental impact statement. 40 CFR 1508.4. FEMA's ''List of exclusion categories'' at 44 CFR 10.8(d)(2)(ii) categorically excludes the preparation, revision, and adoption of regulations related to actions that qualify for categorical exclusions. Further, essential assistance under section 403 and debris removal under section 407 of the Stafford Act are categorically excluded at 44 CFR 10.8(d)(2)(xix)(B) and (C). These categorical exclusions cover all debris removal actions under the Stafford Act.

Finally, FEMA has evaluated the potential for extraordinary circumstances as required in 44 CFR 10.8(d)(3) and determined that the procedure authorized under this rule does not change its environmental effect. The straight-time force account labor provision does not change the nature or extent of debris removal activities reimbursed by FEMA. The potential for reimbursement of straight-time force account labor provides applicants with more flexibility to perform debris removal work with their own employees in addition to, or in place of, contractors, but does not affect the eligibility of debris removal actions under this program. An environmental assessment was not prepared for this rulemaking action because a categorical exclusion applies and no extraordinary circumstances exist.

B. Paperwork Reduction Act of 1995

As required by the Paperwork Reduction Act of 1995 (PRA), as amended, 44 U.S.C. 3501 et seq., an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number. The collection of information associated with the Public Assistance program is approved under OMB Control No. 1660–0017, which expires on April 30, 2013. This rule does not contain any new collections of information.

C. Executive Order 12866, Regulatory Planning and Review & Executive Order 13563, Improving Regulation and Regulatory Review

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

The rule provides (unquantified) benefits that are vitally important to further FEMA's mission. This rule increases efficiency, flexibility, and reduces the costs of performing debris removal work after Hurricane Sandy. The rule affects States, Indian Tribal governments, local governments, as well as certain private non-profit organizations that have been affected by Hurricane Sandy, by maximizing the use of force account labor for debris removal, thus accelerating the recovery process.

Review of FEMA's existing debris regulations revealed that they could be expanded to provide for more efficient and timely debris removal after a disaster. As discussed earlier in this preamble, the reimbursement of force account labor for debris removal under the Pilot Program greatly improved efficient and timely debris removal. In reimbursing force account labor, FEMA provided applicants with an incentive to perform the work in-house, as well as improve oversight of debris removal operations. Therefore, FEMA is expanding the debris regulations to incorporate this procedural improvement into the debris removal program in response to Hurricane Sandy.

D. Executive Order 13132, Federalism

Executive Order 13132, ''Federalism'' (64 FR 43255, Aug. 10, 1999), sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have federalism implications, that is, regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Federal agencies must closely examine the statutory authority supporting any action that would limit the policymaking discretion of the States and, to the extent practicable, must consult with State and local officials before implementing any such action.

FEMA has reviewed this rule under Executive Order 13132 and has concluded that this rule does not have federalism implications as defined by Executive Order 13132. FEMA has determined that this rule does not significantly affect the rights, roles, and

responsibilities of States, and involves no preemption of State law nor does it limit State policymaking discretion. This rulemaking amends a voluntary grant program that may be used by State, local and Tribal governments and eligible private nonprofit organizations to receive Federal grants to assist in the recovery from disasters. States are not required to seek grant funding, and this rulemaking does not limit their policymaking discretion.

E. Executive Order 12898, Environmental Justice

Under Executive Order 12898, as amended ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, Feb. 16, 1994), FEMA has undertaken to incorporate environmental justice into its policies and programs. Executive Order 12898 requires each Federal agency to conduct its programs, policies, and activities that substantially affect human health or the environment, in a manner that ensures that those programs, policies, and activities do not have the effect of excluding persons from participation in, denying persons the benefit of, or subjecting persons to discrimination because of their race, color, or national origin or income level.

The purpose of this rule is to implement a debris-related Public Assistance Pilot Program procedure. This rule reimburses straight- or regular time wages for the permanent employees of Public Assistance applicants while they perform disaster-related debris and wreckage removal activities related to Hurricane Sandy for a period of 30 consecutive calendar days. Reimbursing straight- or regular time for an applicant's permanent employees who perform debris removal work will provide an incentive for applicants to complete debris removal work themselves rather than entering into contracts to perform the work. Removing debris expeditiously provides value to the American people by creating safer communities and reducing loss of life and property, enables communities to recover more rapidly from disasters, and lessens the financial impact of disasters on individuals, the United States Department of the Treasury, State, local and Tribal communities.

No action that FEMA can anticipate under this rule will have a disproportionately high and adverse human health or environmental effect on any segment of the population. Accordingly, the requirements of Executive Order 12898 do not apply to this rule.

F. Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

FEMA has reviewed this rule under Executive Order 13175 ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, Nov. 9, 2000). Under Executive Order 13175, FEMA may not issue a regulation that has Tribal implications, that imposes substantial direct compliance costs on Indian Tribal governments, and that is not required by statute. In reviewing this rule, FEMA finds that because Indian Tribal governments are potentially eligible applicants under the Public Assistance Program, this rule does have ''tribal implications'' as defined in the Executive Order. However, eligibility to receive reimbursement for force account labor for debris removal operations will 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. This rule does not impose substantial direct compliance costs on Indian Tribal governments nor does it preempt tribal law, impair treaty rights nor limit the self-governing powers of Indian Tribal governments.

G. Regulatory Flexibility Act Statement

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, and section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601 note, agencies must consider the impact of their rulemakings on ''small entities'' (small businesses, small organizations and local governments). 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. This rule does not require a notice of proposed rulemaking and therefore is exempt from the requirements of the RFA.

H. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 et seq., requires each Federal agency, to the extent permitted by law, to prepare a written assessment of the effects of any Federal mandate in a proposed or final agency 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. UMRA exempts from its definition of ''Federal intergovernmental mandate'' regulations that establish conditions of Federal assistance or provide for emergency assistance or relief at the request of any State, local, or Tribal government. Therefore, this rule is not an unfunded Federal mandate under that Act.

I. Executive Order 12988, Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, ''Civil Justice Reform'' (61 FR 4729, Feb. 7, 1996), to minimize litigation, eliminate ambiguity, and reduce burden.

J. Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights

FEMA has reviewed this rule under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights'' (53 FR 8859, Mar. 18, 1988) as supplemented by Executive Order 13406, ''Protecting the Property Rights of the American People'' (71 FR 36973, June 28, 2006). Sections 403(a)(3)(A) and 407 of the Stafford Act, 42 U.S.C. 5170b and 5173, respectively, provide FEMA authority to fund debris removal from private property provided that the State or local government arranges an unconditional authorization for removal of the debris, and agrees to indemnify the Federal government against any claim arising from the removal. The regulations implementing Sections 403 and 407 of the Stafford Act at 44 CFR 206.224 establish the requirement that debris removal be in the ''public interest'' in order to be eligible for reimbursement. Generally, debris removal from private property following a disaster is the responsibility of the property owner. However, large-scale disasters may deposit enormous quantities of debris on private property over a large area resulting in widespread immediate threats to the public-at-large. In these cases, the State or local government may need to enter private property to remove debris to: Eliminate immediate threats to life, public health, and safety; eliminate immediate threats of significant damage to improved property; or ensure economic recovery of the affected community to the benefit of the community-at-large. In these situations, debris removal from private property may be considered to be in the public interest and thus may be eligible for reimbursement under the Public Assistance Program. *See* 44 CFR 206.224. FEMA will work with States

affected by a disaster to designate those areas where the debris is so widespread that removal of the debris from private property is in the ''public interest'' pursuant to 44 CFR 206.224, and thus is eligible for FEMA Public Assistance reimbursement on a case-by-case basis. This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630.

K. Congressional Review of Agency Rulemaking

FEMA is sending the rule to Congress and to the Government Accountability Office pursuant to the Congressional Review of Agency Rulemaking Act (Congressional Review Act)(CRA), Public Law 104–121, 110 Stat. 873 (March 29, 1996) (5 U.S.C. 801 et seq). This rule is not a ''major rule'' within the meaning of the CRA. Furthermore, Section 808 of the CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. As stated previously, FEMA has made such a good cause finding, including the reasons therefore.

List of Subjects in 44 CFR Part 206

Administrative practice and procedure, Coastal zone, Community facilities, Disaster assistance, Fire prevention, Grant programs-housing and community development, Housing, Insurance, Intergovernmental relations, Loan programs-housing and community development, Natural resources, Penalties, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Federal Emergency Management Agency amends 44 CFR part 206 as follows:

PART 206—FEDERAL DISASTER ASSISTANCE

■ 1. The authority citation for part 206 is revised to read as follows:

Authority: Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5207; Homeland Security Act of 2002, 6 U.S.C. 101 et seq.; Department of Homeland Security Delegation 9001.1.

■ 2. Revise § 206.228, paragraph (a)(2) to read as follows:

§ 206.228 Allowable costs.

* * * * *

(a) * * *

(2) *Force Account Labor Costs.* The straight- or regular-time salaries and benefits of a grantee's or subgrantee's permanently employed personnel are:

(i) Eligible in calculating the cost of eligible permanent repair, restoration, and replacement of facilities under section 406 of the Stafford Act;

(ii) Eligible, at the Administrator's discretion, in calculating the cost of eligible debris removal work under sections 403(a)(3)(A), 502(a)(5), and 407 of the Stafford Act for a period not to exceed 30 consecutive calendar days, provided the grantee's or subgrantee's permanently employed personnel are dedicated solely to eligible debris removal work for any major disaster or emergency declared by the President on or after October 27, 2012, in response to Hurricane Sandy; and

(iii) Not eligible in calculating the cost of other eligible emergency protective measures under sections 403 and 502 of the Stafford Act, except for those costs associated with host state evacuation and sheltering, as established in § 206.202.

* * * * *

Janet Napolitano,

Secretary.

[FR Doc. 2012–27382 Filed 11–8–12; 8:45 am]

BILLING CODE 9111–23–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MB Docket No. 11–69; PP Docket No. 00–67; FCC 12–126]

Basic Service Tier Encryption Compatibility Between Cable Systems and Consumer Electronics Equipment

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission adopts new rules to allow cable operators to encrypt the basic service tier in all-digital systems, provided that those cable operators undertake certain consumer protection measures for a limited period of time in order to minimize any potential subscriber disruption.

DATES: Effective December 10, 2012.

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Brendan Murray, *Brendan.Murray@fcc.gov,* of the Media Bureau, Policy Division, (202) 418–2120.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order,* FCC 12–126, adopted on October 10, 2012 and released on October 12, 2012. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW., CY–A257, Washington, DC 20554. This document will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) The complete text may be purchased from the Commission's copy contractor, 445 12th Street SW., Room CY–B402, Washington, DC 20554. To request these documents in accessible formats (computer diskettes, large print, audio recording, and Braille), send an email to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Summary of the Report and Order

1. With this Report and Order (*Order*), we amend our rules to allow cable operators to encrypt the basic service tier in all-digital cable systems if they comply with certain consumer-protection measures. As discussed below, this rule change will benefit consumers who can have their cable service activated and deactivated from a remote location. By allowing remote activation and deactivation, we expect our amended rules will result in benefits to both cable operators and consumers by significantly reducing the number of truck rolls associated with provisioning service and significantly reducing the need for subscribers to wait for service calls to activate or deactivate cable service. At the same time, we recognize that this rule change will adversely affect a small number of cable subscribers who currently view the digital basic service tier without using a set-top box or other equipment. If a cable operator decides to encrypt the digital basic tier, then these subscribers will need equipment to continue viewing the channels on this tier. To give those consumers time to resolve the incompatibility between consumer electronics equipment (such as digital television sets) and newly encrypted cable service, we require operators of cable systems that choose to encrypt the basic service tier to comply with certain consumer protection measures for a period of time. In addition, we note that this rule change may impact the ability of a small number of subscribers that use certain third-party equipment that is not CableCARD compatible to access channels on the basic service tier. To address this issue, we require the six

largest incumbent cable operators to comply with additional requirements that are intended to ensure compatibility with certain third-party-provided equipment used to access the basic tier.

2. *Background.* In the Cable Television Consumer Protection and Competition Act of 1992 (''1992 Cable Act''), Congress sought to make sure that consumer electronics equipment could receive cable programming and that compatibility issues did not limit the premium features of that equipment. Section 17 of that law added section 624A to the Communications Act of 1934, as amended. Section 624A requires the Commission to issue regulations to assure compatibility between consumer electronics equipment and cable systems. In 1994, the Commission implemented the requirements of section 624A in part by adding § 76.630(a) to its rules. Section 76.630(a) prohibits cable operators from scrambling or encrypting signals carried on the basic tier of service. Encryption is an essential component of a conditional access system, which cable operators use to ensure that subscribers receive only the services that they are authorized to receive. Nevertheless, the Commission determined that this rule would significantly advance compatibility by ensuring that all subscribers would be able to receive basic tier signals ''in the clear'' and that basic-only subscribers with cable-ready televisions would not need set-top boxes. The Commission concluded that ''[t]his rule also will have minimal impact on the cable industry in view of the fact that most cable systems now generally do not scramble basic tier signals.''

3. In the mid-1990's, cable operators began to upgrade their systems to offer digital cable service in addition to analog cable service (hybrid service). More recently, many cable operators have transitioned to more efficient all-digital service, freeing up spectrum to offer new or improved products and services like higher-speed Internet access and high definition programming. After a cable operator transitions to an all-digital system, most of its subscribers have at least one cable set-top box or retail CableCARD device in their homes. We expect that the percentage of homes with set-top boxes or retail CableCARD devices will continue to increase as more cable operators eliminate analog service from their systems in favor of more efficient digital service.

4. The percentage of homes with set-top boxes or CableCARD devices is high because most cable systems now scramble most of their signals. As cable operators began to transition programming on their cable programming service tier (''CPST'') to digital, many program carriage agreements required cable operators to encrypt that programming as a condition of carriage. In addition, cable operators use encryption as part of their conditional access system to ensure that cable service is available only to those who have paid for it. Particular methods of encryption, however, vary across cable systems, which could lead to incompatibility between consumer devices and cable service. In 2003, the Commission adopted the CableCARD standard to address this incompatibility problem. The CableCARD, which subscribers must lease from their cable provider either as a part of a leased set-top box or separately for use in a compatible retail television or set-top box, decrypts the cable services. At present, over 78 percent of all cable subscribers have at least one leased set-top box or retail CableCARD device in their home. Cable operators who offer only digital service indicate that all of their subscribers have at least one leased set-top box or retail CableCARD device. Some cable subscribers rely on QAM tuners in television sets and consumer electronics devices that allow access to unencrypted digital cable service without additional equipment, but, based on the record before us, we believe that few consumers rely on them for primary access to cable service. The fact that most cable subscribers already have a cable set-top box or retail CableCARD device significantly reduces the number of subscribers who benefit from the prohibition on encryption of the basic service tier in all-digital systems in contrast to systems that carry analog service.

5. Our rules state that requests for waiver of the encryption prohibition ''must demonstrate either a substantial problem with theft of basic tier service or a strong need to scramble basic signals for other reasons.'' Prior to 2010, the Commission had waived the rule based only on theft of service. Recently, the Commission has received several requests for waiver of the rule prohibiting encryption of the basic service tier based on the argument that the rule imposes more burdens than benefits as cable operators transition to all-digital systems. The petitioners argue that there are very few people who subscribe only to the basic service tier in all-digital systems, and that access to the basic tier would therefore be unaffected by encryption for the overwhelming majority of subscribers to such systems because they already have a set-top box or CableCARD-equipped retail device. Furthermore, they contend, encrypting the basic service tier in an all-digital system would eliminate the need for many service calls because it would allow cable operators to enable and disable cable service remotely, activating and deactivating the encryption capability of set-top boxes and CableCARDs from the headend rather than visiting subscribers' homes. Today, cable operators typically must manually connect and disconnect the cable that runs to a home to activate or deactivate service and use traps to block access to particular channels. If the cable operator were allowed to encrypt every signal, the operator could keep every home connected to the cable plant regardless of whether the home subscribes to cable service. In addition, the operator could ensure that only paid subscribers are able to access the service by authorizing and deauthorizing CableCARDs, or other legitimate devices, as people subscribe to or cancel cable service.

6. In January 2010, the Media Bureau granted a conditional waiver of the rule that prohibits encryption of the basic service tier to Cablevision with respect to Cablevision's New York City systems, which are all-digital. The Bureau based its decision on the fact that encryption of the basic service tier on Cablevision's all-digital systems would allow Cablevision to enable and disable cable service remotely. The Bureau also found that remote activation and deactivation of cable service would ''reduce[ ] costs for Cablevision, improve[ ] customer service, and reduce[ ] fuel consumption and CO2 emissions.'' Remote activation and deactivation, the Bureau concluded, would reduce installation costs for Cablevision's subscribers and also benefit these subscribers by reducing the number of occasions when they must wait at home for a service call, as compared to unencrypted cable systems. The Bureau reasoned that Cablevision would sufficiently address the problem of incompatibility with consumer electronics ''by providing basic-only subscribers with set-top boxes or CableCARDs without charge for significant periods of time.'' Finally, the Bureau also concluded that the waiver would ''provide an experimental benefit that could be valuable in the Commission's further assessment of the utility of the encryption rule,'' and therefore required Cablevision to file three reports detailing the effect of encryption on subscribers. Four cable operators have filed similar petitions for waiver with the Commission's Media

Bureau since the release of the Cablevision Waiver.

7. In the wake of these petitions as well as requests from Public Knowledge and Media Access Project for the Commission to deal with the basic service tier encryption issue by launching a rulemaking proceeding, the Commission issued a Notice of Proposed Rulemaking in October 2011. The Commission proposed to allow cable operators to encrypt the basic service tier in all-digital systems, subject to conditions that would minimize disruption for affected subscribers by providing a transition period in which to make informed choices about purchasing or leasing new equipment to continue accessing service. Based on the reports that Cablevision submitted as a condition of its waiver, the Commission in the Encryption NPRM predicted that the rule change would reduce truck rolls and service calls with modest adverse effects on few subscribers. We received comments or reply comments on the Encryption NPRM from 34 parties, and a number of subsequent ex parte filings. The parties' positions are described in the ensuing Discussion.

8. *Discussion.* Because of the public benefits associated with allowing all-digital cable operators to encrypt the basic service tier, we amend our rule to permit this practice as long as the cable operator complies with certain consumer protection measures. Encryption of all-digital cable service will allow cable operators to activate and deactivate cable service remotely, thus relieving many consumers of the need to schedule appointments when they sign up for or cancel cable service. In addition, encryption will reduce the number of truck rolls necessary for manual installations and disconnections, reduce service theft, and establish regulatory parity between cable operators and their satellite competitors, who are not subject to the encryption rule. We find these benefits offset the increased burdens that may result from encryption of the basic service tier. Recognizing, as noted above, that some consumers rely on unencrypted basic tier service, we adopt narrowly tailored consumer protection measures to help ease the transition to encrypted service for those consumers. In the sections below, we first discuss which systems will be allowed to encrypt the basic service tier. Then we discuss the benefits associated with permitting all-digital cable operators to encrypt the basic service tier, as well as the burdens associated with our rule change and consumer protection measures we adopt to mitigate those burdens. Finally, we discuss the legal basis for the rule changes.

9. *Systems Eligible to Encrypt.* In the Encryption NPRM, the Commission proposed to allow encryption of the basic service tier only with respect to all-digital systems ''because remote activation and deactivation of cable service, and its attendant benefits, are only feasible in all-digital systems.'' For this reason, we limit encryption eligibility of the basic tier to all-digital systems. The Commission proposed to define an ''all-digital'' system as one in which ''no television signals are provided using the NTSC system.'' As explained below, we adopt our proposed definition, finding that it will best achieve our goal of facilitating remote activation and deactivation of cable service ''while minimizing interference with the special functions of subscribers' television sets.''

10. Commenters suggested several substantive changes to our proposed rule. Several commenters suggested that we extend encryption eligibility to cable operators that offer unencrypted analog ''barker channels.'' Mikrotec and Inter Mountain Cable suggested that operators should be allowed to encrypt the basic service tier as long as all ''programming'' on the basic tier is transmitted digitally and ''if that condition is met, then there should be no concern that the system otherwise uses analog modulation.'' They also suggest that eligibility to encrypt should be determined subscriber-by-subscriber, not on a system-by-system basis, because cable operators may elect to transition portions of systems to all-digital piecemeal, and the rule should not discourage that practice.

11. We believe the best criterion for eligibility to encrypt the basic service tier is that the system carries only digital signals aside from unencrypted analog barker channels. Encryption on hybrid systems (that is, systems that transmit signals in analog and digital) would not generate the benefits associated with encryption on all-digital systems because the analog portion of the system will still require truck rolls to activate and deactivate service and the Commission does not have a separated security solution like CableCARD to ensure that retail devices can access scrambled analog cable programming. Therefore, permitting hybrid systems to encrypt would not result in the type of benefits that justify easing the encryption requirement for all-digital systems. We do not believe that it is practical to adopt Mikrotec and Inter Mountain Cable's proposal to determine eligibility for encryption on a consumer-by-consumer basis, because encryption disparity on a consumer-by-consumer basis could lead to consumer confusion: Under this proposal, one subscriber could be subject to encryption (and the commensurate consumer-protection measures described below), while his neighbor could face no encryption and be able to access channels on the basic service tier. The administrative burdens of determining the applicability of the rule would also make such a proposal unreasonable. Therefore, we believe that our rule, which determines eligibility for encryption on a system-wide basis, is more reasonable and will better serve the public interest.

12. *Benefits of Permitting Basic Service Tier Encryption.* Remote Activation and Deactivation. Based on examination of the record, we are persuaded that allowing encryption of the basic service tier on all-digital systems will reduce the need for many consumers to schedule a service call and wait for the cable technician to arrive before initiating or terminating their cable service. ACA states in its comments that physical connection and disconnection of cable service in all-digital systems is ''unnecessary but for the existence of the basic service tier encryption prohibition.'' Comcast predicts that encrypting the basic service tier will allow the company to perform nearly half of its activations and 90 percent of its deactivations remotely. Cablevision reports that, since it received waiver of the encryption prohibition, 99.5 percent of its deactivations were performed remotely and a growing number of its new customers are eligible for remote activation. The result for consumers is that in many cases they will no longer need to rearrange their schedules to wait for cable technicians to arrive at their homes in order to activate and deactivate their cable service, making activation and deactivation of service much more convenient.

13. In addition to the projected time savings for subscribers because of remote activation and deactivation, the record is replete with secondary benefits that cable operators and their customers will realize as a result of remote service change. These include savings for cable operators because of a reduction in the need to dispatch service technicians to customers' homes. For example, commenters assert that reduced costs due to truck rolls and system maintenance will save cable operators money that they can use to ''invest in innovative new products that customers demand and highly value.'' In addition, Comcast states that, with remote activation and deactivation,

''technicians would need to access drop lines less frequently, thereby reducing 'wear-and-tear' on the lines and the need for maintenance.'' Many commenters also highlight the benefits remote activation and deactivation will have on vehicle traffic and the environment. Microtek and Inter Mountain Cable even suggest that these increased efficiencies could lead to lower rates for subscribers.

14. *Reduction of Theft and Piracy.* Another benefit of basic tier encryption is the likely reduction in theft of cable service. In 2004, NCTA estimated that five percent of homes passed receive unauthorized cable service, which equates to five billion dollars in unrealized revenue that cable operators could dedicate to offering improved services. The resulting reduction in cable operator revenues may increase the rates operators charge their subscribers. In addition, Comcast explains that theft of service reduces the quality of cable service because thieves sometimes access the cable system by splitting cables and adding unauthorized taps, which degrade connections and can lead to signal leakage and lower broadband speeds. This unauthorized splicing also can add to wear-and-tear on the cable system and increase the need for maintenance. Encryption of the basic service tier will discourage thieves from splicing cable lines as it will not enable viewing of the signals without leasing an authorized set-top box or CableCARD from the operator. Encryption of the basic service tier could also benefit channels that are carried on the basic service tier, as developers of high-value content may be more willing to make the content available to basic service tier channels if they are encrypted and less susceptible to piracy.

15. *Regulatory Parity.* Several commenters emphasized that the proposed rule change will increase regulatory parity between cable operators and satellite providers, which are not subject to the encryption rule. Commenters explain that the technology and market landscapes were quite different when the rule was adopted, when consumers had a reasonable expectation that they would be able to connect their televisions directly to a coaxial cable without the need for a set-top box. In the years since enactment of the 1992 Cable Act, consumer expectations have changed substantially. First, cable operators have introduced new and innovative services, such as video on demand and pay-per-view services, that cannot be accessed by digital subscribers without an authorized set-top box or, in some instances, a CableCARD. As a result, almost all digital subscribers already use set-top boxes or CableCARDs to access cable service. Second, since the 1992 Cable Act, satellite television operators have begun to offer video programming services to tens of millions of subscribers, who access these services through the use of one or more converter boxes. Our rules do not prohibit satellite operators from encrypting their services, and therefore they are able to make service changes remotely and in real time. Cable operators argue that this puts them at a regulatory disadvantage vis-à-vis their competitors that are not constrained by the requirements of § 76.630(a). We believe that by amending our encryption rule we will reduce this regulatory disparity and enable all-digital cable operators to provide a similar level of customer service as their MVPD competitors.

16. *Consumer Protection Measures to Reduce Burdens on Subscribers.* Although we expect our rule change will affect relatively few subscribers, we nonetheless adopt consumer protection measures to mitigate any resulting harm to subscribers who are impacted by encryption of the digital basic tier. This rule change will impact the few digital cable subscribers who access the basic service tier without a set-top box or CableCARD: They will need to obtain a set-top box or CableCARD from their cable operator once the operator encrypts the basic service tier. To give these consumers time to assess their options to access encrypted cable service, we will require cable operators that choose to encrypt to offer affected subscribers equipment necessary to receive the encrypted programming without charge for a limited time, and to notify their subscribers about encryption and the equipment offers. In addition, we require the six largest incumbent cable operators to offer equipment that is compatible with IP-enabled clear-QAM devices provided by third parties. We intend that this requirement will provide an opportunity for affected consumers to make informed choices about whether to purchase a CableCARD-compatible device, lease a set-top box from their cable operator, or use another method to access the broadcast and other channels carried on the basic service tier (for example, by accessing the signals over-the-air or via another MVPD). As we explained in the Encryption NPRM, such an opportunity will minimize the impact of encryption on clear-QAM users by offering a transition period during which they can continue to access the basic tier without an additional equipment charge while they consider their options for device compatibility. In this section, we identify the small class of subscribers that encryption may affect and adopt two categories of measures to protect those subscribers: Transitional equipment requirements and notice requirements.

17. *Subscribers That May Be Affected by Encryption of the BST.* The Commission concluded in 1994 that adopting the basic service tier encryption prohibition ''will have minimal impact on the cable industry in view of the fact that most cable systems now generally do not scramble basic tier signals.'' Today our examination of the record reflects that relaxing the encryption prohibition for all-digital systems will have minimal impact on consumers because most subscribers do not rely on the clear-QAM tuners in their devices to access basic tier signals. Nevertheless, we recognize that lifting the encryption prohibition may impact some cable subscribers who use clear-QAM devices to access the basic tier, such as subscribers who use second or third television sets to access unencrypted digital basic service tier service without set-top boxes or CableCARDs and subscribers that use third-party provided IP-enabled devices that have clear-QAM tuners. Several cable subscribers and equipment manufacturers filed comments claiming that our rule change would have a negative impact on them. These subscribers explain that they rely on clear-QAM tuners in their electronic devices (such as computers and television sets) to access basic tier programming, and that because they have more than two devices on which to view BST programming (e.g., they have multiple televisions in their home), their monthly bills will increase because they will need a greater number of converter boxes than afforded under the free box conditions that the Commission proposed in the Encryption NPRM. We are concerned about the effect of this rule change on the small group of subscribers who access unencrypted basic service tier programming through clear-QAM receivers, but, at the same time, recognize that no consumer protection measure could fully satisfy every affected subscriber. Nonetheless, we believe that the consumer-protection measures outlined below are appropriate and necessary to minimize disruption to affected subscribers by providing a reasonable transition period

to make informed choices about the options available to access the basic tier.

18. *Transitional Equipment Requirements Applicable to All Cable Operators.* To limit the costs that affected consumers may face due to encryption, we adopt our proposed consumer-protection measures that require a cable operator that chooses to encrypt the basic service tier to: (i) Offer to existing subscribers who subscribe only to the basic service tier and do not use a set-top box or CableCARD, the subscriber's choice of a set-top box or CableCARD on up to two television sets without charge for two years from the date of encryption; (ii) offer existing subscribers who subscribe to a level of service above ''basic only'' but use an additional television set to access only the basic service tier without the use of a set-top box or CableCARD at the time of encryption, the subscriber's choice of a set-top box or CableCARD on one television set without charge for one year from the date of encryption; and (iii) offer existing subscribers who receive Medicaid, subscribe only to the basic service tier, and do not use a set-top box or CableCARD, the subscriber's choice of a set-top box or CableCARD on up to two television sets without charge for five years from the date of encryption. These consumer protections apply to televisions and devices connected to the cable system at the time of encryption. To ensure that any subscriber likely to be affected by encryption has adequate time to consider these offers, we will require cable operators to keep the offer open to subscribers for at least 30 days before the date the operator begins encrypting the first basic tier channel on the channel lineup and for at least 120 days after that date. NCTA suggested that the offer extend for only 30 days after the date that encryption begins. We believe that 30 days after the date of encryption would not afford affected consumers sufficient time to learn about the effect of encryption and the consumer-protection measures available to them and act on the information. Furthermore, because encryption will affect only a very small number of subscribers, the consumer protection measures we adopt will not be unduly onerous on cable operators. We expect these transitional protections will substantially mitigate the costs to affected subscribers while they consider alternative means for accessing the basic service tier.

19. *Equipment Requirements Applicable to Top Six Incumbent Cable Operators.* A few commenters assert that the free equipment conditions described above do not mitigate any disruption because some consumers may own third-party provided IP-enabled devices that do not have the ability to decrypt cable signals. Therefore, these commenters call for the Commission to reject the proposed rule, or adopt special measures to mitigate disruption to consumers that use those third-party devices. Specifically, these parties complain that existing cable set-top boxes and DTAs are not compatible with IP-enabled devices because they do not output signals in a manner that third-party-provided IP-enabled devices can access. Accordingly, such devices would not be compatible with the operator's free equipment offering—i.e., there would be no connection by which such devices could access the basic tier channels—thus rendering such devices useless if a cable operator chooses to encrypt the basic tier. Commenters assert that such devices were purchased or manufactured on the expectation that unencrypted basic service tier QAM signals would continue to be available from cable operators. The record indicates that at least four companies have developed products that rely on customers' ability to access clear-QAM signals, and that a relatively small number of consumers have purchased these devices for this capability. As explained above, however, we anticipate the impact of encryption of the basic tier on the public at large will be minimal because the record indicates that only a small number of consumers rely on clear-QAM devices to access the basic tier. And the record further indicates that subscribers who use IP-enabled clear-QAM devices that would be incompatible with the free equipment offerings by cable operators represent an even smaller subset of clear-QAM users.

20. To mitigate any harm to the small group of consumers that may use such devices, NCTA's six largest incumbent cable members—serving 86 percent of all cable subscribers—have committed to adopt, prior to encrypting, a solution that would provide basic service tier access to third-party provided IP-enabled clear QAM devices. Pursuant to this commitment, these six cable operators will make basic service tier channels available either via connection from operator-supplied equipment or by providing access to the operator's security technology. Specifically, these cable operators have proposed to either (i) provide a converter box with ''standard home networking capability'' that can provide IP-enabled clear QAM devices access to basic service tier channels on the same terms proposed in the Encryption NPRM (''Option 1''), or (ii) enable IP-enabled clear QAM devices to access basic service tier channels without any additional hardware through the use of commercially available software upgrades (''Option 2''). NCTA proposed to sunset these commitments three years after we adopt this Order unless the Commission extends them. Boxee and CEA argue that these commitments do not sufficiently support the operation of IP-enabled clear QAM devices. Instead, they advocate that all cable operators should be required to make the basic service tier available to IP-enabled devices without additional hardware. CEA further encourages the Commission not to sunset the commitments after three years. The AllVid Alliance suggests that the Commission initiate a Notice of Proposed Rulemaking seeking comment on ''a nationally-portable common IP-based interface from MVPD services to consumer devices.''

21. We believe that the commitments from the six largest incumbent cable operators will be sufficient to address the compatibility issue concerning IP-enabled devices and achieve the objectives of section 624A of the Act—i.e., to ensure compatibility between cable service and consumer electronics equipment. We do not extend the additional equipment requirement to smaller cable operators because we do not believe it is necessary at this time. As noted above, based on the current record, only a small number of consumers rely on IP-enabled devices to access the basic tier and thus we expect this particular compatibility problem to be extremely limited in scope. Because the six largest incumbent cable operators subject to the rule serve 86 percent of all cable subscribers nationwide, we expect most consumers that use such devices will have ready access to the necessary equipment. Moreover, large cable operators generally dictate equipment features to manufacturers and commonly get priority in delivery of that equipment. We anticipate that the large operators' demand for this equipment eventually will lead all equipment to include this functionality in the marketplace, and thus the equipment small cable operators provide will eventually include the IP functionality as well, regardless whether they specify this particular feature. Nonetheless, we may revisit this issue if the equipment market does not develop as expected or if we find that small cable operators do not make their service compatible with these consumer devices.

22. Contrary to Boxee's argument, nothing in section 624A requires that consumer equipment compatibility be

achieved by means of a hardware-free solution. Under the equipment measure we adopt today, the vast majority of consumers will be able to access service that is encrypted using a commercially available security technology or via equipment with standard home-networking capability in much the same way they do today. In fact, if this standard home-networking capability is connected to a wireless home network, the consumer experience could improve because consumers will be able to access basic service tier channels without physically connecting a device to a coaxial plug from the wall. Thus, mandating a hardware-free solution is not necessary to protect consumers in the context of the instant proceeding.

23. We adopt these commitments as required preconditions to encrypting by the top six incumbent cable operators with slight modifications and clarifications. These conditions will automatically sunset three years from the release date of this Order unless the Media Bureau (''Bureau'') determines prior to this date that the IP-enabled device protections remain necessary to protect consumers. We believe that a future review of these rules is warranted because the market for these IP-based devices is nascent and it is unclear whether consumer demand for this equipment will flourish. Accordingly, we delegate authority to the Bureau to initiate a review two years after the release of this Order to decide whether these IP-enabled device protections remain necessary to protect consumers or whether it is appropriate to sunset the IP-enabled device protections. If the Bureau does not release an order extending these protections within three years from the release date of this Order, then the consumer protection measures concerning IP-enabled devices detailed above will no longer apply to the top-six cable operators for purposes of encryption of the basic service tier. In deciding whether the sunset is appropriate, the Bureau shall consider the costs to cable operators and the benefits to consumers, whether competitive services are available, regulatory parity between cable and other MVPDs, the state of technology and the marketplace, and cable operators' efforts to meet these commitments and ensure compatibility. The Bureau shall also consider whether the IP-enabled device protections should be extended to small cable operators.

24. Second, we add some clarifying language to address Boxee and CEA's concerns that cable operators could use licenses to limit retail device manufacturers from building compatible devices. Any license terms that cable operators require for the ''standard home networking capability'' used to offer access to the basic service tier in Option 1 and the ''requirements necessary (including any authentication processes)'' in Option 2 must be made available on a good faith basis. In adopting this ''good faith'' licensing requirement, we intentionally do not specify any particular technology or technology licensing model (e.g., we do not require or specify ''fair, reasonable, and non-discriminatory'' licensing, as that term has been interpreted in other contexts, as urged by Boxee and CEA). Third, we require the operators that choose to offer access to the basic service tier using Option 1 to ''publicly disclose the DLNA profile or other protocol that is being used for the home-networking capability on such operator-supplied equipment.'' Such a requirement is necessary to ensure that third-party manufacturers have the information necessary to build a device that works with cable-provided equipment. We also remind cable operators that § 76.640(b)(4)(iii) of our rules, which goes into effect in December of this year, requires all high definition set-top boxes (except for one-way, non-recording set-top boxes) to include an IP-compatible output based on an open industry standard that provides for audiovisual communications including service discovery, video transport, and remote control command pass-through standards for home networking. We believe that these additional consumer protection measures will ease the transition to encrypted service for the vast majority of the small subset of customers that rely on third-party provided IP-enabled devices to access the basic service tier.

25. *Other Issues.* Public Knowledge and Media Access Project state in their comments that there have been no complaints from customers in Cablevision's encrypted systems about ''hidden fees'' related to the free device offers, and they anticipate that cable operators ''intend to act in good faith.'' Out of an abundance of caution, however, they suggest we affirmatively state that cable operators may not impose service fees (such as ''digital access fees'' or ''outlet fees'') in lieu of rental fees for the free devices. Consistent with Public Knowledge and Media Access Project's suggestion, we clarify that boxes provided by cable operators that choose to encrypt the basic service tier must be provided without any additional service charges related to the equipment.

26. Public Knowledge and Media Access Project also suggest that we tie the low-income condition to Lifeline/Linkup eligibility because Medicaid eligibility can vary from state to state. We reject that suggestion as unnecessary. As several commenters point out, Medicaid eligibility presents an easily verifiable, bright-line test, and is less likely to cause confusion among subscribers and cable customer service representatives.

27. We also reject calls from some commenters to require free equipment in perpetuity for existing subscribers, and not to limit free boxes to existing subscribers. The consumer protection measures we adopt are intended to mitigate the disruption that may be experienced by current cable subscribers. We do not agree that free equipment is necessary for new subscribers: Given the movement to digital services, many subscribers have become accustomed to leasing set-top devices, and that trend seems likely to continue. Furthermore, we agree with NCTA that unnecessarily burdensome conditions such as free devices for all new subscribers could discourage cable operators from encrypting and prevent the public from realizing the benefits that stem from cable operators' ability to remotely activate and deactivate service which benefits most subscribers. Accordingly, we do not condition this rule change on cable operators' supplying free devices in perpetuity to existing subscribers or to new subscribers.

28. Certain commenters express concern about the impact that basic service tier encryption could have on institutional subscribers and schools in particular. They suggest that the Commission extend the free-device consumer protections to institutional subscribers to prevent the rule change from placing a financial burden on them. Cable operators, however, suggest that these commenters conflate encryption with digitization, and we agree. As cable operators transition to all-digital service, these institutional subscribers will need devices to convert digital signals to analog regardless of whether the service is encrypted unless the institutional subscribers use television sets with clear-QAM tuners and only use those televisions to access the basic service tier. Furthermore, Comcast argues that cable operators establish agreements with local institutions on a case-by-case basis, and that each franchising authority negotiates consumer protection measures to meet its needs. We are persuaded that it is unnecessary to adopt consumer-protection measures

with respect to institutional subscribers, because we expect that cable operators will continue to work with local institutions—and may be required to do so by franchising authorities—to ensure that the institutions' needs will be met. We emphasize that our rules are not intended to limit or preempt existing, renegotiated, or future franchise agreements that provide institutional subscribers more equipment on different terms than our rules require for residential subscribers. We expect that cable operators will work closely with local franchising authorities and institutions to ensure that any disruption institutional subscribers experience as a result of encryption will be minimized.

29. ACA and BendBroadband express concern about the effect that the conditions will have on small cable operators. We agree with ACA and BendBroadband that in some instances the benefits of encryption may be outweighed by the burdens of administrative upgrades to account for the new billing procedures needed to offer free devices for a limited period of time. We note, however, that the decision to encrypt the basic service tier will be a voluntary decision made at the sole discretion of the cable operator under the rules we adopt here. Thus, each cable operator may use its business judgment to decide whether, and when, the benefits of encryption outweigh the costs of upgrading billing software and providing equipment to its subscribers to ease the transition to encrypted service.

30. *Notification Requirements.* Based on the record, we believe that notification requirements are also necessary to protect consumers. Therefore, we will require cable operators to notify their subscribers about the planned encryption and the device offers at least 30 days before the date encryption of the basic tier commences. We will also require cable operators to notify their subscribers at least 30 days, but no more than 60 days, before the end of the free device transitional period. These notifications are necessary to make the device-based consumer protection measures meaningful to consumers; the measures would be meaningless if affected consumers were not made aware of the offers.

31. NCTA proposed that our rules require cable operators to notify their subscribers about encryption and free device offers at least 30 days prior to the date encryption of the basic service tier commences. Several commenters supported NCTA's proposal, and we agree that it is important to identify when cable operators must notify their subscribers about encryption. Therefore, we will require cable operators to notify their subscribers that they will encrypt at least 30 days before the date encryption of the basic service tier commences, at which time they must also include information about the transitional device requirements set forth in Section 76.630. The notice must state:

On (DATE), (NAME OF CABLE OPERATOR) will start encrypting (INSERT NAME OF CABLE BASIC SERVICE TIER OFFERING) on your cable system. If you have a set-top box, digital transport adapter (DTA), or a retail CableCARD device connected to each of your TVs, you will be unaffected by this change. However, if you are currently receiving (INSERT NAME OF CABLE BASIC SERVICE TIER OFFERING) on any TV without equipment supplied by (NAME OF CABLE OPERATOR), you will lose the ability to view any channels on that TV.

If you are affected, you should contact (NAME OF CABLE OPERATOR) to arrange for the equipment you need to continue receiving your services. In such case, you are entitled to receive equipment at no additional charge or service fee for a limited period of time. The number and type of devices you are entitled to receive and for how long will vary depending on your situation. If you are a (INSERT NAME OF CABLE BASIC SERVICE TIER OFFERING) customer and receive the service on your TV without (NAME OF CABLE OPERATOR)-supplied equipment, you are entitled to up to two devices for two years (five years if you also receive Medicaid). If you subscribe to a higher level of service and receive (INSERT NAME OF CABLE BASIC SERVICE TIER OFFERING) on a secondary TV without (NAME OF CABLE OPERATOR)-supplied equipment, you are entitled to one device for one year.

You can learn more about this equipment offer and eligibility at (WEBPAGE ADDRESS) or by calling (PHONE NUMBER). To qualify for any equipment at no additional charge or service fee, you must request the equipment between (DATE THAT IS 30 DAYS BEFORE ENCRYPTION) and (DATE THAT IS 120 DAYS AFTER ENCRYPTION) and satisfy all other eligibility requirements.

32. We believe that 30 days' notice will provide a reasonable opportunity for affected consumers to avail themselves of free device offers in advance of basic service tier encryption without unduly burdening cable operators. In addition, at least 30 days, but no more than 60 days, before the end of the free device transitional period, a cable operator that encrypts must notify subscribers that have taken advantage of the transitional period that the period is ending as follows:

You currently receive equipment necessary to descramble or decrypt the basic service tier signals (either a set-top box or CableCARD) free of charge. Effective with the (MONTH/YEAR) billing cycle, (NAME OF CABLE OPERATOR) will begin charging you for the equipment you received to access (INSERT NAME OF CABLE BASIC SERVICE TIER OFFERING) when (NAME OF CABLE OPERATOR) started encrypting those channels on your cable system. The monthly charge for the (TYPE OF DEVICE) will be (AMOUNT OF CHARGE).

33. While our rule prescribes the language that cable operators must use to notify their subscribers about encryption and the device-based protection measures, we leave open the option for cable operators to supplement this notice as they see fit. We will not require the six largest incumbent cable operators to provide special notice to their subscribers about the availability of IP-enabled device compatibility, though they must comply with existing notice requirements. Third-party IP-enabled device manufacturers have an economic incentive to ensure their customers are aware of the functions and features of their devices, e.g., provide notice to their customers in marketing materials about the need to obtain IP-enabled equipment from their cable operator and the special equipment the six largest incumbent cable operators are required to offer their subscribers under Commission rules.

34. Public Knowledge and Media Access Project proposed that we require operators to notify subscribers when their free device period is ending on each monthly bill for the three months preceding the end of the transition period. We agree that preventing ''bill shock'' is important, and § 76.1603(d) of our rules requires cable operators to provide written notice of any increase in price to be charged for equipment necessary to access the basic service tier at least 30 days before the increase is effective. We do not believe that the three notices that Public Knowledge and Media Access Project propose are necessary. But we are concerned that cable operators could notify their subscribers too early in the transition period to render notification essentially meaningless. Therefore, we believe it is important to define the window for notices more precisely so that affected subscribers are notified no more than 60

days before the end of the transitional free-device period. At that time, affected subscribers can determine the course that best suits their circumstances. Some subscribers may opt to continue their current level of service and pay for the additional equipment charges. Other subscribers may choose to reduce their level of service or terminate their existing cable service and pursue a competitive alternative that better meets their service needs and budgets.

35. The New York City Department of Information Technology and Telecommunications (NYC DoITT) argues that, because Cablevision's encryption of its New York City systems is nascent, the Commission cannot be sure of the long-term effects that basic service tier encryption may have. Therefore, NYC DoITT encourages the Commission to make this rule change temporary. We agree that we cannot predict how our rule change will affect the cable industry and subscribers with absolute certainty. The information before us indicates, however, that this rule change will result in the substantial public interest benefits discussed above and that any additional burdens imposed on a limited number of subscribers will be tempered by the consumer protection measures adopted herein. The Commission will keep apprised of the consequences of the rule change and, if the situation develops differently than predicted, we can revisit the issue on our own initiative or in response to a petition for rulemaking. In the future, we may seek information from the operators that have chosen to encrypt to ensure that the expected benefits are being achieved and any burdens to consumers are being minimized. However, nothing in the record persuades us that it is necessary to build a sunset into the rule.

36. *Legal Basis.* Section 624A of the Communications Act provides the Commission broad authority to make changes to our encryption rule and to impose the consumer-protection measures we adopt today. Congress's objective in enacting section 624A was to ensure compatibility between cable systems and consumer TV (receiving and recording) equipment, consistent with the need to prevent theft of cable service. Section 624A(b)(2) directs the Commission to ''determine whether and, if so, under what circumstances to permit cable systems to scramble or encrypt signals or to restrict cable systems in the manner in which they encrypt or scramble signals.'' Section 624A(d) directs the Commission to periodically review and modify regulations adopted pursuant to section 624A ''to reflect improvements and changes in cable systems, television receivers, video cassette recorders and similar technology.'' The record suggests that to achieve the statutory goals of section 624A a blanket ban on encryption is no longer necessary, and that changes in cable technology justify relaxing the rule for all-digital cable systems, provided consumer protection measures are addressed. As explained above, cable technology is markedly different than it was when the Commission first adopted the encryption prohibition set forth in § 76.630. For example, the transition to all-digital systems means that encryption of the basic service tier will permit remote activation and deactivation of cable service resulting in significant savings of time and resources for both cable operators and the vast majority of cable customers. Furthermore, as discussed below, the CableCARD standard provides an avenue for consumers to purchase consumer electronics devices that are compatible with digital cable service, which achieves Congress' stated goal in section 624A.

37. Relaxing the encryption rule in this manner will not impede section 624A's goal of compatibility between consumer electronics equipment and cable systems. The Commission has adopted a standard that allows for ''plug and play'' compatibility between consumer electronics devices and cable systems. This standard provides a clear path for device manufacturers to follow if they wish to build devices that are compatible with digital cable systems and can access all linear digital cable services. Montgomery County, Maryland argues that the CableCARD standard is not successful, and that the Commission should endeavor to relieve compatibility problems, rather than compound them. According to Montgomery County, relaxing the encryption rule will lead to compatibility problems because consumers will no longer be able to use clear-QAM tuners on non-primary television sets. However, the Commission has already adopted a solution for compatibility between consumer electronics equipment and digital cable: The CableCARD standard is intended to allow consumers to buy compatible retail devices to access all linear digital cable services as opposed to the basic-only service that clear-QAM tuners can access without additional equipment. Indeed, the Commission's cable-ready labeling rules prohibit device manufacturers from labeling their devices as ''digital cable ready'' unless they comply with the CableCARD standards. Thus, under our existing rules, manufacturers should not have indicated to consumers that devices could receive digital cable service unless those devices were, in fact, CableCARD-compatible. Therefore, we disagree with Montgomery County's characterization that encryption will lead to an abundance of compatibility problems due to the rule changes adopted herein. Section 624A(c)(1)(B) expressly directs the Commission to consider ''the costs and benefits to consumers of imposing compatibility requirements on cable operators.'' As discussed above, the costs associated with a blanket encryption prohibition in all-digital systems greatly outweigh the anticipated benefits to consumers, particularly in light of the consumer protection measures we are also adopting. Furthermore, in 2010, the Commission adopted changes to the CableCARD rules, including streamlined device approval procedures, a self-installation option, and a prohibition on price discrimination against CableCARD devices, that should increase the retail availability and the quality of experience for CableCARD devices and further increase compatibility between consumer electronics and cable service by ensuring that retail devices can access all linear digital cable services. Given these technological and rule changes, we conclude that a complete prohibition on basic service tier encryption in all-digital systems is no longer necessary to ensure compatibility between consumer electronics devices and cable service, provided certain consumer protection measures are satisfied.

38. We also conclude that the requirement in section 623(b)(3)(A) of the Act to base any price or rate standards for equipment installation and leasing on actual cost does not bar the Commission from imposing the consumer protection measures set forth in § 76.630(a)(1)(ii)–(vi) of our new rules. The commenters who addressed our legal authority agree that the consumer protection measures—which are adopted as a transitional measure and implicate a limited number of affected customers—do not run afoul of section 623 of the Communications Act, and we did not receive any comments claiming that the consumer protection measures, as structured, would violate section 623. These measures are not being imposed as a regulation of equipment rates under section 623. Rather, the consumer protection measures are being adopted pursuant to section 624A(b)(2)'s broad grant of authority to the Commission to determine ''under what circumstances

to permit cable systems to scramble or encrypt signals or to restrict cable systems in the manner in which they encrypt or scramble signals.'' We have determined that relaxing the encryption prohibition should be permitted for all-digital systems, provided the potential harm to affected consumers is minimized. Our new rule permits a cable operator to elect to abide by the encryption prohibition without having any obligation to offer subscribers equipment for a transitional period. It is only when a cable operator chooses to encrypt the basic service tier that it is required to comply with the requisite regulatory conditions (by providing set-top boxes at no cost to affected subscribers for a limited transitional period). Thus, this requirement is imposed as a condition of a cable operator's voluntary election to encrypt the basic service tier, and not as a rate regulation imposed under section 623(b)(3)(A).

39. *Waiver Requests.* As mentioned above, the Commission has pending before it four petitions for waiver of the encryption ban. These petitions have been pending for more than a year. Petitioners seek immediate relief, claiming that they face extraordinary theft of service. We find good cause to grant these waiver requests effective upon release of this Order to prevent further delay. For the reasons set forth above, these waivers are conditioned upon the petitioners' complying with the consumer protection requirements discussed in this Order.

40. *Conclusion.* We conclude that allowing cable operators to encrypt the basic service tier in all-digital systems will result in substantial, tangible benefits to both consumers and cable operators with minimal countervailing burdens on affected subscribers. We believe that the consumer-protection measures that we adopt will mitigate any burdens that encryption will have on the limited number of consumers that may be affected by the instant rule change.

41. *Paperwork Reduction Act Analysis.* The Report and Order in this document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4).

42. *Final Regulatory Flexibility Analysis.* As required by the Regulatory Flexibility Act, the Commission has prepared a Final Regulatory Flexibility Analysis (''FRFA'') relating to this Report and Order. The FRFA is set forth below.

43. *Congressional Review Act.* The Commission will send a copy of this Third Report and Order in a report to be send to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

44. Ordering Clauses. Accordingly, *it is ordered* that, pursuant to the authority contained in sections 1, 4(i), 4(j), 303(r), 601, and 624A of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), 303(r), 521, and 544a, this Report and Order *is adopted.*

45. *It is further ordered* that, pursuant to the authority contained in sections 1, 4(i), 4(j), 303(r), 601, and 624A of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), 303(r), 521, and 544a, Part 76 of the Commission's rules *is amended* as set forth in the rules and is effective December 10, 2012. It is our intention that all of the rule changes adopted in this order are interdependent and inseparable and that if any provision of the rules, or the application thereof to any person or circumstance, are held to be unlawful or invalid, the remaining rule changes adopted herein shall not be effective.

46. *It is further ordered* that, pursuant to § 1.3 of the Commission's rules, 47 CFR 1.3, the requests for waiver of § 76.630(a) of the Commission's rules, 47 CFR 76.630(a), filed by RCN Corporation, Mikrotec CATV, LLC, Inter Mountain Cable, Inc., and Coaxial Cable TV *are granted,* to the extent described herein and conditioned as set forth above.

47. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Report and Order, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

48. *It is further ordered* that the Commission *shall send* a copy of this Report and Order in a report to be sent to Congress and the General Accounting Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

49. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the Notice of Proposed Rule Making (NPRM). The Commission sought written public comment on the proposals in the NPRM, including comment on the IRFA. No commenting parties specifically addressed the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA. The Commission will send a copy of the R&O, including this FRFA, to the Chief Counsel for Advocacy of the Small Business Administration. In addition, the R&O and FRFA (or summaries thereof) will be published in the **Federal Register**.

50. *Need for, and Objectives of the Proposed Rules.* With this Report and Order, the Commission amends its rules to allow cable operators to encrypt the basic service tier in all-digital cable systems if they comply with certain consumer-protection measures. This rule change will benefit consumers who can have their cable service activated and deactivated from a remote location. By allowing remote activation and deactivation, we expect our amended rules will result in benefits to both cable operators and consumers by significantly reducing the number of service calls associated with provisioning service and significantly reducing the need for subscribers to wait for service calls to activate or deactivate cable service. At the same time, we recognize that this rule change will adversely affect a small number of cable subscribers who currently view the digital basic service tier without using a set-top box or other equipment. If a cable operator decides to encrypt the digital basic tier, then these subscribers will need equipment to continue viewing the channels on this tier. To give those consumers time to resolve the incompatibility between consumer electronics equipment (such as digital television sets) and newly encrypted cable service, we require operators of cable systems that choose to encrypt the basic service tier to comply with certain consumer protection measures for a period of time. The Commission concludes that allowing cable operators to encrypt the basic service tier in all-digital systems will lead to benefits like decreased service calls and theft of service, with few associated burdens on consumers. Therefore the Commission believes that this rule change will reduce burdens on small entities. The Commission predicts that encryption of the basic service tier will not substantially affect compatibility between cable service and consumer electronics equipment for most subscribers because over 75 percent of subscribers already have set-top boxes to decrypt the signals. Because the rule is voluntary—a cable operator with an all-digital system may choose whether to encrypt that system—each cable operator may decide whether the benefits of encryption (which include

reduced service calls and reduced theft) outweigh the cost of providing its subscribers with the equipment they will need to continue viewing the channels on the basic service tier.

51. The need for FCC regulation in this area derives from changing technology in the cable services market. When the Commission adopted technical rules in the 1990s, digital cable service was in its infancy, and therefore the rules were adopted with analog cable service in mind. Today, digital cable service is common, and the encryption rule does not translate well in systems that offer all-digital service. Therefore, the Commission will allow all-digital cable operators to encrypt the basic service tier.

52. We recognize that some consumers subscribe only to a cable operator's digital basic service tier and currently are able to do so without using a set-top box or other equipment. Similarly, there are consumers that may have a set-top box on a primary television but access the unencrypted digital basic service tier on second or third televisions in their home without using a set-top box or other equipment. Although we expect the number of subscribers in these situations to be extremely small, these consumers may be affected by lifting the encryption prohibition for all-digital cable systems. To address this problem, we conclude that operators of all-digital cable systems that choose to encrypt the basic service tier must comply with certain consumer protection measures for a limited period of time in order to minimize any potential subscriber disruption, including a requirement that the six largest cable operators offer IP-enabled set-top boxes to subscribers as part of these protections.

53. The Commission believes that the rule will save small entities money. The consumer protection element of the rule—the requirement that cable operators offer existing basic tier customers set-top boxes without charge for certain lengths of time—does associate a cost with the rule. But the Commission believes that the financial benefit to small cable operators in reduced truck rolls and theft of services will far outweigh that cost. Furthermore, because the decision of whether to encrypt the basic tier is voluntary, small businesses will be able to make a business decision about whether to encrypt.

54. *Legal Basis.* The authority for the action proposed in this rulemaking is contained in sections 1, 4(i) and (j), 303(r), 601, and 624A of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i) and (j), 303(r), 521, and 544a.

55. *Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply.* The RFA directs the Commission to provide a description of and, where feasible, an estimate of the number of small entities that will be affected by the proposed rules. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental entity'' under Section 3 of the Small Business Act. In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (''SBA'').

56. *Cable and Other Program Distribution.* Since 2007, these services have been defined within the broad economic census category of Wired Telecommunications Carriers; that category is defined as follows: ''This industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies.'' The SBA has developed a small business size standard for this category, which is: All such firms having 1,500 or fewer employees. According to Census Bureau data for 2007, there were a total of 955 firms in this previous category that operated for the entire year. Of this total, 939 firms had employment of 999 or fewer employees, and 16 firms had employment of 1000 employees or more. Thus, under this size standard, the majority of firms can be considered small and may be affected by rules adopted pursuant to the NPRM.

57. *Cable Companies and Systems (Rate Regulation Standard).* The Commission has also developed its own small business size standards for the purpose of cable rate regulation. Under the Commission's rules, a ''small cable company'' is one serving 400,000 or fewer subscribers nationwide. As of 2008, out of 814 cable operators, all but 10 (that is, 804) qualify as small cable companies under this standard. In addition, under the Commission's rules, a ''small system'' is a cable system serving 15,000 or fewer subscribers. Current Commission records show 6,000 cable systems. Of these, 726 have 20,000 subscribers or more, based on the same records. We estimate that there are 5,000 small systems based upon this standard.

58. *Cable System Operators (Telecom Act Standard).* The Communications Act of 1934, as amended, also contains a size standard for small cable system operators, which is ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1 percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000.'' There are approximately 63.7 million cable subscribers in the United States today. Accordingly, an operator serving fewer than 637,000 subscribers shall be deemed a small operator, if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate. Based on available data, we find that the number of cable operators serving 637,000 subscribers or less is also 804. We note that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million. Although it seems certain that some of these cable system operators are affiliated with entities whose gross annual revenues exceed $250,000,000, we are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

59. *Direct Broadcast Satellite (''DBS'') Service.* DBS service is a nationally distributed subscription service that delivers video and audio programming via satellite to a small parabolic ''dish'' antenna at the subscriber's location. DBS, by exception, is now included in the SBA's broad economic census category, ''Wired Telecommunications Carriers,'' which was developed for small wireline firms. Under this category, the SBA deems a wireline business to be small if it has 1,500 or fewer employees. However, the data we have available as a basis for estimating the number of such small entities were gathered under a superseded SBA small business size standard formerly titled ''Cable and Other Program Distribution.'' The definition of Cable and Other Program Distribution provided that a small entity is one with $12.5 million or less in annual receipts. Currently, only two entities provide DBS service, which requires a great investment of capital for operation:

DIRECTV and EchoStar Communications Corporation (''EchoStar'') (marketed as the DISH Network). Each currently offer subscription services. DIRECTV and EchoStar each report annual revenues that are in excess of the threshold for a small business. Because DBS service requires significant capital, we believe it is unlikely that a small entity as defined by the SBA would have the financial wherewithal to become a DBS service provider. We seek comments that have data on the annual revenues and number of employees of DBS service providers.

60. *Satellite Master Antenna Television (SMATV) Systems, also known as Private Cable Operators (PCOs).* SMATV systems or PCOs are video distribution facilities that use closed transmission paths without using any public right-of-way. They acquire video programming and distribute it via terrestrial wiring in urban and suburban multiple dwelling units such as apartments and condominiums, and commercial multiple tenant units such as hotels and office buildings. SMATV systems or PCOs are now included in the SBA's broad economic census category, ''Wired Telecommunications Carriers,'' which was developed for small wireline firms. Under this category, the SBA deems a wireline business to be small if it has 1,500 or fewer employees. However, the data we have available as a basis for estimating the number of such small entities were gathered under a superseded SBA small business size standard formerly titled ''Cable and Other Program Distribution.'' The definition of Cable and Other Program Distribution provided that a small entity is one with $12.5 million or less in annual receipts. As of June 2004, there were approximately 135 members in the Independent Multi-Family Communications Council (IMCC), the trade association that represents PCOs. The IMCC indicates that, as of June 2006, PCOs serve about 1 to 2 percent of the multichannel video programming distributors (MVPD) marketplace. Individual PCOs often serve approximately 3,000–4,000 subscribers, but the larger operations serve as many as 15,000–55,000 subscribers. In total, as of June 2006, PCOs serve approximately 900,000 subscribers. Because these operators are not rate regulated, they are not required to file financial data with the Commission. Furthermore, we are not aware of any privately published financial information regarding these operators. Based on the estimated number of operators and the estimated number of units served by the largest 10 PCOs, we believe that a substantial number of PCOs may have been categorized as small entities under the now superseded SBA small business size standard for Cable and Other Program Distribution.

61. *Open Video Services.* The open video system (''OVS'') framework was established in 1996, and is one of four statutorily recognized options for the provision of video programming services by local exchange carriers. The OVS framework provides opportunities for the distribution of video programming other than through cable systems. Because OVS operators provide subscription services, OVS falls within the SBA small business size standard covering cable services, which is ''Wired Telecommunications Carriers.'' The SBA has developed a small business size standard for this category, which is: All such firms having 1,500 or fewer employees. According to Census Bureau data for 2007, there were a total of 3,188 firms in this previous category that operated for the entire year. Of this total, 3,144 firms had employment of 999 or fewer employees, and 44 firms had employment of 1000 employees or more. Thus, under this size standard, most cable systems are small and may be affected by rules adopted pursuant to the NPRM. In addition, we note that the Commission has certified some OVS operators, with some now providing service. Broadband service providers (''BSPs'') are currently the only significant holders of OVS certifications or local OVS franchises. The Commission does not have financial or employment information regarding the entities authorized to provide OVS, some of which may not yet be operational. Thus, again, at least some of the OVS operators may qualify as small entities.

62. *Computer Terminal Manufacturing.* ''Computer terminals are input/output devices that connect with a central computer for processing.'' The SBA has developed a small business size standard for this category of manufacturing; that size standard is 1,000 or fewer employees. According to 2007 Census Bureau data, there were 42 establishments in this category that operated during 2007. Only 3 had more than 100 employees. Consequently, we estimate that all of these establishments are small entities.

63. *Other Computer Peripheral Equipment Manufacturing.* Examples of peripheral equipment in this category include keyboards, mouse devices, monitors, and scanners. The SBA has developed a small business size standard for this category of manufacturing; that size standard is 1,000 or fewer employees. According to 2007 Census Bureau data, there were 647 establishments in this category that operated in 2007. Of these, only 62 had more than 100 employees. Consequently, we estimate that the majority of these establishments are small entities.

64. *Audio and Video Equipment Manufacturing.* The SBA has classified the manufacturing of audio and video equipment under in NAICS Codes classification scheme as an industry in which a manufacturer is small if it has less than 750 employees. Data contained in the 2007 U.S. Census indicate that 491 establishments operated in that industry for all or part of that year. In that year, 376 establishments had between 1 and 19 employees; 80 had between 20 and 99 employees; and 35 had more than 100 employees. Thus, under the applicable size standard, a majority of manufacturers of audio and video equipment may be considered small.

65. *Description of Reporting, Recordkeeping and Other Compliance Requirements.* The rules adopted in the Order will require cable operators to notify their subscribers about offers of free equipment associated with encryption. The rule also requires a cable operator to notify its subscribers when those subscribers are subject to charges at the end of the free equipment period.

66. *Steps Taken To Minimize Significant Impact on Small Entities, and Significant Alternatives Considered.* The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

67. As an alternative to the rules the Commission adopted, the Commission considered leaving the current rule in place—with the result that no cable operator would realize the benefits of encryption—or exempting small cable companies from the consumer protection rules that require encrypting cable operators to provide certain subscribers with free set-top boxes for a limited time. The Commission rejected

leaving the rule in place because that alternative would not lead to the benefits of reduced service calls and reduced cable theft. The Commission rejected exempting small cable companies from the consumer protection rules because it concluded that the protections are necessary to give affected consumers time to consider how to make consumer electronics equipment (such as digital television sets) compatible with newly encrypted cable service. For these reasons, the Commission concluded that basic service tier encryption prohibition should be relaxed. The Commission also concluded that transitional consumer protection measures are necessary to serve the limited number of consumers who currently access unencrypted cable service without the use of a set-top box.

68. *Federal Rules Which Duplicate, Overlap, or Conflict With the Commission's Proposals.* None.

List of Subjects in 47 CFR Part 76

Administrative practice and procedure, Cable television, Equal employment opportunity, Political candidates, Reporting and recordkeeping requirements.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Rule Changes

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 76 as follows:

PART 76—MULTICHANNEL VIDEO AND CABLE TELEVISION SERVICE

■ 1. The authority citation for part 76 continues to read as follows:

Authority: 47 U.S.C. 151, 152, 153, 154, 301, 302, 302a, 303, 303a, 307, 308, 309, 312, 315, 317, 325, 339, 340, 341, 503, 521, 522, 531, 532, 534, 535, 536, 537, 543, 544, 544a, 545, 548, 549, 552, 554, 556, 558, 560, 561, 571, 572, 573.

■ 2. Amend § 76.630 by revising paragraph (a) and revising section notes 1 and 2 and removing notes 3 and 4.

The revisions read as follows:

§ 76.630 Compatibility with consumer electronics equipment.

(a) Cable system operators shall not scramble or otherwise encrypt signals delivered to a subscriber on the basic service tier.

(1) This prohibition shall not apply in systems in which:

(i) No encrypted signals are carried using the NTSC system; and

(ii) The cable system operator offers to its existing subscribers who subscribe only to the basic service tier without use of a set-top box or CableCARD at the time of encryption the equipment necessary to descramble or decrypt the basic service tier signals (the subscriber's choice of a set-top box or CableCARD) on up to two television sets without charge or service fee for two years from the date encryption of the basic service tier commences; and

(iii) The cable system operator offers to its existing subscribers who subscribe to a level of service above ''basic only'' but use a digital television or other device with a clear-QAM tuner to receive only the basic service tier without use of a set-top box or CableCARD at the time of encryption, the equipment necessary to descramble or decrypt the basic service tier signals (the subscriber's choice of a set-top box or CableCARD) on one television set without charge or service fee for one year from the date encryption of the basic service tier commences; and

(iv) The cable system operator offers to its existing subscribers who receive Medicaid and also subscribe only to the basic service tier without use of a set-top box or CableCARD at the time of encryption the equipment necessary to descramble or decrypt the basic service tier signals (the subscriber's choice of a set-top box or CableCARD) on up to two television sets without charge or service fee for five years from the date encryption of the basic service tier commences;

(v) The cable system operator notifies its existing subscribers of the availability of the offers described in paragraphs (ii) through (iv) of this section at least 30 days prior to the date encryption of the basic service tier commences and makes the offers available for at least 30 days prior to and 120 days after the date encryption of the basic service tier commences. The notification to subscribers must state:

On (DATE), (NAME OF CABLE OPERATOR) will start encrypting (INSERT NAME OF CABLE BASIC SERVICE TIER OFFERING) on your cable system. If you have a set-top box, digital transport adapter (DTA), or a retail CableCARD device connected to each of your TVs, you will be unaffected by this change. However, if you are currently receiving (INSERT NAME OF CABLE BASIC SERVICE TIER OFFERING) on any TV without equipment supplied by (NAME OF CABLE OPERATOR), you will lose the ability to view any channels on that TV.

If you are affected, you should contact (NAME OF CABLE OPERATOR) to arrange for the equipment you need to continue receiving your services. In such case, you are entitled to receive equipment at no additional charge or service fee for a limited period of time. The number and type of devices you are entitled to receive and for how long will vary depending on your situation. If you are a (INSERT NAME OF CABLE BASIC SERVICE TIER OFFERING) customer and receive the service on your TV without (NAME OF CABLE OPERATOR)-supplied equipment, you are entitled to up to two devices for two years (five years if you also receive Medicaid). If you subscribe to a higher level of service and receive (INSERT NAME OF CABLE BASIC SERVICE TIER OFFERING) on a secondary TV without (NAME OF CABLE OPERATOR)-supplied equipment, you are entitled to one device for one year.

You can learn more about this equipment offer and eligibility at (WEBPAGE ADDRESS) or by calling (PHONE NUMBER). To qualify for any equipment at no additional charge or service fee, you must request the equipment between (DATE THAT IS 30 DAYS BEFORE ENCRYPTION) and (DATE THAT IS 120 DAYS AFTER ENCRYPTION) and satisfy all other eligibility requirements.

(vi) The cable system operator notifies its subscribers who have received equipment described in paragraphs (a)(1)(ii) through (iv) of this section at least 30 days, but no more than 60 days, before the end of the free device transitional period that the transitional period will end. This notification must state:

You currently receive equipment necessary to descramble or decrypt the basic service tier signals (either a set-top box or CableCARD) free of charge. Effective with the (MONTH/YEAR) billing cycle, (NAME OF CABLE OPERATOR) will begin charging you for the equipment you received to access (INSERT NAME OF CABLE BASIC SERVICE TIER OFFERING) when (NAME OF CABLE OPERATOR) started encrypting those channels on your cable system. The monthly charge for the (TYPE OF DEVICE) will be (AMOUNT OF CHARGE).

(2) Requests for waivers of this prohibition must demonstrate either a substantial problem with theft of basic tier service or a strong need to scramble basic signals for other reasons. As part of this showing, cable operators are required to notify subscribers by mail of waiver requests. The notice to subscribers must be mailed no later than 30 calendar days from the date the request for waiver was filed with the Commission, and cable operators must inform the Commission in writing, as soon as possible, of that notification

date. The notification to subscribers must state:

On (date of waiver request was filed with the Commission), (cable operator's name) filed with the Federal Communications Commission a request for waiver of the rule prohibiting scrambling of channels on the basic tier of service. 47 CFR 76.630(a). The request for waiver states (a brief summary of the waiver request). A copy of the request for waiver shall be available for public inspection at (the address of the cable operator's local place of business).

Individuals who wish to comment on this request for waiver should mail comments to the Federal Communications Commission by no later than 30 days from (the date the notification was mailed to subscribers). Those comments should be addressed to the: Federal Communications Commission, Media Bureau, Washington, DC 20554, and should include the name of the cable operator to whom the comments are applicable. Individuals should also send a copy of their comments to (the cable operator at its local place of business).

Cable operators may file comments in reply no later than 7 days from the date subscriber comments must be filed.

* * * * *

Note 1 to § 76.630: 47 CFR 76.1621 contains certain requirements pertaining to a cable operator's offer to supply subscribers with special equipment that will enable the simultaneous reception of multiple signals.

Note 2 to § 76.630: 47 CFR 76.1622 contains certain requirements pertaining to the provision of a consumer education program on compatibility matters to subscribers.

■ 3. Section 76.1603 is amended by revising paragraph (d) to read as follows:

§ 76.1603 Customer service—rate and service changes.

* * * * *

(d) A cable operator shall provide written notice to a subscriber of any increase in the price to be charged for the basic service tier or associated equipment at least 30 days before any proposed increase is effective. If the equipment is provided to the consumer without charge pursuant to § 76.630, the cable operator shall provide written notice to the subscriber no more than 60 days before the increase is effective. The notice should include the price to be charged, and the date that the new charge will be effective, and the name and address of the local franchising authority.

* * * * *

[FR Doc. 2012–27350 Filed 11–8–12; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[FWS–R8–FHC–2011–0046]; [FF08E00000–FXES11130800000D2–123]

RIN 1018–AX51

Endangered and Threatened Wildlife and Plants; Termination of the Southern Sea Otter Translocation Program; Final Supplemental Environmental Impact Statement on the Translocation of Southern Sea Otters

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of our final Supplemental Environmental Impact Statement on the Translocation of Southern Sea Otters (final SEIS). The final SEIS evaluates options for continuing, revising, or terminating the southern sea otter translocation program, which was initiated in 1987. The purpose of the program was to achieve a primary recovery action for the southern sea otter: to create an established population at San Nicolas Island sufficient to repopulate other areas of the range should a catastrophic event affect the mainland population. The document describes the proposed action and alternatives under consideration and discloses the direct, indirect, and cumulative environmental effects of each of the alternatives.

DATES: We will execute a Record of Decision no sooner than 30 days after the date the Environmental Protection Agency publishes its notice of availability of the final SEIS in the **Federal Register**.

ADDRESSES: The final SEIS and other documents are available in electronic format at the following places:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* In the search field, enter FWS–R8–FHC–2011–0046, which is the docket number. Then click on the Search button. On the resulting screen, you may view documents associated with the docket.
- *Agency Web site:* You can view supporting documents on our Web site at *http://www.fws.gov/ventura/.*
- *Our office:* Call 805–644–1766 to make an appointment, during normal business hours, to view the documents, comments, and materials in person at the U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office, 2493 Portola Road, Suite B, Ventura, CA 93003–7726.

Alternatively, a limited number of CD–ROMs and hard copies of the final SEIS are available from the U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office, 2493 Portola Road, Suite B, Ventura, CA 93003–7726.

FOR FURTHER INFORMATION CONTACT: Lilian Carswell, at the above Ventura street address, by telephone (805–612–2793), or by electronic mail (*Lilian_Carswell@fws.gov*). Persons who use a telecommunications device for the deaf may call the Federal Information Relay Services at 800–877–8339.

SUPPLEMENTARY INFORMATION: We announce the availability of our final Supplemental Environmental Impact Statement on the Translocation of Southern Sea Otters (final SEIS). The final SEIS evaluates options for continuing, revising, or terminating the southern sea otter translocation program (52 FR 29754, Aug. 11, 1987). The document describes the proposed action and alternatives under consideration and discloses the direct, indirect, and cumulative environmental effects of each of the alternatives.

Background

The final SEIS reevaluates the effects of the southern sea otter translocation plan, as described in the U.S. Fish and Wildlife Service's 1987 environmental impact statement on our program for translocation of southern sea otters (May 8, 1987, 52 FR 17486). Using information obtained over the decades since the program's implementation, we evaluate the impacts of alternatives to the current translocation program, including termination or revisions to the program. The need for action stems from our inability to meet the goals of the southern sea otter translocation program. Contrary to the primary recovery objective of the program, the translocation of sea otters to San Nicolas Island has not resulted in an established population sufficient to repopulate other areas of the range should a catastrophic event affect the mainland population. Additionally, maintenance of a management zone has proven to be more difficult than anticipated and hinders or may prevent recovery of the southern sea otter.

We consider six alternatives, including a No Action Alternative. Alternative 1 resumes implementation of the 1987 southern sea otter translocation program as originally defined. Alternative 2 resumes implementation of the 1987 southern sea otter translocation program but reduces the size of the management zone. Alternatives 3A, 3B, and 3C allow for the natural range expansion of southern sea otters through termination of the 1987 translocation program, including its associated translocation zone and management zone, but differ in the actions to be taken with sea otters existing in these zones upon termination of the program. Alternative 3A requires the short-term removal of sea otters from both the management zone and the translocation zone before natural range expansion is allowed. Alternative 3B requires the short-term removal of sea otters from the translocation zone only. The Service's preferred alternative (Alternative 3C) is to allow for the natural range expansion of sea otters through termination of the 1987 translocation program and to allow sea otters existing in the former translocation and management zones to remain there.

We have afforded other government agencies and the public extensive opportunity to participate in the preparation of this EIS. On July 27, 2000, we published in the **Federal Register** a notice of intent to prepare a SEIS on the southern sea otter translocation program (65 FR 46172). The notice of intent announced that public scoping meetings would be held on August 15, 2000, in Santa Barbara, California, and on August 17, 2000, in Monterey, California. In April 2001, we published a scoping report and distributed it to scoping meeting participants and other interested parties (the scoping report is included as Appendix E to the final SEIS).

We announced the availability of the draft SEIS and the beginning of the public comment period on October 7, 2005 (70 FR 58737). The comment period was originally scheduled to end on January 5, 2006 (70 FR 58737). On December 30, 2005, we extended the comment period to March 6, 2006 (70 FR 77380), based on requests for a 30-day or 60-day extension of the comment period by fishing and environmental groups. We accepted oral and written testimony during public hearings held in Santa Barbara, California, on November 1, 2005, and Monterey, California, on November 3, 2005. During the 5-month comment period, we received approximately 20,000 comments from interested individuals and organizations.

Continuing efforts to resolve stakeholder concerns forestalled publication of a final SEIS for several years. On September 30, 2009, two environmental groups filed suit against the Service under provisions of the Administrative Procedure Act, alleging that we had unreasonably delayed a decision on the translocation program. Publication of a final SEIS on the translocation program is part of the settlement agreement we reached with plaintiffs on November 23, 2010.

In order to ensure that our analysis reflects current conditions, we revised the draft SEIS. We announced the availability of a revised draft SEIS and a proposed rule to implement the preferred alternative on August 26, 2011 (76 FR 53381). Appendix G to the revised draft SEIS included a list of commenters, summaries of comments received on the draft SEIS, and our responses to those comments. The comment period for the revised draft SEIS was originally scheduled to end on October 24, 2011 (76 FR 53381). On November 4, 2011, we announced a reopening of the comment period until November 21, 2011 (76 FR 68393), based on a request for a 45-day extension by the California Sea Urchin Commission. We were unable to grant the full 45-day extension because we required sufficient time to consider public comments and to revise the SEIS as appropriate while still meeting court settlement deadlines; however, the reopened comment period allowed us to accept public comments for 18 additional days. We accepted oral and written testimony during public hearings held in Ventura, California, on September 27, 2011; Santa Barbara, California, on October 4, 2011; and Santa Cruz, California, on October 6, 2011. Approximately 190 people attended the public hearings, and 68 provided testimony.

In the 78 days during which comments were accepted, we received 6,843 comment letters, postcards, and emails from interested individuals and organizations. Among the comment letters were 5 petitions with 12,514 signatories.

Appendix G to the final SEIS includes a list of commenters, summaries of comments received on the revised draft SEIS, and our responses to those comments.

Authority

This notice is provided pursuant to Fish and Wildlife Service regulations for implementing the National Environmental Policy Act of 1969 (40 CFR 1506.6).

Dated: November 1, 2012.

Alexandra Pitts,

Acting Regional Director, Pacific Southwest Region.

[FR Doc. 2012–27310 Filed 11–8–12; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 120417412–2412–01]

RIN 0648–BB90

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Gray Triggerfish Management Measures

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

ACTION: Temporary rule; interim measures extended.

SUMMARY: NMFS issues this temporary rule to extend the expiration date of interim measures to reduce overfishing of gray triggerfish in the Gulf of Mexico (Gulf) implemented by a temporary rule published by NMFS on May 14, 2012. This temporary rule extends the reduced commercial quota (commercial annual catch target (ACT)), commercial and recreational annual catch limits (ACLs), and recreational ACT; and the revised recreational accountability measures (AMs) for gray triggerfish, as requested by the Gulf of Mexico Fishery Management Council (Council). The intended effect of this temporary rule is to reduce overfishing of the gray triggerfish resource in the Gulf while the Council develops permanent management measures.

DATES: The expiration date for the interim rule published at 77 FR 28308, May 14, 2012, is extended from November 10, 2012, through May 15, 2013, unless NMFS publishes a superseding document in the **Federal Register**.

ADDRESSES: Electronic copies of documents supporting this temporary rule, which include an environmental assessment (EA) and a regulatory flexibility analysis, may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Peter Hood, telephone: 727–824–5305 or email: *Peter.Hood@noaa.gov.*

SUPPLEMENTARY INFORMATION: The reef fish fishery of the Gulf is managed under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP). The FMP was prepared by the Council and is implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Magnuson-Stevens Act provides the legal authority for the promulgation of interim regulations under section 305(c) (16 U.S.C. 1855(c)).

Section 305(c)(2) of the Magnuson-Stevens Act provides the Council the authority to request interim measures, if necessary, to reduce overfishing. On April 19, 2012, the Council requested that NMFS implement a temporary rule to reduce overfishing of gray triggerfish in the Gulf while the Council and NMFS develop Amendment 37 to the FMP. Amendment 37 will contain permanent measures to end overfishing of the gray triggerfish stock. On May 14, 2012, NMFS published the final temporary rule (77 FR 28308) to implement measures to reduce overfishing of gray triggerfish in the Gulf and requested public comment. The interim measures implemented revised commercial and recreational ACLs and ACTs and revised the AMs for the recreational sector. Through the final temporary rule, the commercial sector ACL was reduced to 64,100 lb (29,075 kg), round weight, and the commercial ACT (commercial quota) was reduced to 60,900 lb (27,624 kg), round weight. The recreational sector ACL was reduced to 241,200 lb (109,406 kg), round weight, and the recreational ACT was reduced to 217,100 (98,475 kg), round weight. Additionally, the temporary rule established an in-season AM for the gray triggerfish recreational sector that prohibits the recreational harvest of gray triggerfish (a recreational sector closure) after the recreational ACT is reached or projected to be reached.

The Council requested an extension of the interim rule on August 23, 2012, to ensure that management measures remain in effect for gray triggerfish to reduce overfishing while more permanent measures are developed through Amendment 37. Section 305(c)(3)(B) of the Magnuson-Stevens Act allows for interim measures to be extended for one additional period of 186 days provided that the public has had an opportunity to comment on the interim measures and the Council is actively preparing a plan amendment to address the overfishing on a permanent basis.

Amendment 37 is scheduled to be implemented early in the 2013 fishing year.

Comments and Responses

Section 305(c)(3)(B) of the Magnuson-Stevens Act requires that the public has an opportunity to comment on interim measures after the regulation is published and the Council is actively preparing a plan amendment to address overfishing on a permanent basis. Therefore, NMFS solicited comments in the May 14, 2012, final temporary rule. NMFS received comments from a total of 11 entities on the final temporary rule. The following is a summary of the substantive comments NMFS received and NMFS' respective responses. Similar comments have been grouped together.

Comment 1: Personal observations do not support the stock assessment findings that the stock is overfished and undergoing overfishing. Therefore, there is no reason for the temporary rule.

Response: Gray triggerfish are known to be highly site specific and so it is possible that gray triggerfish abundance is greater in some areas of the Gulf than in others. However, both the 2006 benchmark and 2011 update Southeast Data, Assessment, and Review (SEDAR) assessments of the gray triggerfish stock used data from a variety of sources throughout the Gulf. Both of these assessments, which are considered the best available science, indicate the stock size is too low (overfished) and that too many fish are being caught and landed (overfishing). The Magnuson-Stevens Act requires the Council and NMFS to end overfishing and allow the stock to recover; therefore, the Council and NMFS are obligated to revise the gray triggerfish rebuilding plan to achieve these objectives.

Comment 2: Personal observations support that gray triggerfish abundances are low, but the cause of the reduction in abundance is not due to overfishing. Reductions in abundance are due to the number of red snapper feeding on juvenile reef fish, including gray triggerfish.

Response: The 2011 SEDAR update assessment indicated that for 2005–2009, gray triggerfish recruitment has been less than average. However, the reason for the reduced recruitment is currently unknown. At this time, there is no evidence to support that low gray triggerfish recruitment is a result of red snapper predation.

Comment 3: Rather than closing gray triggerfish recreational harvest when the ACL is reached, a reduced recreational bag limit should have been implemented to avoid any closures.

Response: In evaluating long-term measures to reduce the recreational harvest of gray triggerfish in Amendment 37, the Council is evaluating reduced recreational bag limits. However, their analyses indicate that even if the bag limit were reduced to 1-fish per person per day from the current 20-fish reef fish aggregate bag limit, some type of seasonal closure is needed to reduce harvest consistent with reductions needed for the rebuilding plan. The Council is evaluating a combination of these measures in Amendment 37 to the FMP.

Comment 4: The 2011 SEDAR gray triggerfish update stock assessment did not account for changes in gray triggerfish fishing as a result of the increase in the minimum size limit and the requirement to use circle hooks.

Response: The 2011 SEDAR update assessment did account for the increase from 12-inches (30.5 cm), total length, to 14-inches (35.6 cm), fork length. This change was noted in the regulatory history section in the final 2011 SEDAR update assessment report. The effects of the size limit change were reflected in length data from fishery-dependent sampling programs after August 4, 2008, when Amendment 30A to the FMP became effective and these measures were implemented (73 FR 38139, July 3, 2008). Although the effects of circle hooks on gray triggerfish fishing were not specifically examined in the 2011 update assessment, the 2011 SEDAR update stock assessment showed declines in both the commercial and recreational harvest starting in 2005, well before the circle hook requirement went into effect on June 1, 2008. Therefore, other factors are responsible for the declining gray triggerfish stock. In addition, differences between catch-per-unit-effort estimates between the 2011 SEDAR update assessment and the 2006 SEDAR benchmark assessment did not vary by much, suggesting the change to circle hooks has had little effect on gray triggerfish fishing.

Comment 5: The gray triggerfish commercial sector should be closed until the gray triggerfish stock recovers.

Response: The temporary rule reduces overfishing of the gray triggerfish stock while the Council develops a rebuilding plan in Amendment 37. In rebuilding overfished stocks, the Magnuson-Stevens Act requires that regulations shall ''allocate both overfishing restrictions and recovery benefits fairly and equitably among sectors of the fishery'' (Magnuson-Stevens Act section 304(e)(4)(B)). The action proposed in the comment would place all overfishing

restrictions to the commercial sector, and as the stock recovers, allocate these benefits to the recreational sector. Thus, this action would not be fair and equitable and would not conform to the Magnuson-Stevens Act.

Additionally, the current allocation between the commercial and recreational sector is 29 percent and 71 percent, respectively. Given the needed reduction in gray triggerfish harvest from 2011 levels to 2012 levels is approximately 50 percent, closing the commercial sector would not achieve the needed reduction in harvest that would allow the stock to recover by 2017, the end year of the 10-year gray triggerfish rebuilding plan. Therefore, even with an established commercial closure, recreational measures would still need to be implemented for the stock to recover within the allotted time of the rebuilding plan.

Classification

The Administrator, Southeast Region, NMFS, (RA) has determined that the interim measures this temporary rule extends are necessary for the conservation and management of the Gulf gray triggerfish stock, until more permanent measures are implemented, and is consistent with the Magnuson-Stevens Act and other applicable laws. The Council and NMFS are developing Amendment 37 to the FMP to establish long-term measures to end the overfishing of Gulf gray triggerfish and rebuild the stock. Amendment 37 and its associated regulations are still being implemented and are not expected to become effective until the 2013 fishing year.

This temporary rule has been determined to be not significant for purposes of E.O. 12866.

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

An EA was prepared for the interim measures contained in the May 14, 2012, final temporary rule (77 FR 28308). The EA analyzed the impacts of reduced harvest through the 2012 fishing year, which includes the impacts related to extending the interim rule. Therefore, the impacts of continuing the interim measures through this extension have already been considered. Copies of the EA are available from NMFS (see **ADDRESSES**).

The Assistant Administrator for Fisheries, NOAA (AA) finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and opportunity for public comment on this temporary rule extension. Providing prior notice and opportunity for public comment would be contrary to the public interest. This rule would continue interim measures implemented by the May 14, 2012, final temporary rule, for not more than an additional 186 days beyond the current expiration date of November 10, 2012. The conditions prompting the initial temporary rule still remain, and more permanent measures to be completed through Amendment 37 have not yet been finalized. Failure to extend these interim measures, while NMFS finalizes the more permanent measures in Amendment 37, would result in additional overfishing of the Gulf gray triggerfish stock, which is contrary to the public interest and in violation of National Standard 1 of the Magnuson-Stevens Act.

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

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

Dated: November 6, 2012.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2012–27444 Filed 11–8–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 120917459–2591–01]

RIN 0648–BC57

Fisheries of the Northeastern United States; Atlantic Mackerel, Squid, and Butterfish Fisheries; Specifications and Management Measures

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

ACTION: Interim final rule.

SUMMARY: NMFS is implementing revised 2012 specifications for the butterfish fishery, which is managed as part of the Atlantic Mackerel, Squid, and Butterfish Fishery Management Plan. This action raises the butterfish acceptable biological catch (ABC) to 4,200 mt (from 3,622 mt), and specifies the butterfish annual catch target (ACT) at 3,780 mt, the domestic annual harvest (DAH) and domestic annual processing (DAP) at 872 mt, and the butterfish mortality cap at 3,165 mt. These specifications promote the utilization and conservation of the butterfish resource.

DATES: Effective on November 8, 2012. Comments must be received by November 26, 2012.

ADDRESSES: Copies of the revised 2012 specifications document, including the Environmental Assessment (EA), is available from John K. Bullard, Northeast Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. This document is also accessible via the Internet at *http://www.nero.noaa.gov*.

You may submit comments, identified by NOAA–NMFS–2012–0209, by any one of the following methods:

- Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal *www.regulations.gov*. To submit comments via the e-Rulemaking Portal, first click the ''submit a comment'' icon, then enter NOAA–NMFS–2012–0209 in the keyword search. Locate the document you wish to comment on from the resulting list and click on the ''Submit a Comment'' icon on the right of that line.
- Mail to NMFS, Northeast Regional Office, 55 Great Republic Dr, Gloucester, MA 01930. Mark the outside of the envelope ''Comments on Interim Final 2012 Butterfish Specifications.''
- Fax: (978) 281–9135, Attn: Aja Szumylo.

Instructions: Comments must be submitted by one of the above methods to ensure that they are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word or Excel, WordPerfect, or Adobe PDF file formats only. Comments on this interim final rule will be addressed in the final rule for 2013 Specifications and Management Measures for the

Atlantic Mackerel, Squid, and Butterfish Fishery Management Plan.

FOR FURTHER INFORMATION CONTACT: Aja Szumylo, Fishery Policy Analyst, 978–281–9195, fax 978–281–9135.

SUPPLEMENTARY INFORMATION:

Background

At the August 2012 Mid-Atlantic Fishery Management Council (Council) meeting, several longfin squid industry members expressed concern that the current 2012 acceptable biological catch (ABC) for butterfish (3,622 mt) was too conservative, and that the butterfish mortality cap on the longfin squid fishery derived from this ABC may close the longfin squid fishery prior to the end of the 2012 fishing year. In response to this concern, and in light of the Council's Scientific and Statistical Committee's (SSC) recommended butterfish ABC for the 2013 fishing year (8,400 mt), the Council requested that the SSC reconsider its butterfish ABC recommendation for 2012. The SSC met on September 13, 2012, and revised its 2012 butterfish ABC recommendation to 4,200 mt based on the information that supported their 2013 ABC recommendation, and noted that the additional mortality at the end of the 2012 fishing year should not result in overfishing. The recommendation of 4,200 mt represents the projected butterfish mortality on November 1, 2012 (2,800 mt), plus the prorated mortality that would have been allocated for the months of November and December (700 mt per month) if the SSC had recommended a 2012 ABC of 8,400 mt (2,800 mt + (700 mt × 2) = 4,200 mt).

A detailed summary of the SSC's rationale for its 2013 butterfish ABC recommendation is available in its May 2012 Report (available, along with other materials from the SSC discussion, at: *http://www.mafmc.org/meeting_materials/SSC/2012-05/SSC_2012_05.htm*), and will be discussed in the documentation for the 2013 MSB specifications recommendations. It is summarized below because of its relevance to this action.

Because of the uncertainty in the most recent butterfish stock assessment, on April 6, 2012, the Council requested that NMFS Northeast Fisheries Science Center (NEFSC) offer additional analysis of the butterfish stock to aid the SSC in the ABC setting process for the 2013 fishing year. The NEFSC analysis (May 2, 2012, also available with the SSC meeting report) applied ranges of a number of different factors (such as natural mortality and survey catchability) to develop a range of likely stock biomasses that would be consistent with recent survey results and observed butterfish catch. The NEFSC also examined a range of fishing mortalities that would result from these biomass estimates. The SSC used the NEFSC analysis, along with guidance (Patterson, 1992) that suggests maintaining a natural mortality/fishing mortality ratio of 67 percent for small pelagic species, to develop a proxy overfishing limit (OFL) for butterfish. Consistent with the 2010 butterfish assessment, the SSC assumed a high level of natural mortality (M = 0.8) and applied the 67-percent ratio to result in a fishing mortality of F = 0.536, which the SSC used as a proxy maximum fishing mortality rate threshold for butterfish. In the NEFSC analysis, a catch of 16,800 mt would only lead to fishing mortality rates higher than F = 0.536 (i.e., rates consistent with overfishing based on the maximum fishing mortality rate threshold proxy) under very extreme assumptions. The SSC therefore adopted 16,800 mt as a proxy OFL. The SSC buffered the proxy OFL by 50 percent to reach the butterfish ABC of 8,400 mt. Its justification for this buffer noted that the short life history of butterfish gives limited time for management to respond to adverse patterns, that recruitment of butterfish is highly variable and uncertain, that the stock status of butterfish is unknown, and that butterfish are susceptible to environmental and ecosystem variability, in particular inter-annual variability in natural mortality.

Based on the SSC's revised recommendation, the Council met on September 14, 2012, and recommended an increase of the butterfish ABC and annual catch limit (ACL) to 4,200 mt for the remainder of the 2012 fishing year (until December 31, 2012). The Council recommended maintaining the current 10-percent buffer for management uncertainty and set an annual catch target (ACT) of 3,780 mt (a 520-mt increase over the current ACT of 3,260 mt).

The Council also recommended re-specifying the butterfish mortality cap at 3,165 mt, and the butterfish domestic annual harvest (DAH) and domestic annual processing (DAP) at 872 mt. The current butterfish mortality cap on the longfin squid fishery is 2,445 mt, and the Council proposed using the entire 520 mt added to the ACT to increase the butterfish mortality cap, as well as transferring 200 mt from the current DAH (1,072 mt) to the cap, for a total increase of 720 mt (2,445 mt + 520 mt + 200 mt = 3,165 mt). Butterfish landings and the butterfish cap are tracked in parallel such that all landings count against the DAH for quota monitoring, while all butterfish catch (landings and discards) by vessels that land over 2,500 lb (1.13 mt) of longfin squid count against the butterfish mortality cap. The Council requested that 200 mt of the current DAH be moved to the butterfish mortality cap to balance the use of butterfish in the mortality cap and the directed fishery, while constraining overall catch within the ABC. Current landing trends suggest that total 2012 butterfish landing should not exceed 650 mt, thus transferring an additional 200 mt from the DAH into the butterfish cap would allow for additional longfin squid landings without constraining butterfish landings.

NMFS found that there is sufficient scientific justification for the Council's recommendations, and is implementing the revised specifications as recommended. The authority for this rulemaking is 50 CFR 648.22(e), which allows the Regional Administrator to adjust specifications during the fishing year, in consultation with the Council, by publishing notification in the **Federal Register**. The allocations for Research Set-Aside (RSA) and joint venture processing (JVP) remain as specified in the interim final butterfish specifications (77 FR 16472; March 21, 2012). The total allowable level of foreign fishing (TALFF) for butterfish is only specified to address bycatch by foreign fleets targeting mackerel TALFF. Because there was no mackerel TALFF specified in the final 2012 specifications for mackerel, butterfish TALFF is also set at zero.

TABLE 1—INTERIM FINAL SPECIFICATIONS, IN METRIC TONS (MT), FOR BUTTERFISH FOR THE 2012 FISHING YEAR

Specifications	Butterfish
OFL	(1)
ABC	4,200
ACL	4,200
ACT	3,780
RSA	15
DAH/DAP	872
JVP	0
TALFF	0
Butterfish Mortality Cap	3,165

[1] Unknown.

Classification

The Administrator, Northeast Region, NMFS, determined that these specifications are necessary for the conservation and management of the butterfish fishery and that they are

consistent with the Magnuson-Stevens Fishery Conservation and Management Act and other applicable laws.

The Assistant Administrator for Fisheries, NOAA, finds good cause under section 553(b)(B) of the Administrative Procedure Act to waive the requirement that NMFS provide prior notice of this rule and an opportunity for comment because they are contrary to the public interest. Allowing time for prior notice and public comment would be contrary to the public interest because of the unnecessary economic harm it would cause to the longfin squid fishery. The interim final 2012 butterfish specifications will aid the longfin squid fishery because the rule will increase the butterfish mortality cap in that fishery to 3,165 mt (a 720-mt increase from status quo). Recently available data indicate that the butterfish biomass has sufficiently increased to allow NMFS to increase the butterfish mortality cap without risking harm to the species. This action did not allow for prior public comment because the request for Council reconsideration of the 2012 butterfish specifications, the SSC's scientific review process, and the determination could not have been completed any earlier, due to the inherent time constraints associated with the process. While the information supporting this change became available during the specifications setting process for the 2013 fishing year in May 2012, the need to use this information to adjust the 2012 butterfish specifications only became apparent in August 2012, after high squid availability and rapid utilization of the lower (2,445-mt) butterfish mortality cap made the possibility of a Trimester III longfin squid closure imminent. The request to consider the applicability of the SSC's 2013 butterfish ABC recommendation to the 2012 fishing year was made on August 16, 2012. The SSC met to review this request on September 13, 2012, which was the earliest possible date that they could meet given public notice requirements necessary to schedule and convene SSC meetings. Similarly, the Council met to consider the SSC's revised recommendation and recommend the adjustment to the butterfish ABC at the earliest possible date given public notice requirements, which was September 14, 2012. Allowing time for prior public notice and comment in addition to that offered through the Council process would further delay the use of available scientific information to increase the butterfish mortality cap on the longfin squid fishery, which negates direct benefits to the longfin squid fleet.

The Assistant Administrator for Fisheries also finds good cause under section 553(d) of the Administrative Procedure Act to waive the 30-day delay in effectiveness for this action. Increasing the butterfish mortality cap should allow for the longfin squid fishery to operate for the duration of the 2012 fishing year. Longfin squid migrate throughout their range and have sporadic availability. The fleet is quick to target longfin squid aggregations when they do appear, and is capable of landing over 550 mt in a single week. Analysis of this year's fishing activity indicates that longfin squid was particularly abundant this spring and summer, and historical availability patterns suggest that longfin squid abundance could remain high until the close of the fishing year on December 31, 2012. Only 11,598 mt of the 22,220 mt longfin squid quota has been harvested as of October 31, 2012, meaning that 52.1 percent of the quota remains to be harvested during the final 2 months of the fishing year. Closing the longfin squid fishery during the 30-day delay period prior to the implementation of this rule could prevent the harvest of a significant amount of longfin squid quota. With current squid prices at $1 per pound, the lost revenue from such a closure (up to 1,200 mt of the remaining 10,622 mt of longfin squid quota—the average monthly squid landings for the 2012 fishing year) could amount to $2.6 million, which would negate any benefit of implementing this rule. As noted above, allowing the longfin squid fishery to extend its fishing activity through the end of the 2012 fishing year will not result in harm to the butterfish population. Moreover, the fishing entities affected by this rule need not change their practice or gear, or make any other modifications to come into compliance with this action. These fishing vessels can continue to fish as they do now without any change after this rule goes into effect.

The Council prepared an EA for the 2012 specifications, and the NOAA Assistant Administrator for Fisheries concluded that there will be no significant impact on the human environment as a result of this rule. A copy of the EA is available upon request (see **ADDRESSES**).

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

This rule is exempt from the procedures of the Regulatory Flexibility Act to prepare a regulatory flexibility analysis because the rule is issued without opportunity for prior public comment.

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

Dated: November 5, 2012.

Paul N. Doremus,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. 2012–27335 Filed 11–8–12; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 77, No. 218
Friday, November 9, 2012

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2012–1200; Notice No. 25–12–07–SC]

Special Conditions: Embraer S.A., Model EMB–550 Airplane; Hydrophobic Coatings in Lieu of Windshield Wipers

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This action proposes special conditions for the Embraer S.A., Model EMB–550 airplane. This airplane will have a novel or unusual design feature(s) associated with hydrophobic coatings. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Send your comments on or before December 24, 2012.

ADDRESSES: Send comments identified by docket number [FAA–2012–1200] using any of the following methods:

- *Federal eRegulations 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 8 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: Paul Bernado, FAA, Airplane and Flight Crew Interface Branch, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98057–3356; telephone 425–227–1209; facsimile 425–227–1320.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive on or before the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On May 14, 2009, Embraer S.A. applied for a type certificate for their new Model EMB–550 airplane. The Model EMB–550 airplane is the first of a new family of jet airplanes designed for corporate flight, fractional, charter, and private owner operations. The aircraft has a conventional configuration with low wing and T-tail empennage. The primary structure is metal with composite empennage and control surfaces. The Model EMB–550 airplane is designed for 8 passengers, with a maximum of 12 passengers. It is equipped with two Honeywell HTF7500–E medium bypass ratio turbofan engines mounted on aft fuselage pylons. Each engine produces approximately 6,540 pounds of thrust for normal takeoff. The primary flight controls consist of hydraulically powered fly-by-wire elevators, aileron and rudder, controlled by the pilot or copilot sidestick.

The Model EMB–550 airplane will use a hydrophobic coating on the windshield in lieu of windshield wipers. The existing regulation, Title 14, Code of Federal Regulations (14 CFR) 25.773(b)(1), requires a means to maintain a sufficiently clear portion of the windshield for both pilots to have sufficiently extensive view along the flight path during precipitation conditions in heavy rain at speeds up to 1.5 V_{SR1}. The heavy rain and high speed conditions in the rule do not necessarily represent the limiting condition for this new technology. For example, airflow over the windshield may be necessary to remove moisture, but may not be adequate to maintain a sufficiently clear area of the windshield in low speed flight or during surface operations. Alternatively, airflow over the windshield may be disturbed during critical times such as the approach to land, where the airplane is at higher-than-normal pitch angle.

Type Certification Basis

Under the provisions of 14 CFR 21.17, Embraer S.A. must show that the Model EMB–550 airplane meets the applicable provisions of part 25, as amended by Amendments 25–1 through 25–127 thereto.

If the Administrator finds that the applicable airworthiness regulations (i.e., 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model EMB–550 airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, the special

conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Embraer S.A. Model EMB–550 airplane must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36 and the FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92–574, the ''Noise Control Act of 1972.''

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The Embraer S.A. Model EMB–550 airplane will incorporate the following novel or unusual design features: The Model EMB–550 airplane has a hydrophobic coating on the windshield to provide adequate pilot compartment view in precipitation in lieu of windshield wipers.

Discussion

14 CFR 25.773(b)(1) requires a means to maintain a clear portion of the windshield for both pilots to have a sufficiently extensive view along the flight path during precipitation conditions. The regulations require this means to maintain such an area during precipitation in heavy rain at speeds up to 1.5 V_{SR1}. The requirement that the means to maintain a clear area of forward vision must function at high speeds and high precipitation rates is based on the use of windshield wipers as the means to maintain an adequate area of clear vision in precipitation conditions. The requirement in 14 CFR 121.313(b), and in 14 CFR 125.213(b), to provide ''a windshield wiper or equivalent for each pilot station'' has remained unchanged since at least 1953.

The effectiveness of windshield wipers to maintain an area of clear vision normally degrades as airspeed and precipitation rates increase. It is assumed that because high speeds and high precipitation rates represent limiting conditions for windshield wipers, they will also be effective at lower speeds and precipitation levels. Accordingly, § 25.773(b)(1)(i) does not require maintenance of a clear area of forward vision at lower speeds or lower precipitation rates.

A forced airflow blown directly over the windshield has also been used to maintain an area of clear vision in precipitation. The limiting conditions for this technology are comparable to those for windshield wipers. Accordingly, introduction of this technology did not present a need for special conditions to maintain the level of safety embodied in the existing regulations.

Hydrophobic windshield coatings may depend to some degree on airflow directly over the windshield to maintain a clear vision area. The heavy rain and high-speed conditions specified in the current rule do not necessarily represent the limiting conditions for this new technology. For example, airflow over the windshield, which may be necessary to remove moisture from the windshield, may not be adequate to maintain a sufficiently clear area of the windshield in low speed flight or during ground operations. Alternatively, airflow over the windshield may be disturbed during such critical times as the approach to land, where the airplane is at a higher than normal pitch attitude. In these cases, areas of airflow disturbance or separation on the windshield could cause failure to maintain a clear vision area on the windshield.

In addition to potentially depending on airflow to function effectively, hydrophobic coatings may also be dependent on water droplet size for effective precipitation removal. For example, precipitation in the form of a light mist may not be sufficient for the coating's properties to result in maintaining a clear area of vision.

In summary, the current regulations identify speed and precipitation rate requirements that represent limiting conditions for windshield wipers and blowers, but not for hydrophobic coatings, so it is necessary to issue special conditions to maintain the level of safety represented by the current regulations.

These special conditions provide an appropriate safety standard for the hydrophobic coating technology as the means to maintain a clear area of vision by requiring it to be effective at low speeds and precipitation rates as well as the higher speeds and precipitation rates identified in the current regulation.

Applicability

As discussed above, these special conditions are applicable to the Embraer S.A. Model EMB–550 airplane. Should Embraer S.A. apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model of airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for Embraer S.A. Model EMB–550 airplanes.

Hydrophobic Coatings in Lieu of Windshield Wipers

The airplane must have a means to maintain a clear portion of the windshield, during precipitation conditions, enough for both pilots to have a sufficiently extensive view along the ground or flight path in normal taxi and flight attitudes of the airplane. This means must be designed to function, without continuous attention on the part of the flightcrew, in conditions from light misting precipitation to heavy rain at speeds from fully stopped in still air, to 1.5 V_{SR1} with lift and drag devices retracted.

Issued in Renton, Washington, on November, 5, 2012.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–27373 Filed 11–8–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA–2012–1199; Notice No. 25–12–06–SC]

Special Conditions: Embraer S.A., Model EMB–550 Airplanes; Flight Envelope Protection: Performance Credit for Automatic Takeoff Thrust Control System (ATTCS) During Go-Around

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This action proposes special conditions for the Embraer S.A. Model

EMB–550 airplane. This airplane will have a novel or unusual design feature(s) associated with the use of an Automatic Takeoff Thrust Control System (ATTCS) during go-around. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Send your comments on or before December 24, 2012.

ADDRESSES: Send comments identified by docket number FAA–2012–1199 using any of the following methods:

- *Federal eRegulations 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 8 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: Joe Jacobsen, FAA, Airplane and Flight Crew Interface Branch, ANM–111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98057–3356; telephone 425–227–2011; facsimile 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive on or before the closing date for comments. We may change these special conditions based on the comments we receive.

Background

On May 14, 2009, Embraer S.A. applied for a type certificate for their new Model EMB–550 airplane. The Model EMB–550 airplane is the first of a new family of jet airplanes designed for corporate flight, fractional, charter, and private owner operations. The aircraft has a conventional configuration with low wing and T-tail empennage. The primary structure is metal with composite empennage and control surfaces. The Model EMB–550 airplane is designed for 8 passengers, with a maximum of 12 passengers. It is equipped with two Honeywell HTF7500–E medium bypass ratio turbofan engines mounted on aft fuselage pylons. Each engine produces approximately 6,540 pounds of thrust for normal takeoff. The primary flight controls consist of hydraulically powered fly-by-wire elevators, ailerons and rudder, controlled by the pilot or copilot sidestick.

Embraer S.A. has incorporated an ATTCS function into the engine of the Model EMB–550 airplane. It has a full authority digital electronic control system architecture. Embraer S.A. proposed allowing performance credit for this function during go-arounds to show compliance with the requirements of § 25.121(d) for approach climb performance. Since the airworthiness requirements do not contain appropriate safety standards for approach climb performance using ATTCS, special conditions are required to establish a level of safety equivalent to that of the regulations.

Part 25 appendix I contains standards for use of ATTCS during takeoff. These special conditions establish standards to extend the use of ATTCS to the go-around phase.

Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.17, Embraer S.A. must show that the Model EMB–550 airplane meets the applicable provisions of part 25, as amended by Amendments 25–1 through 25–127 thereto.

If the Administrator finds that the applicable airworthiness regulations (i.e., 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model EMB–550 airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, the special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Model EMB–550 airplane must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36 and the FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92–574, the ''Noise Control Act of 1972.''

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The Embraer S.A. Model EMB–550 airplane has an ATTCS that is used for both takeoff and go-around functions.

Section 25.904 and part 25 appendix I refer to operations of ATTCS only during takeoff. The Embraer S.A. Model EMB–550 airplane also provides for use of ATTCS for go-arounds. As a result, if an engine failure occurs during a go-around, the remaining engine automatically applies maximum go-around thrust. In addition, in the case of an approach with one engine already inoperative, if it is necessary to perform a go-around, the operating engine automatically applies maximum go-around thrust.

These special conditions are intended to ensure that the ATTCS functions correctly and meets expected performance requirements during go-arounds when the airplane is limited by weight, altitude, and/or temperature during an approach.

Discussion

Since current airworthiness requirements do not contain safety standards to allow credit for ATTCS in determining approach climb performance, these special conditions are required to establish a level of safety equivalent to that of the regulations. The definition of a critical time interval for the approach climb case similar to the critical time interval for takeoff defined in part 25 appendix I is of primary importance. During an approach climb, it must be extremely improbable to violate a flight path based on the climb gradient requirement of § 25.121(d). This climb gradient requirement implies a minimum one-engine-inoperative flight path capability with the airplane in the approach configuration. The engine may have been inoperative before initiating the go-around, or it may become inoperative during the go-around. The definition of the critical time interval must consider both possibilities.

The propulsive thrust used to determine compliance with the approach climb requirements of § 25.121(d) is limited to the lesser of:

- The thrust provided by the ATTCS, or
- 111% of the thrust resulting from the initial thrust setting with the ATTCS failing to perform its uptrim function and without action by the flightcrew to reset thrust.

This requirement serves to limit the adverse performance effects of a combined engine and ATTCS failure, and ensures adequate performance of an all-engines-operating go-around.

Applicability

As discussed above, these special conditions are applicable to the Embraer S.A. Model EMB–550 airplane. Should Embraer S.A. apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model of airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for Embraer S.A. Model EMB–550 airplanes.

1. The Model EMB–550 airplane must comply with the requirements of 14 CFR 25.904 and appendix I to 14 CFR part 25 and the following requirements pertaining to the go-around phase of flight:

2. Definitions

a. Takeoff/go-around (TOGA): throttle lever in takeoff or go-around position.

b. Automatic takeoff thrust control system (ATTCS): the ATTCS in Model EMB–550 airplanes is defined as the entire automatic system available during takeoff and in go-around mode, including all devices, both mechanical and electrical, that sense engine failure, transmit signals, actuate fuel controls or power levers (or increase engine power by other means on operating engines to achieve scheduled thrust or power increase), and furnish cockpit information on system operation.

c. Critical time interval: the definition of the critical time interval in 14 CFR appendix I 25.2(b) must be expanded to include the following:

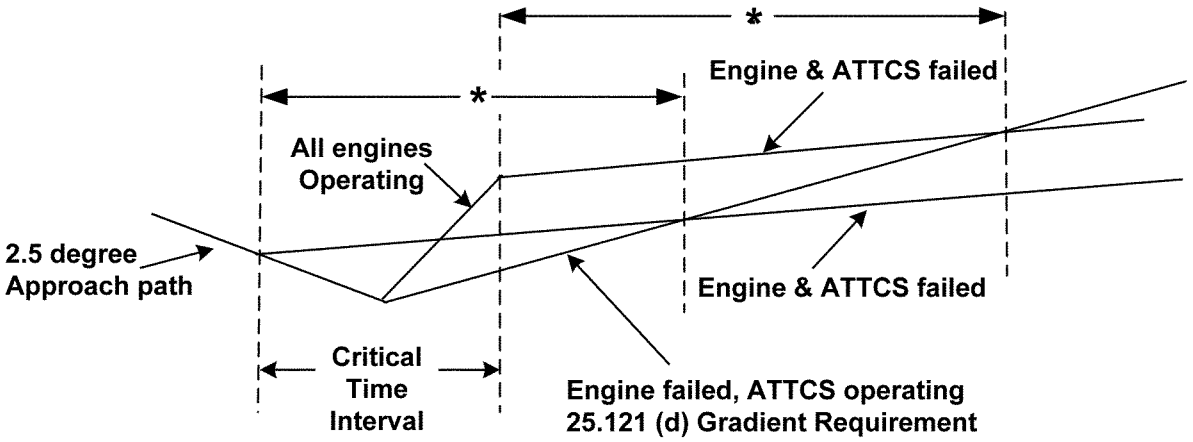
i. When conducting an approach for landing using ATTCS, the critical time interval is defined as follows:

a. The critical time interval *begins* at a point on a 2.5 degree approach glide path from which, assuming a simultaneous engine and ATTCS failure, the resulting approach climb flight path intersects a flight path originating at a later point on the same approach path corresponding that corresponds to the 14 CFR part 25 one-engine-inoperative approach climb gradient. The period of time from the point of simultaneous engine and ATTCS failure to the intersection of these flight paths must be no shorter than the time interval used in evaluating the critical time interval for takeoff beginning from the point of simultaneous engine and ATTCS failure and ending upon reaching a height of 400 feet.

b. The critical time interval *ends* at the point on a minimum performance, all-engines-operating go-around flight path from which, assuming a simultaneous engine and ATTCS failure, the resulting minimum approach climb flight path intersects a flight path corresponding to the 14 CFR part 25 minimum one-engine-inoperative approach climb gradient. The all-engines-operating go-around flight path and the 14 CFR part 25 one-engine-inoperative approach climb gradient flight path originate from a common point on a 2.5 degree approach path. The period of time from the point of simultaneous engine and ATTCS failure to the intersection of these flight paths must be no shorter than the time interval used in evaluating the critical time interval for the takeoff beginning from the point of simultaneous engine and ATTCS failure and ending upon reaching a height of 400 feet.

ii. The critical time interval must be determined at the altitude resulting in the longest critical time interval for which one-engine-inoperative approach climb performance data are presented in the airplane flight manual (AFM).

iii. The critical time interval is illustrated in the following figure:



*** The engine and ATTCS failed time interval must be no shorter than the time interval from the point of simultaneous engine and ATTCS failure to a height of 400 feet used to comply with I25.2(b) for ATTCS use during takeoff.**

3. Performance and system reliability requirements: The applicant must comply with the performance and ATTCS reliability requirements as follows:

a. An ATTCS failure or a combination of failures in the ATTCS during the critical time interval:

i. Must not prevent the insertion of the maximum approved go-around thrust or power, or must be shown to be a remote event.

ii. Must not result in a significant loss or reduction in thrust or power, or must be shown to be an extremely improbable event.

b. The concurrent existence of an ATTCS failure and an engine failure during the critical time interval must be shown to be extremely improbable.

c. All applicable performance requirements of 14 CFR part 25 must be met with an engine failure occurring at the most critical point during go-around with the ATTCS functioning.

d. The probability analysis must include consideration of ATTCS failure occurring after the time at which the flightcrew last verifies that the ATTCS is in a condition to operate until the beginning of the critical time interval.

e. The propulsive thrust obtained from the operating engine after failure of the critical engine during a go-around used to show compliance with the one-engine-inoperative climb requirements of § 25.121(d) may not be greater than the lesser of:

i. The actual propulsive thrust resulting from the initial setting of power or thrust controls with the ATTCS functioning; or

ii. 111% of the propulsive thrust resulting from the initial setting of power or thrust controls with the ATTCS failing to reset thrust or power and without any action by the flightcrew to reset thrust or power.

4. Thrust setting

a. The initial go-around thrust setting on each engine at the beginning of the go-around phase may not be less than any of the following:

i. That required to permit normal operation of all safety-related systems and equipment dependent upon engine thrust or power lever position; or

ii. That shown to be free of hazardous engine response characteristics and not to result in any unsafe aircraft operating or handling characteristics when thrust or power is advanced from the initial go-around position to the maximum approved power setting.

b. For approval to use an ATTCS for go-arounds, the thrust setting procedure must be the same for go-arounds initiated with all engines operating as for go-around initiated with one engine inoperative.

5. Powerplant controls

a. In addition to the requirements of § 25.1141, no single failure or malfunction, or probable combination thereof, of the ATTCS, including associated systems, may cause the failure of any powerplant function necessary for safety.

b. The ATTCS must be designed to:

i. Apply thrust or power on the operating engine(s), following any one-engine failure during a go-around, to achieve the maximum approved go-around thrust without exceeding the engine operating limits;

ii. Permit manual decrease or increase in thrust or power up to the maximum go-around thrust approved for the airplane under the existing conditions through the use of the power lever. For airplanes equipped with limiters that automatically prevent the engine operating limits from being exceeded under existing ambient conditions, other means may be used to increase the thrust in the event of an ATTCS failure, provided that the means:

1. Is located on or forward of the power levers;

2. Is easily identified and operated under all operating conditions by a single action of either pilot with the hand that is normally used to actuate the power levers; and

3. Meets the requirements of § 25.777(a), (b), and (c).

iii. Provide a means to verify to the flightcrew before beginning an approach for landing that the ATTCS is in a condition to operate (unless it can be demonstrated that an ATTCS failure combined with an engine failure during an entire flight is extremely improbable); and

iv. Provide a means for the flightcrew to deactivate the automatic function. This means must be designed to prevent inadvertent deactivation.

6. Powerplant instruments: In addition to the requirements of § 25.1305:

a. A means must be provided to indicate when the ATTCS is in the armed or ready condition; and

b. If the inherent flight characteristics of the airplane do not provide adequate warning that an engine has failed, a warning system that is independent of the ATTCS must be provided to give the pilot a clear warning of any engine failure during a go-around.

Issued in Renton, Washington, on November 5, 2012.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–27372 Filed 11–8–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1926

[Docket ID–OSHA–2012–0025]

RIN 1218–AC75

Revising the Exemption for Digger Derricks in the Cranes and Derricks in Construction Standard

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

ACTION: Notice of proposed rulemaking.

SUMMARY: OSHA is broadening the exemption for digger derricks in its standard for cranes and derricks. OSHA issued a final standard updating the requirements for cranes and derricks on August 9, 2010, and the Edison Electric Institute (EEI) petitioned for review of the standard in the United States Court of Appeals. After petitioning, EEI provided OSHA with new information regarding digger derricks. OSHA reviewed the additional information and the rulemaking record, and decided to broaden the exemption for digger derricks used in the electric-utility industry by means of this proposed rule.

DATES: Comment by December 10, 2012. All submissions, whether transmitted, mailed, or delivered, must bear a postmark or provide other evidence of the submission date.

ADDRESSES: Submit comments (including comments to the information-collection (paperwork) determination described under the section titled AGENCY DETERMINATIONS), hearing requests, and other information and materials, identified by Docket No. OSHA–2012–0025, by any of the following methods:

Electronically: Submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: OSHA allows facsimile transmission of comments that are 10 pages or fewer in length (including attachments). Fax these documents to the OSHA Docket Office at (202) 693–1648; OSHA does not require hard copies of these documents. Instead of transmitting facsimile copies of attachments that supplement these documents (*e.g.,* studies, journal articles), commenters must submit these attachments to the OSHA Docket Office, Technical Data Center, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210. These attachments must clearly identify the sender's name, the date, and the docket number (OSHA–2012–0025), so that the Docket Office can attach them to the appropriate document.

Regular or express mail, hand delivery, or messenger (courier) service: Submit comments and any additional information or material to the OSHA Docket Office, Docket No. OSHA–2012–0025 or RIN No. 1218–AC75, Technical Data Center, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210; telephone: (202) 693–2350. (OSHA's TTY number is (877) 889–5627.) Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by express mail, hand delivery, and messenger service. The Docket Office will accept deliveries (express mail, hand delivery, and messenger service) during the Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m. ET.

Docket: To read or download comments or other information or material in the docket, go to *http://www.regulations.gov* or to the OSHA Docket Office at the address above. Documents in the docket are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not available publicly to read or download through this Web site. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT: *General information and press inquiries:* Mr. Frank Meilinger, Director, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

Technical inquiries: Mr. Garvin Branch, Directorate of Construction, Room N–3468, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–2020; fax: (202) 693–1689; email: *branch.garvin@dol.gov.*

For copies of this Federal Register notice, news releases, and other relevant document: Electronic copies of these documents are available at OSHA's Web page at *http://www.osha.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Request for Comment
II. Direct Final Rulemaking
III. Discussion of the Digger-Derrick Exemption in 29 CFR 1926, Subpart CC
A. Background
B. Changes to the Text of the Exemption in 29 CFR 1926.1400(c)(4)
C. Discussion of Conforming Revisions to 29 CFR 1926, Subpart V (Power Transmission and Distribution)
IV. Agency Determinations
A. Significant Risk
B. Final Economic Analysis and Final Regulatory Flexibility Analysis
C. Technological Feasibility
D. Paperwork Reduction Act of 1995
E. Federalism
F. State Plan States
G. Unfunded Mandates Reform Act
H. Consultation and Coordination With Indian Tribal Governments
List of Subjects in 29 CFR Part 1926
Authority and Signature
Amendments to Standards

I. Request for Comment

OSHA requests comments on all issues related to this proposed rule, including economic, paperwork, or other regulatory impacts of this rule on the regulated community. If OSHA receives no significant adverse comment to either this proposal or the direct final rule, OSHA will publish a **Federal Register** document confirming the effective date of the direct final rule and withdrawing this companion proposed rule published in the ''Proposed Rules'' section of today's **Federal Register**. Such confirmation may include minor stylistic or technical changes to the document. For the purpose of judicial review, OSHA views the date of confirmation of the effective date of this direct final rule as the date of promulgation.

II. Direct Final Rulemaking

In direct final rulemaking, an agency publishes a direct final rule in the **Federal Register** with a statement that the rule will go into effect unless the agency receives significant adverse comment within a specified period. The agency may publish an identical proposed rule at the same time. If the agency receives no significant adverse comment in response to the direct final rule, the rule goes into effect. OSHA typically confirms the effective date of a direct final rule through a separate **Federal Register** notice. If the agency receives a significant adverse comment, the agency withdraws the direct final rule and treats such comment as a

response to the proposed rule. An agency typically uses direct final rulemaking when an agency anticipates that a rule will not be controversial.

For purposes of this proposed rule and the companion direct final rule, a significant adverse comment is one that explains why the amendments to OSHA's digger-derrick exemption would be inappropriate. In determining whether a comment necessitates withdrawal of the direct final rule, OSHA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. OSHA will not consider a comment recommending an additional amendment to be a significant adverse comment unless the comment states why the direct final rule would be ineffective without the addition. Furthermore, OSHA will not consider a comment requesting any narrowing of the existing digger-derrick exemption to be a significant adverse comment because narrowing the existing exemption is beyond the scope of this rulemaking. Moreover, a comment requesting an expansion of the exemption to encompass activities not related to digger-derrick use by electric utilities also would be beyond the scope of this rulemaking, and OSHA will not consider such a comment to be a significant adverse comment unless the commenter explains why the provisions of the direct final rule, as these provisions apply to digger derricks, would be ineffective without the expansion.

In addition to publishing this proposed rule, OSHA is publishing a companion direct final rule in the ''Final Rules'' section of today's **Federal Register**. The comment period for this proposed rule runs concurrently with that of the direct final rule. OSHA also will treat comments received on the companion direct final rule as comments regarding the proposed rule. Likewise, OSHA will consider significant adverse comment submitted to the proposed rule as comment to the direct final rule. Therefore, if OSHA receives a significant adverse comment on either the direct final rule or this proposed rule, it will publish a timely withdrawal of the direct final rule and proceed with this proposed rule. In the event that OSHA withdraws the direct final rule because of significant adverse comment, OSHA will consider all timely comments received in response to the direct final rule when it continues with this proposed rule. After carefully considering all comments to the direct final rule and the proposal, OSHA will decide whether to publish a new final rule.

OSHA determined that the subject of this rulemaking is suitable for direct final rulemaking. OSHA originally included the digger-derrick exemption in the proposed Cranes and Derricks in Construction standard as a result of negotiated rulemaking involving stakeholders from many affected sectors. The existing rule for Cranes and Derricks in Construction, subpart CC of 29 CFR part 1926, exempts the majority of digger derricks used in the telecommunications and electric-utility industries from the requirements of that subpart. Because the revision specified in this proposed rule extends the exemption to a small number of digger derricks used in the electric-utility industry, and does not impose any new costs or duties, OSHA does not expect objections from the public to this rulemaking action.

III. Discussion of the Digger-Derrick Exemption in 29 CFR 1926, Subpart CC

A. Background of the Digger-Derrick Exemption

A ''digger derrick'' or ''radial boom derrick'' is a specialized type of equipment designed to install utility poles. A digger derrick typically is equipped with augers to drill holes for the poles and with a hydraulic boom to lift the poles and set them in the holes. Employers also use the booms to lift objects other than poles; accordingly, electric utilities, telecommunication companies, and their contractors use booms both to place objects on utility poles and for general lifting purposes at worksites (Docket ID OSHA–2007–0066–0139.1). When OSHA promulgated subpart V (Power Transmission and Distribution) in 1972, it excluded digger derricks from certain requirements of 29 CFR 1926, subpart N, the predecessor to the current 29 CFR 1926, subpart CC, standard.

OSHA developed the proposed standard for cranes and derricks in construction through a negotiated rulemaking involving stakeholders from many affected sectors. The proposed standard included a limited exemption for digger derricks (73 FR 59714, 59916 (Oct. 9, 2008)). After the publication of the proposed rule, OSHA received many comments criticizing the scope of the exemption because the scope applied to digger derricks designed for the electric-utility industry, and then only when used to dig holes for utility work. Commenters noted that customary use of the digger derrick also involved placing a pole in the hole and attaching transformers and other items to the pole. Commenters complained that the exemption would be largely meaningless unless it also encompassed these functions. Several representatives of the telecommunications industry noted that the industry used digger derricks routinely for similar purposes, and requested that OSHA expand the digger-derrick exemption to encompass telecommunications work in addition to electric-utility work (Docket ID OSHA–2007–0066–0234 and OSHA–2007–0066–0129.1).

When OSHA issued the final Cranes and Derricks in Construction rule, it noted concerns about the scope of the exemption, and broadened the scope of the exemption (see 75 FR 47906, 47924–47926, and 48136 (Aug. 9, 2010)). Current subpart CC, therefore, exempts digger derricks used by both the electric-utility and the telecommunications industries, and encompasses all pole work in these industries, including placing utility poles in the ground and attaching transformers and other equipment to the poles (see 29 CFR 1400(c)(4)). In that exemption, OSHA clarifies that digger derricks in construction that are exempt from subpart CC must still comply with the applicable worker protections in the OSHA standards governing electric-utility and telecommunications work at §§ 1910.268 and 1910.269. The existing exemption in § 1926.1400(c) states that the subpart does not cover digger derricks when used for augering holes for poles carrying electric and telecommunication lines, placing and removing the poles, and for handling associated materials to be installed on or removed from the poles. Digger derricks used in work subject to 29 CFR part 1926, subpart V, must comply with 29 CFR 1910.269. Digger derricks used in construction work for telecommunication service (as defined at 29 CFR 1910.268(s)(40)) must comply with 29 CFR 1910.268.

When the activities are exempt from subpart CC of 29 CFR part 1926, they must still comply with all other applicable construction standards, such as 29 CFR part 1926, subpart O (Motor Vehicles, Mechanized Equipment, and Marine Operations), and subpart V.[1]

[1] For telecommunications work, compliance with the provisions of § 1910.268 is a condition of the exemption in § 1926.400(c)(4). The scope limitations in § 1910.268(a) (such as the language stating that it does not apply to construction) are irrelevant to application of the exemption. If an employer uses a digger derrick for telecommunications construction work and does not comply with the provisions in § 1910.268, then that employer fails to qualify for the exemption in § 1926.400(c)(4). As a result, that employer must comply with all of the requirements in subpart CC of part 1926, including the operator-certification

On October 6, 2010, Edison Electrical Institute petitioned for review of the Cranes and Derricks in Construction standard in the U.S. Court of Appeals for the District of Columbia. During subsequent discussions with OSHA, EEI provided new information to OSHA regarding the use of digger derricks in the electric-utility industry and the resulting impact on the utilities' operations under the current digger-derrick exemption in subpart CC. According to EEI, the exemption from subpart CC covers roughly 95 percent of work conducted by digger derricks in the electric-utility industry (see OSHA–2012–0025–0004 for EEI Dec. 7, 2010, letter, page 2). The majority of the work under the remaining five percent is work that is closely related to the exempted work. *Id.* For example, when electric utilities use digger derricks to perform construction work involving pole installations, the same digger-derrick crew that performs the pole work typically installs pad-mount transformers on the ground as part of the same power system as the poles. While the pole work is exempt under 29 CFR 1926.1400(c)(4), the placement of the pad-mount transformer on the ground is not.

Furthermore, in comparison to currently exempted pole work, OSHA believes most (if not all) of the remaining five percent of work is at least as safe. Weight measurements provided by EEI demonstrate that transformers placed on a pad on the ground are roughly the same weight as, or in some cases lighter than, the weight of the transformers lifted onto the poles, or the poles themselves (see OSHA–2012–0025–0003 for EEI handout, ''Typical Weights'' chart).[2] In addition, electric utilities typically place distribution transformers in a right of way along front property lines, close to a roadway, or along rear property lines, irrespective of whether the transformers are pole- or pad-mounted. In those cases, the lifting radius of a digger derrick placing a transformer on a pad is similar to the lifting radius of a digger derrick placing a transformer on a pole. Consequently, the lifting forces on a digger derrick should be approximately the same regardless of whether the transformer is pole- or pad-mounted (see, e.g., OSHA–2012–0025–0003). Finally, the approximate height of the transformer relative to the employee installing the transformer is the same for the two types of transformers. An employee installing a pad-mounted transformer is on the ground, near the pad, whereas an employee installing a pole-mounted transformer is either on the pole, or in an aerial lift, near the mounting point for the transformer. In either case, the transformer would be around the same height as the employee.

Because the same workers generally perform both types of work, utility employers must, when the standard becomes fully effective in November 2014, incur the cost of meeting all other requirements in subpart CC, including the operator-certification requirements, for those workers to perform the five percent of the work not currently exempted. The result could be a sizable cost (about $21.6 million annually) for an activity that does not appear significantly more dangerous than the type of activity that OSHA already exempted. (See Section IV.B. (Final Economic Analysis and Final Regulatory Flexibility Act Analysis) in this preamble for a summary of these costs.) OSHA did not consider this result when it promulgated the standard.

OSHA acknowledges the arguments that there are minimal safety benefits attributable to imposing the standard's requirements on the remaining five percent of non-exempted work; moreover, the exempted digger-derrick operations are still subject to the protections afforded to workers by OSHA's electric-utility and telecommunications standards (§ 1910.269, subpart V of 29 CFR part 1926, and § 1910.268, respectively). OSHA also notes that the largest labor organization for workers in the electric-utility industry, the International Brotherhood of Electrical Workers, participated in settlement discussions, corroborated the general validity of the information provided by EEI, and actively supported EEI's request for an expanded digger-derrick exemption. In light of these factors, OSHA is removing the burdens on employers for the remaining five percent of non-exempted work, and revising the digger-derrick exemption to include all digger derricks used in construction work subject to 29 CFR part 1926, subpart V. Based on its estimates in the Final Economic Analysis in the 2010 final rule, the Agency determined that expanding the exemption for digger derricks will enable employers in NAICS 221120 to avoid compliance costs of about $15.9 million per year, while employers in NAICS 221110 will avoid about $5.7 million per year, for a total cost savings of about $21.6 million annually.

When the Agency promulgated the final Cranes and Derricks in Construction rule, OSHA's primary concern about extending the digger-derrick exemption beyond pole work was that such an extension would provide employers with an incentive to use digger derricks on construction sites to perform construction tasks normally handled by cranes—tasks that are beyond the original design capabilities of a digger derrick. In discussing this concern, OSHA stated, ''[T]he general lifting work done at those other worksites would be subject to this standard if done by other types of lifting equipment, and the same standards should apply as apply to that equipment . . . .'' (75 FR 47925). OSHA acknowledges that revising the exemption would extend the digger-derrick exemption to include some work at substations. However, EEI indicated that the employers in the electric-utility industry limit such uses to assembly or arrangement of substation components, and that these employers use other types of cranes instead of digger derricks to perform lifting and installation work at substations (see OSHA–2012–0025–0005 for Jan. 2011 EEI letter). If OSHA finds that, should the direct final rule become a final rule, employers are using digger derricks increasingly for other tasks, the Agency may revisit this issue and adjust the exemption accordingly. The Agency also recognizes that, because the exemption only applies to work subject to the electrical-power and telecommunications standards, employers cannot use digger derricks within this exemption to perform unrelated tasks such as the construction of a building or the foundation or structural components of a substation before the installation of electric power-transmission or power-distribution equipment. A digger derrick used for this type of construction will still be subject to the requirements in 29 CFR 1926, subpart CC, and operators will

requirements in § 1926.1427. If the employer fails to comply with subpart CC, and cannot demonstrate that it complied with § 1910.268 for telecommunications work, or § 1910.269 for electric-utility work, then OSHA will cite the employer under subpart CC (not § 1910.268 or § 1910.269). If the employer demonstrates that it complies with the exemption in subpart CC, but does not comply with the separate requirements in subpart O applicable to all motorized vehicles in construction, then OSHA will cite the employer under subpart O. Note that this explanation does not suggest that OSHA is restricting its enforcement discretion on whether to issue citations at all.

[2] EEI's chart does not show weights for concrete and plastic transformer pads, and EEI did not indicate that utilities use digger derricks to place those pads. If utilities do use digger derricks to lift pads, EEI's presentation indicates that the digger derricks lift the transformers separately. Because the surface area of these pads is comparable to the transformers on them, and because these pads are generally only a few hundred millimeters thick, OSHA does not believe that the pads weigh any more than transformers or poles.

have to be certified in accordance with § 1926.1427.

B. Changes to the Text of the Exemption in 29 CFR 1926.1400(c)(4)

OSHA is revising the exemption in 29 CFR 1926.1400(c)(4) to include within the exemption ''any other work subject to subpart V of 29 CFR part 1926.'' This revision expands the exemption to remove from coverage under subpart CC of 29 CFR part 1926 the types of non-pole, digger-derrick work described by EEI. OSHA is not expanding the exemption for pole work performed by employers in the telecommunications industry because no party raised or requested such an exemption in the litigation; therefore, this issue is outside the scope of this rulemaking.

The Agency also is making several minor clarifications to the text of the exemption. First, OSHA is making a minor grammatical clarification by replacing ''and'' with ''or'' in the phrase ''poles carrying electric *or* telecommunication lines'' (emphasis added). This revision will ensure that the regulated community does not misconstrue the exemption as limited to poles that carry both electric and telecommunications lines. This clarification is consistent with OSHA's explanation in the preamble of the Cranes and Derricks in Construction final rule (see 75 FR 47925).

Second, OSHA is adding the phrase ''to be eligible for this exclusion'' at the beginning of the sentence requiring compliance with § 1910.268 and subpart V of 29 CFR part 1926, respectively. This revision limits the exemption to the use of digger derricks that comply with the requirements in subpart V or § 1910.268; if an employer uses a digger derrick for subpart V or telecommunications work without complying with all of the requirements in subpart V or § 1910.268, then the work is not exempt, and the employer must comply with all of the requirements of subpart CC of 29 CFR part 1926. This clarification is consistent with OSHA's explanation of the exemption in the preamble of the final rule (see 75 FR 47925–47926).

Third, OSHA is replacing the reference to § 1910.269 with a reference to 29 CFR part 1926, subpart V. The current exemption in § 1926.1400(c)(4) requires employers using digger derricks for work covered by subpart V to comply with the requirements in § 1910.269. However, in the 2010 final rule for Cranes and Derricks in Construction, OSHA also revised 29 CFR 1926.952(c)(2) of subpart V to require digger derricks used for the purposes exempted from subpart CC to comply with § 1910.269. Thus, although the revised exemption in this proposed rule specifies compliance with subpart V instead of § 1910.269, there is no substantive revision to digger derricks used for augering holes and handling associated materials. The primary purpose for this revision is to harmonize the § 1926.1400(c)(4) exemption with 29 CFR 1926.952(c)(2) to ensure that non-pole digger-derrick work covered by subpart V receives the same protections as pole work covered by subpart V.

C. Discussion of Conforming Revisions to 29 CFR Part 1926, Subpart V

As part of this harmonizing process, OSHA also is revising the corresponding provision in subpart V that requires compliance with § 1910.269 for all digger-derrick work exempted from subpart CC, including §§ 1910.269(p) (Mechanical equipment), 1910.269(a)(2) (Training), and 1910.269(l) (Working on or near exposed energized parts) (see new 29 CFR 1926.952(c)(2)). When OSHA promulgated subpart CC of 29 CFR part 1926 in 2010, the Agency also revised § 1926.952(c)(2) in subpart V of its construction standards (75 FR 48135). The revision mirrored the terminology in the digger-derrick exemption in § 1926.1400(c)(4), and required employers using digger derricks so exempted to comply with § 1910.269 (Electric power generation, transmission, and distribution). In making this revision, the Agency noted that it added specific minimum clearance-distance requirements, which are applicable to subpart V work, to the cranes and derricks in construction rules at subpart CC, and explained that it revised § 1926.952(c) to require digger derricks to comply with § 1910.269 to provide ''comparable safety requirements'' (75 FR 47921).

As revised, paragraph § 1926.952(c)(2) requires employers using digger derricks for subpart V work and, thus, not subject to the requirements of subpart CC of 29 CFR part 1926, to comply with the requirements in § 1910.269. OHSA also is clarifying that paragraph (c)(2) applies in addition to, not in place of, the general requirement in § 1926.952(c) that all equipment (including digger derricks) must comply with subpart O of 29 CFR part 1926. As noted in the preamble to the subpart CC final rule, OSHA currently is developing a rule that will amend subpart V to avoid inconsistencies between subpart V of the construction standards and § 1910.269 (see 70 FR 34822 (June 15, 2005)). Pending completion of that rulemaking, digger derricks excluded from subpart CC of 29 CFR 1926 will be subject to the same requirements regardless of whether employers use them for work covered by subpart V or work covered by § 1910.269, and regardless of whether employers use them for pole work or other subpart V work.

IV. Agency Determinations

A. Significant Risk

The purpose of the Occupational Safety and Health Act of 1970 (OSH Act; 29 U.S.C. 651 *et al.*) is ''to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources'' (29 U.S.C. 651(b)). To achieve this goal, Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards (29 U.S.C. 654(b), 655(b)). An occupational safety or health standard is a standard that ''requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment'' (29 U.S.C. 652(8)). A standard is reasonably necessary or appropriate within the meaning of Section 652(8) if it substantially reduces or eliminates significant risk (see *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607 (1980)).

This proposed rule does not impose any additional requirements on employers. Because OSHA previously determined that the Cranes and Derricks in Construction standard substantially reduces a significant risk (see 75 FR 47913), it is unnecessary for the Agency to make additional findings on risk for the purposes of this minor amendment to the digger-derrick exemption (see, *e.g., Public Citizen Health Research Group* v. *Tyson,* 796 F.2d 1479, 1502 n.16 (D.C. Cir. 1986) (rejecting the argument that OSHA must ''find that each and every aspect of its standard eliminates a significant risk'').

B. Final Economic Analysis and Final Regulatory Flexibility Act Analysis

When it issued the final rule for Cranes and Derricks in Construction, OSHA prepared a Final Economic Analysis (FEA) as required by the Occupational Safety and Health Act of 1970 (''OSH Act''; 29 U.S.C. 651 *et seq.*) and Executive Orders 12866 and 13563. OSHA also published a final regulatory flexibility analysis as required by the Regulatory Flexibility Act (5 U.S.C. 601–612).

In the FEA for the final rule (OSHA–2007–0066–0422), the Agency estimated

that there were about 10,000 crane operators in NAICS 221110 Electric Power Generation, and about 20,000 crane operators in NAICS 221120 Electric Power Transmission, Control, and Distribution. OSHA based these figures on estimates of the number of construction work crews in these industries from its subpart V FEA, with an allowance (to assure maximum flexibility) that there be three trained crane operators for every work crew. Based on submissions to the record, OSHA estimated that 85 percent of these 30,000 operators (25,500) worked on digger derricks, while 15 percent of the operators operated truck-mounted cranes, or boom trucks; therefore, a total of 25,500 digger-derrick operators would require operator certification.

In its FEA for the final rule, OSHA estimated that the total costs for NAICS 221110 would be $6.7 million ($4 million for operator certification), and the total costs for NAICS 221120 would be $18.7 million annually ($8.7 million for operator certification) (see FEA Table B–9 in the Aug. 9, 2010, FR notice). Fully exempting digger derricks from the scope of the standard also eliminates costs for other activities besides operator certification, such as inspections and power-line safety. In the original FEA, the two main cost components for an industry were the number of crane operators and the number of jobs involving cranes. The original FEA estimated that digger derricks represented 85 percent of operators, and 85 percent of jobs involving cranes. OSHA, therefore, estimates that digger derricks account for 85 percent of the costs attributed to NAICS 221110 and NAICS 221120. Applying this 85 percent factor to the total costs for the industries yields costs for digger derricks of $5.7 million per year in NAICS 221110 and $15.9 million per year in NAICS 221120, for a total of $21.6 million per year.[3]

This proposed rule will eliminate nearly all of the estimated $21.6 million per year in costs associated with digger derricks. These estimated cost savings may be slightly overstated because OSHA noted in its FEA that the cost assumptions might not represent the most efficient way to meet the requirements of the rule. However, OSHA wanted to assure the regulated community that, even with somewhat overstated cost estimates, the proposed rule would still be economically feasible.

In its original FEA (OSHA–2007–0066–0422), OSHA reported an average of 0.5 crane-related fatalities per year in SIC codes NAICS 221110 and NAICS 221120. However, the original FEA did not indicate that any of these fatalities involved digger derricks or other equipment covered by the standard. Moreover, in light of the information provided by EEI, there is no indication that the additional five percent of digger-derrick activity exempted through this rulemaking poses any hazard greater than the hazard posed by the digger-derrick activities OSHA already exempted in the 2010 final rule.

Because this proposed rule estimates cost savings of $21.6 million per year, this proposed rule is not economically significant within the meaning of Executive Order 12866 (58 FR 51735). The proposed rule does not impose additional costs on any private-sector or public-sector entity, and does not meet any of the criteria for an economically significant or major rule specified by Executive Order 12866 and the relevant statutes. This rule is not a ''major rule'' under Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*).

OSHA developed this proposed rule consistent with the provisions of Executive Orders 12866 and 13563. Accordingly, this proposed rule follows closely the principle of EO 13563 that agencies should use new data developed after completion of a rulemaking (retrospective analysis) to determine if a regulation ''should be modified, streamlined, expanded, or repealed.'' In this case, review of data submitted after completion of the initial rulemaking provided OSHA with the opportunity to streamline a rule by dropping its application to digger derricks, thereby saving the industry an estimated $21.6 million per year. As described previously, this action removes duties and costs for the electric-utility industry, and does not impose any new duties on any employer. Because small entities will have reduced costs as a result of this proposed rule, the Agency certifies that the final standard would not impose significant economic costs on a substantial number of small entities.

C. Technological Feasibility

A standard is technologically feasible when the protective measures it requires already exist, when available technology can bring the protective measures into existence, or when that technology is reasonably likely to develop (see *American Textile Mfrs. Institute* v. *OSHA,* 452 U.S. 490, 513 (1981) (ATMI); *American Iron and Steel Institute* v. *OSHA,* 939 F.2d 975, 980 (D.C. Cir. 1991) (AISI)). This proposed rule does not require any additional protective measures. In the original FEA, OSHA found the standard to be technologically feasible (75 FR 48079). OSHA concludes that this revision is feasible as well because it reduces or removes current requirements on employers.

D. Paperwork Reduction Act of 1995

When OSHA issued the final rule on August 9, 2010, the Agency submitted an Information Collection Request (ICR) to OMB titled *Cranes and Derricks in Construction (29 CFR Part 1926 Subpart CC).* On November 1, 2010, OMB approved the ICR under OMB Control Number 1218–0261, with an expiration date of November 30, 2013. Subsequently, in December 2010, OSHA discontinued the *Cranes and Derricks Standard for Construction (29 CFR 1926.550)* ICR (OMB Control Number 1218–0113) because the new ICR superseded this ICR. In addition, OSHA retitled the new ICR to *Cranes and Derricks in Construction (29 CFR Part 1926, Subpart CC and Subpart DD).*

This proposed rule, which expands the digger-derrick exemption, does not require any additional collection of information or alter the substantive requirements detailed in the 2010 ICR. The only impact on the collection of information will be a reduction in the number of entities collecting information. Accordingly, OSHA does not believe it is necessary to submit a new ICR to OMB. OSHA will identify any reduction in burden hours when it renews the ICR.

Interested parties may comment on OSHA's determination that this proposal contains no additional paperwork requirements by sending their written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for OSHA, Office of Management and Budget, Room 10235, 726 Jackson Place, NW., Washington, DC 20503. The Agency also encourages commenters to submit their comments on this paperwork determination to OSHA, along with their other comments on this proposed

[3] Based on the size of digger derricks and EEI's descriptions of digger-derrick activities, OSHA understands that the vast majority of digger-derrick use for construction activity in the electric-utility industry will involve transmission and distribution work subject to subpart V of 29 CFR part 1926. Employers categorized under NAICS 221120 generally conduct electric-transmission and -distribution work. However, OSHA is including digger derricks under NAICS 221110, which is the SIC code for power generation, because some employers may be under that SIC code because their primary work is in that area, but those employers also may engage in transmission work covered by subpart V. Because the record does not indicate that employers use digger derricks for power-generation construction activities, OSHA assumes that the use of digger derricks under NAICS 221110 is for subpart V work.

rule, within the specified comment period.

OSHA notes that a federal agency cannot conduct or sponsor a collection of information unless it is approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* and the agency also displays a currently valid OMB control number for the collection of information, and that the public need not respond to a collection of information requirement unless the agency displays a currently valid OMB control number. Also, notwithstanding any other provisions of law, no person shall be subject to a penalty for failing to comply with a collection of information requirement if the requirement does not display a currently valid OMB control number.

E. Federalism

OSHA reviewed this proposed rule in accordance with the Executive Order on Federalism (Executive Order 13132 (64 FR 43255 (Aug. 10, 1999))), which requires that Federal agencies, to the extent possible, refrain from limiting state policy options, consult with states prior to taking any actions that would restrict state policy options, and take such actions only when clear constitutional authority exists and the problem is national in scope. Executive Order 13132 provides for preemption of state law only with the expressed consent of Congress. Federal agencies must limit any such preemption to the extent possible.

Under Section 18 of the OSH Act, Congress expressly provides that states may adopt, with federal approval, a plan for the development and enforcement of occupational safety and health standards. The OSH Act refers to states that obtain federal approval for such a plan as ''State Plan States'' (29 U.S.C. 667). Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the federal standards. Subject to these requirements, State Plan States are free to develop and enforce under state law their own requirements for safety and health standards.

OSHA previously concluded that its promulgation of subpart CC complies with Executive Order 13132 (75 FR 48128 and 48129). Because the current rulemaking does not impose any additional burdens, that analysis applies to the revision of the digger-derrick exemption. Therefore, this proposed rule complies with Executive Order 13132. In states without OSHA-approved state plans, any standard developed from this proposed rule would impact state policy options in the same manner as every standard promulgated by OSHA. In states with OSHA-approved state plans, this proposed rulemaking does not limit state policy options.

F. State Plan States

When federal OSHA promulgates a new standard or more stringent amendment to an existing standard, the 27 states and U.S. territories with their own OSHA-approved occupational safety and health plans must amend their standards to reflect the new standard or amendment, or show OSHA why such action is unnecessary, *e.g.,* because an existing state standard covering this area is at least as effective in protecting employees as the new federal standard or amendment (29 CFR 1953.5(a)). The state standard must be at least as effective in protecting employees as the final federal rule. State Plan States must issue the standard within six months of the promulgation date of the final federal rule. When OSHA promulgates a new standard or amendment that does not impose additional or more stringent requirements than an existing standard, State Plan States are not required to amend their standards, although OSHA may encourage them to do so. The 27 states and U.S. territories with OSHA-approved occupational safety and health plans are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Washington, and Wyoming. Connecticut, Illinois, New Jersey, New York, and the Virgin Islands have OSHA-approved State Plans that apply to state and local government employees only.

The amendments made in this proposed rule do not impose any new requirements on employers. Accordingly, State Plan States are not required to amend their standards to incorporate the expanded exemption specified in this proposal, but they may do so if they so choose.

G. Unfunded Mandates Reform Act

When OSHA issued the final rule for Cranes and Derricks in Construction (75 FR 48130), it reviewed the rule according to the Unfunded Mandates Reform Act of 1995 (UMRA; 2 U.S.C. 1501 *et seq.*) and Executive Order 13132 (64 FR 43255 (Aug. 10, 1999)), and concluded that the final rule did not meet the definition of a ''Federal intergovernmental mandate'' under the UMRA. OSHA's standards do not apply to state or local governments except in states that have voluntarily adopted state plans. OSHA further noted that the rule imposed costs of over $100 million per year on the private sector and, therefore, required review under the UMRA for those costs; the Agency determined that its Final Economic Analysis met that requirement. *Id.*

As discussed above in Section IV.B. (Final Economic Analysis and Final Regulatory Flexibility Act Analysis) of this preamble, this proposed rule reduces expenditures by private-sector employers. For the purposes of the UMRA, OSHA certifies that this proposed rule does not mandate that state, local, or tribal governments adopt new, unfunded regulatory obligations, or increase expenditures by the private sector of more than $100 million in any year.

H. Consultation and Coordination with Indian Tribal Governments

OSHA reviewed this proposed rule in accordance with Executive Order 13175 (65 FR 67249 (Nov. 9, 2000)), and determined that it does not have ''tribal implications'' as defined in that order. This proposed rule does not have substantial direct effects 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.

List of Subjects in 29 CFR Part 1926

Cranes and derricks, Construction industry, Occupational safety and health.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC 20210, authorized the preparation of this notice. OSHA is issuing this direct final rule under the following authorities: 29 U.S.C. 653, 655, 657; 40 U.S.C. 3701 *et seq.;* 5 U.S.C. 553; Secretary of Labor's Order No. 1–2012 (77 FR 3912, Jan. 25, 2012); and 29 CFR part 1911.

Signed at Washington, DC, on October 9, 2012.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Proposed Amendments to Standards

For the reasons stated in the preamble of this proposed rule, OSHA is proposing to amend 29 CFR part 1926 as follows:

PART 1926—[AMENDED]

Subpart V—Power Transmission and Distribution

1. Revise the authority citation for subpart V to read as follows:

Authority: 40 U.S.C. 3701; 29 U.S.C. 653, 655, 657; Secretary of Labor's Order Nos. 12–71 (36 FR 8754); 8–76 (41 FR 25059); 9–83 (48 FR 35736), 1–90 (55 FR 9033), 5–2007 (72 FR 31159), or 1–2012 (77 FR 3912), as applicable. Section 1926.951 also is issued under 29 CFR part 1911.

2. Amend § 1926.952 by revising paragraph (c)(2) to read as follows:

§ 1926.952 Mechanical equipment.

* * * * *

(c) * * *

(2) Use of digger derricks must comply with § 1910.269 (in addition to 29 CFR part 1926, subpart O) whenever such use is excluded from 29 CFR part 1926, subpart CC, in accordance with § 1926.1400(c)(4).

* * * * *

Subpart CC—Cranes and Derricks in Construction

3. Revise the authority citation for subpart CC to read as follows:

Authority: 40 U.S.C. 3701; 29 U.S.C. 653, 655, 657; and Secretary of Labor's Order No. 5–2007 (72 FR 31159) or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911.

4. Amend § 1926.1400 by revising paragraph (c)(4) to read as follows:

§ 1926.1400 Scope.

* * * * *

(c) * * *

(4) Digger derricks when used for augering holes for poles carrying electric or telecommunication lines, placing and removing the poles, and for handling associated materials for installation on, or removal from, the poles, or when used for any other work subject to subpart V of this part. To be eligible for this exclusion, digger-derrick use in work subject to subpart V of this part must comply with all of the provisions of that subpart, and digger-derrick use in construction work for telecommunication service (as defined at § 1910.268(s)(40)) must comply with all of the provisions of § 1910.268.

* * * * *

[FR Doc. 2012–27209 Filed 11–8–12; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2012–0918]

RIN 1625–AA09

Drawbridge Operation Regulation; Lake Champlain, Swanton, VT

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to modify the operating schedule that governs the New England Central Railroad Bridge across Missisquoi Bay, mile 105.6, at Swanton Vermont. The owner of the bridge has requested to operate the bridge from a remote location, at St. Albans, Vermont. It is expected that this change to the regulations would provide relief to the bridge owner from crewing the bridge while continuing to meet the reasonable needs of navigation.

DATES: Comments and related material must be received by the Coast Guard on or before January 8, 2013.

ADDRESSES: You may submit comments identified by docket number U.S.C.G.–2012–0918 using any one of the following methods:

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

(2) *Fax:* 202–493–2251.

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

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

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Mr. John W. McDonald, Project Officer, First Coast Guard District Bridge Program, telephone (617) 223–8364, email *john.w.mcdonald@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Tables of Acronyms

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR **Federal Register**
NPRM Notice of Proposed Rulemaking
§ Section Symbol
U.S.C. United States Code

A. Public Participation and Request for Comments

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

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2012–0918), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (*http://www.regulations.gov*), or by fax, mail or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov*, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov*, click on the ''submit a comment'' box, which will then become highlighted in blue. In the ''Document Type'' drop down menu select ''Proposed Rules'' and insert ''USCG–2012–0918'' in the ''Keyword'' box. Click ''Search'' then click on the balloon shape in the ''Actions'' column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov*, click on the ''read comments'' box, which will then become highlighted in blue. In the ''Keyword'' box insert ''USCG–2012–0918'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit either the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

3. Privacy Act

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

4. Public Meeting

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

C. Basis and Purpose

The New England Central Railroad Bridge, formerly the Central Vermont Railway Bridge, at mile 105.6, across Missisquoi Bay, at Swanton, Vermont, has a vertical clearance in the closed position that ranges between 9.5 feet and zero feet depending on the time of year and other conditions. The waterway users are predominantly seasonal recreational vessels.

The existing drawbridge operation regulations are listed at 33 CFR 117.993(c), which require the draw to operate as follows: From June 15 through September 15, the draw shall open on signal, Monday through Friday between 9 a.m. and 5 p.m. and on Saturday, Sunday, Independence Day, and Labor Day, between 7 a.m. and 11 p.m. At all other times, after at least a two hour notice is given. From September 16 through June 14, on signal after at least a twenty four hour notice is given.

The Coast Guard received a request from the owner of the bridge, New England Central Railroad Inc., to change the drawbridge operation regulations to allow the bridge to be operated remotely from the New England Central Railroad Dispatcher's Office located at St. Albans, Vermont.

The bridge had been operated manually by hand crank since it was constructed in 1912. An operator would be dispatched to the bridge to manually close the draw to facilitate the passage of a train and then crank the draw back into the open position.

The Federal Railroad Administration funded the motorization of the bridge to allow remote operation of the bridge by New England Central Railroad. As a result, in 2012, the operating system was modified by adding electric bridge opening motors to swing the draw open and closed, a standby electric generator to be used in the event of a power outage, local bridge operation controls installed at the tenders building on the bridge to be used to locally operate the draw, LED navigation lights, and electric illuminated signs both up and down stream to warn mariners that the bridge will be closing for the passage of an approaching train.

Presently, rail traffic crosses the bridge seven days a week. There are normally two train passages daily crossing the bridge in the morning and returning later in the same day.

Under this notice of proposed rulemaking the bridge would be opened and closed remotely, from the New England Central Railroad Dispatchers Office at St. Albans, Vermont.

During the boating season, June 15 through September 15, the bridge would remain in the open position at all times, except for the passage of rail traffic. Once rail traffic crosses the bridge the bridge would be returned to the full open position.

In the off season, September 16 through June 14, the bridge would remain in the closed position at all times.

The bridge would be opened for the passage of vessel traffic September 16 through June 14, upon receipt of a twenty-four hour advance notice to open the bridge.

The bridge opens on average two to three times a week during the period 16 September through 14 June when the bridge owner proposes to open the draw upon receipt of a twenty-four hour advance notice.

In addition, the waterway is normally frozen December through April each winter when the recreational vessels that normally transit this bridge are in winter storage.

As a result of the above information the Coast Guard believes it is reasonable for the bridge owner to operate the bridge from a remote location and that the reasonable needs of navigation will continue to be addressed.

D. Discussion of Proposed Rule

The Coast Guard proposes to revise 33 CFR 117.993(c), to allow remote operation of the New England Central Railroad Bridge, and also eliminate paragraph (d) under the same section which governs the operation of the SR78 highway bridge.

The SR78 highway bridge has been replaced with a new fixed span highway bridge; therefore, the drawbridge operations for that bridge will be deleted because they are now obsolete and unnecessary.

For the of the New England Central Railroad Bridge, the Coast Guard received a request from the owner, New England Central Railroad Inc., to operate the bridge from a remote location at the New England Central railroad Dispatcher's Office at St. Albans, Vermont.

The existing drawbridge operations incorporated an operating schedule that listed the days and times the bridge would open for the passage of vessel traffic. That operation schedule was established many years ago when the bridge was crewed.

In recent years the bridge was not crewed and didn't operate according to the operating schedule but rather it was left in the open position during the boating season June through September, except when a train was scheduled to cross the bridge. Rail personnel would be dispatched to the bridge two hours in advance of a train crossing to manually crank the draw closed to facilitate the passage of the rail traffic and then return the bridge to the full open position once the train cleared the bridge.

The bridge was motorized in 2012, to facilitate remote operation, and thereby eliminate the dispatching of personnel back and forth daily to operate the bridge.

Under this notice of proposed rulemaking, as a result of operating the draw remotely, the bridge will simply remain in the open position at all times from June 15 through September 15, except for the passage of rail traffic. From September 16 through June 14, the draw would remain in the closed position at all times, except for the passage of vessel traffic, that provides at least a twenty four hour notice to open the draw.

The New England Central Railroad Bridge is listed in the existing regulations as the Central Vermont Railway Bridge. We are changing the name of the bridge under this proposed rule to update the present name and ownership of the bridge.

E. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

1. Regulatory Planning and Review

This proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Order 12866, or under section 1 of Executive Order 13563 because the bridge will continue to operate under the same operation schedule, except that, it will be opened and closed from a remote location. The Office of Management and Budget has not reviewed it under those Orders.

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this proposed rule on small entities. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This proposed rule would affect the following entities, some of which might be small entities: The owners or operators of vessels needing to transit through the bridge.

This action will not have a significant economic impact on a substantial number of small entities for the following reasons:

The bridge will continue to operate under the same opening schedule, except that it will be opened and closed from a remote location.

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

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

3. Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

4. Federalism

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

5. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

6. Unfunded Mandates Reform Act

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

7. Taking of Private Property

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

8. Civil Justice Reform

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

9. Protection of Children

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

10. Indian Tribal Governments

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

11. Energy Effects

This proposed rule is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use because it is not a ''significant regulatory action'' under Executive Order 12866, and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Offices of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

12. Technical Standards

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

13. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01, and Commandant Instruction M16475.lD which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have made a preliminary determination

that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This proposed rule simply promulgates the operating regulations or procedures for drawbridges. This rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule. We seek any comments or information that may lead to the discovery of significant environmental impact from the proposed rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

2. Revise § 117.993 paragraph (c) and remove paragraph (d) to read as follows:

§ 117.993 Lake Champlain.

* * * * *

(c) The draw of the New England Central Railroad Bridge across Missiquoi Bay, mile 105.6, at Swanton, Vermont, shall operate as follows:

(1) From June 15 through September 15, the draw shall remain in the full open position at all times and shall only be closed for the passage of rail traffic or the performance of maintenance authorized in accordance with subpart A of this part.

(2) From September 16 through June 14, the draw may remain in the closed position and shall be opened on signal for the passage of vessel traffic after at least a twenty four hour notice is given by calling the number posted at the bridge.

(3) The draw may be operated either remotely by the New England Central Railroad train dispatcher located at St. Albans, Vermont or manually by a draw tender located at the bridge.

(4) A sufficient number of infrared cameras shall be maintained in good working order at all times with a clear unobstructed view of the channel under the bridge, and the up and down stream approaches to the bridge. A signal horn and message boards located both up and down stream, necessary to warn marine traffic that the bridge will be closing, shall also be maintained in good working order at all times. In the event that any of the cameras, navigation lights, horn, or message board become disabled, personnel shall be deployed to the bridge to be on scene within two hours from the known time of the equipment failure.

(5) The draw may operate remotely as follows: Once it is determined that the draw must be opened or closed, the train dispatcher shall observe the waterway both up and down stream via the infrared cameras to verify that the channel is clear of all approaching vessel traffic. All approaching vessel traffic shall be allowed to pass before the bridge may closed. Once it is determined that no vessel traffic is approaching the dispatcher shall sound the warning horn and activate the up and down stream message boards indicating that the bridge will be closing. After at least a one minute delay the draw may then be closed and the swing span navigation lights shall display as red to indicate the bridge is in the closed position. Once the train clears the bridge the draw shall be returned to the full open position and the swing span lights shall display as green to indicate the draw is in the full open position.

(6) In the event that the dispatcher cannot verify that the channel is clear of all vessel traffic and the bridge cannot be safely closed, an on-scene train crewmember shall observe the waterway for any vessel traffic and then communicate with the train dispatch office either by radio or telephone to request the bridge be safely closed. Personnel shall then be deployed to the bridge to arrive within two hours to inspect and repair the bridge remote operation equipment. The bridge shall be operated manually from the tender's house located at the bridge until all necessary repairs are completed to the remote operation equipment.

* * * * *

Dated: October 16, 2012.

Daniel B. Abel,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 2012–27369 Filed 11–8–12; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2012–0790; FRL–9750–2]

Revisions to the California State Implementation Plan, Placer County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the Placer County Air Pollution Control District (PCAPCD) portion of the California State Implementation Plan (SIP). These revisions concern oxides of nitrogen (NOx) emissions from biomass boilers. We are approving a local rule that regulates these emission sources under the Clean Air Act (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by December 10, 2012.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2012–0790, by one of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the on-line instructions.

2. *Email: steckel.andrew@epa.gov.*

3. *Mail or deliver:* Andrew Steckel (Air–4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments 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 Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *www.regulations.gov* or email. *www.regulations.gov* is an ''anonymous access'' system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send email directly to EPA, your email address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Docket: Generally, documents in the docket for this action are available electronically at *www.regulations.gov*

and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed at *www.regulations.gov,* some information may be publicly available only at the hard copy location (e.g., copyrighted material, large maps), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Idalia Pérez, EPA Region IX, (415) 972–3248, *perez.idalia@epa.gov*.

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

Table of Contents

I. The State's Submittal
A. What rule did the State submit?
B. Are there other versions of this rule?
C. What is the purpose of the submitted rule?
II. EPA's Evaluation and Action.
A. How is EPA evaluating the rule?
B. Does the rule meet the evaluation criteria?
C. EPA Recommendations To Further Improve the Rule
D. Public Comment and Final Action
III. Statutory and Executive Order Reviews

I. The State's Submittal

A. What rule did the State submit?

Table 1 lists the rule addressed by this proposal with the dates that it was adopted by the local air agency and submitted by the California Air Resources Board.

TABLE 1—SUBMITTED RULE

Local agency	Rule No.	Rule title	Amended	Submitted
PCAPCD	233	Biomass Boilers	06/14/12	09/21/12

On October 11, 2012, EPA determined that the submittal for PCAPCD Rule 233 met the completeness criteria in 40 CFR Part 51 Appendix V, which must be met before formal EPA review.

B. Are there other versions of this rule?

We finalized a limited approval and limited disapproval of an earlier version of Rule 233 on January 19, 2012 (77 FR 2643). That action incorporated Rule 233 into the California SIP, including those provisions identified as deficient.

C. What is the purpose of the submitted rule?

NO_X helps produce ground-level ozone, smog and particulate matter, which harm human health and the environment. Section 110(a) of the CAA requires States to submit regulations that control NO_X emissions. Rule 233 limits NO_X emissions from biomass boilers. EPA's technical support document (TSD) has more information about this rule.

II. EPA's Evaluation and Action

A. How is EPA evaluating the rule?

Generally, SIP rules must be enforceable (see section 110(a) of the Act), must require Reasonably Available Control Technology (RACT) for each category of sources covered by a Control Techniques Guidelines (CTG) document as well as each major source in nonattainment areas (see sections 182(b)(2) and 182(f)), and must not relax existing requirements (see sections 110(l) and 193). The PCAPCD regulates an ozone nonattainment area (see 40 CFR part 81), so Rule 233 must fulfill RACT.

Guidance and policy documents that we use to evaluate enforceability and RACT requirements consistently include the following:

1. ''State Implementation Plans; Nitrogen Oxides Supplement to the General Preamble; Clean Air Act Amendments of 1990 Implementation of Title I; Proposed Rule,'' (the NO_X Supplement), 57 FR 55620, November 25, 1992.
2. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' EPA, May 25, 1988 (the Bluebook).
3. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' EPA Region 9, August 21, 2001 (the Little Bluebook).
4. ''Determination of Reasonably Available Control Technology and Best Available Retrofit Control Technology for Industrial, Institutional, and Commercial Boilers, Steam Generators, and Process Heaters,'' CARB, July 18, 1991.
5. ''Alternative Control Techniques Document—NO_X Emissions from Industrial/Commercial/Institutional (ICI) Boilers,'' U.S. EPA *453/R–94–022,* March 1994.
6. ''Alternative Control Techniques Document—NO_X Emissions from Utility Boilers,'' US EPA *452/R–93–008,* March 1994.

B. Does the rule meet the evaluation criteria?

We believe this rule is consistent with the relevant policy and guidance regarding enforceability, RACT, and SIP relaxations. The TSD has more information on our evaluation.

C. EPA Recommendations To Further Improve the Rule

The TSD describes additional rule revisions that we recommend for the next time the local agency modifies the rule but are not currently the basis for rule disapproval.

D. Public Comment and Final Action

Because EPA believes the submitted rule fulfills all relevant requirements, we are proposing to fully approve it as described in section 110(k)(3) of the Act. We will accept comments from the public on this proposal for the next 30 days. Unless we receive convincing new information during the comment period, we intend to publish a final approval action that will incorporate this rule into the federally enforceable SIP. Final approval of Rule 233 would satisfy California's obligation to implement RACT under CAA section 182 for this source category and thereby terminate both the sanctions clocks and the Federal Implementation Plan (FIP) clock associated with limited approval and limited disapproval of this rule which we finalized on January 19, 2012 (77 FR 2643).

III. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under

Executive Order 12866 (58 FR 51735, October 4, 1993);

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

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

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

Dated: October 30, 2012.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2012–27324 Filed 11–8–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA–2011–0002; Internal Agency Docket No. FEMA–B–1233]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed rule; correction.

SUMMARY: On November 29, 2011 FEMA published in the **Federal Register** a proposed rule that contained an erroneous table. This document provides corrections to that table, to be used in lieu of the information published at 76 FR 73537. The table provided here represents the flooding sources, location of referenced elevations, effective and modified elevations, and communities affected for Sullivan County, Pennsylvania (All Jurisdictions). Specifically, it addresses the flooding sources Big Run, Little Loyalsock Creek, Loyalsock Creek, and Muncy Creek.

DATES: Comments are to be submitted on or before February 7, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FEMA–B–1233, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4064 or (email) *Luis.Rodriguez3@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4064 or (email) *Luis.Rodriguez3@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) publishes proposed determinations of Base (1% annual-chance) Flood Elevations (BFEs) and modified BFEs for communities participating in the National Flood Insurance Program (NFIP), in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed BFEs and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are minimum requirements. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in those buildings.

Correction

In the proposed rule published at 76 FR 73537, in the November 29, 2011, issue of the **Federal Register**, FEMA published a table under the authority of 44 CFR 67.4. The table, entitled ''Sullivan County, Pennsylvania (All Jurisdictions)'' addressed the flooding sources Big Run, Little Loyalsock Creek, Loyalsock Creek, and Muncy Creek. That table contained inaccurate information as to the location of referenced elevation, effective and modified elevation in feet, and/or communities affected for Loyalsock Creek. In this document, FEMA is publishing a table containing the accurate information, to address these prior errors. The information provided below should be used in lieu of that previously published.

Flooding source(s)	Location of referenced elevation **	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL)		Communities affected
		Effective	Modified	
Sullivan County, Pennsylvania (All Jurisdictions)				
Big Run	At the Muncy Creek confluence	+968	+965	Township of Davidson.
	Approximately 1,600 feet upstream of Fairman Road	None	+1153	
Little Loyalsock Creek	Approximately 1,150 feet downstream of the Marsh Run confluence.	None	+1432	Borough of Dushore.
	Approximately 540 feet upstream of Main Street	None	+1458	
Loyalsock Creek	Approximately 2.6 miles downstream of the Ogdonia Creek confluence.	+789	+780	Borough of Forksville, Township of Elkland, Township of Forks, Township of Hillsgrove.
	At the Little Loyalsock Creek confluence	None	+1004	
Muncy Creek	At the Muncy Creek Tributary 1 confluence	+787	+783	Township of Davidson, Township of Shrewsbury.
	Approximately 0.76 mile upstream of Pecks Road	+991	+988	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.
** BFEs to be changed include the listed downstream and upstream BFEs, and include BFEs located on the stream reach between the referenced locations above. Please refer to the revised Flood Insurance Rate Map located at the community map repository (see below) for exact locations of all BFEs to be changed.

Send comments to Luis Rodriguez, Chief, Engineering Management Branch, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472.

ADDRESSES

Borough of Dushore
Maps are available for inspection at the Municipal Building, 216 Julia Street, Dushore, PA 18614.

Borough of Forksville
Maps are available for inspection at Sullivan County Planning and Community Development, 245 Muncy Street, Suite 110, Laporte, PA 18626.

Township of Davidson
Maps are available for inspection at the Davidson Township Municipal Building, 20 Michelle Road, Muncy Valley, PA 17758.

Township of Elkland
Maps are available for inspection at the Elkland Township Municipal Office Building, 909 Kobbe Road, Forksville, PA 18616.

Township of Forks
Maps are available for inspection at the Forks Township Hall, 627 Molyneux Hill Road, Dushore, PA 18614.

Township of Hillsgrove
Maps are available for inspection at the Township Hall, 2232 Route 87, Hillsgrove, PA 18619.

Township of Shrewsbury
Maps are available for inspection at the Shrewsbury Township Building, 1793 Edkin Hill Road, Muncy Valley, PA 17758.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: October 12, 2012.

James A. Walke,

Acting Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2012–27365 Filed 11–8–12; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA–2011–0002; Internal Agency Docket No. FEMA–B–1229]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed rule; correction.

SUMMARY: On November 14, 2011, FEMA published in the **Federal Register** a proposed rule that contained an erroneous table. This document provides corrections to that table, to be used in lieu of the information published at 76 FR 70397. The table provided here represents the flooding sources, location of referenced elevations, effective and modified elevations, and communities affected for Sauk County, Wisconsin, and Incorporated Areas. Specifically, it addresses the following flooding sources: Baraboo River, Devil's Lake Tributary (backwater effects from Baraboo River), Hay Creek (backwater effects from Baraboo River), Little Baraboo River (backwater effects from Baraboo River), Narrows Creek

(backwater effect from Baraboo River), Plum Creek (backwater effects from Baraboo River), and Seeley Creek (backwater effects from Baraboo River).

DATES: Comments are to be submitted on or before February 7, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FEMA–B–1229, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4064 or (email) *Luis.Rodriguez3@fema.dhs.gov*.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4064 or (email) *Luis.Rodriguez3@fema.dhs.gov*.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) publishes proposed determinations of Base (1% annual-chance) Flood Elevations (BFEs) and modified BFEs for communities participating in the National Flood Insurance Program (NFIP), in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed BFEs and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are minimum requirements. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in those buildings.

Correction

In the proposed rule published at 76 FR 70397, in the November 14, 2011, issue of the **Federal Register,** FEMA published a table under the authority of 44 CFR 67.4. The table, entitled ''Sauk County, Wisconsin, and Incorporated Areas'' addressed the flooding sources: Baraboo River, Devil's Lake Tributary (backwater effects from Baraboo River), Hay Creek (backwater effects from Baraboo River), Little Baraboo River (backwater effects from Baraboo River), Narrows Creek (backwater effect from Baraboo River), Plum Creek (backwater effects from Baraboo River), and Seeley Creek (backwater effects from Baraboo River). That table contained inaccurate information as to the location of referenced elevation, effective and modified elevation in feet, and/or communities affected for the Baraboo River. In this document, FEMA is publishing a table containing the accurate information, to address these prior errors. The information provided below should be used in lieu of that previously published.

Flooding source(s)	Location of referenced elevation **	* Elevation in feet (NGVD) + Elevation in feet (NAVD) #Depth in feet above ground ^ Elevation in meters (MSL)		Communities affected
		Effective	Modified	
Sauk County, Wisconsin and Incorporated Areas				
Baraboo River	At the Columbia County boundary	+802	+804	City of Baraboo, City of Reedsburg, Unincorporated Areas of Sauk County, Village of La Valle, Village of North Freedom, Village of Rock Springs, Village of West Baraboo
	At the Juneau County boundary	+910	+912	
Devil's Lake Tributary (backwater effects from Baraboo River).	At the Baraboo River confluence	+819	+820	City of Baraboo
	Approximately 780 feet downstream of Old Lake Road.	+819	+820	
Hay Creek (backwater effects from Baraboo River).	Approximately 75 feet downstream of County Highway V.	+881	+882	City of Reedsburg, Unincorporated Areas of Sauk County
	Approximately 1,860 feet upstream of County Highway V.	+881	+882	
Little Baraboo River (backwater effects from Baraboo River).	At the Baraboo River confluence	+892	+895	Unincorporated Areas of Sauk County, Village of La Valle
	Approximately 70 feet downstream of State Highway 58.	+892	+895	
Narrows Creek (backwater effects from Baraboo River).	At the Baraboo River confluence	+870	+872	Unincorporated Areas of Sauk County, Village of Rock Springs
	At the downstream side of State Highway 154	+870	+872	
Plum Creek (backwater effects from Baraboo River).	At the Baraboo River confluence	+909	+912	Unincorporated Areas of Sauk County
	Approximately 0.78 mile upstream of the Baraboo River confluence.	+911	+912	

Flooding source(s)	Location of referenced elevation **	* Elevation in feet (NGVD) + Elevation in feet (NAVD) #Depth in feet above ground ∧ Elevation in meters (MSL)		Communities affected
		Effective	Modified	
Seeley Creek (backwater effects from Baraboo River).	At the Baraboo River confluence	+864	+865	Unincorporated Areas of Sauk County
	Approximately 1,450 feet downstream of Freedom Road.	+864	+865	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.
** BFEs to be changed include the listed downstream and upstream BFEs, and include BFEs located on the stream reach between the referenced locations above. Please refer to the revised Flood Insurance Rate Map located at the community map repository (see below) for exact locations of all BFEs to be changed.

Send comments to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472.

ADDRESSES

City of Baraboo
Maps are available for inspection at City Hall, 135 4th Street, Baraboo, WI 53913.

City of Reedsburg
Maps are available for inspection at City Hall, 134 South Locust Street, Reedsburg, WI 53959.

Unincorporated Areas of Sauk County
Maps are available for inspection at West Square Building, 505 Broadway, Baraboo, WI 53913.

Village of La Valle
Maps are available for inspection at Village Hall, 103 West Main Street, La Valle, WI 53941.

Village of North Freedom
Maps are available for inspection at Village Hall, 103 North Maple Street, North Freedom, WI 53951.

Village of Rock Springs
Maps are available for inspection at Village Hall, 101 1st Street, Rock Springs, WI 53961.

Village of West Baraboo
Maps are available for inspection at Village Hall, 500 Cedar Street, Baraboo, WI 53913.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: October 23, 2012.

James A. Walke,

Acting Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2012–27367 Filed 11–8–12; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

RIN 0648–BC28

Fisheries Off West Coast States; West Coast Salmon Fisheries; Notice of Availability for Amendment 17 to the Salmon Fishery Management Plan

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

ACTION: Availability of amendment to a fishery management plan; request for comments.

SUMMARY: NMFS announces that the Pacific Fishery Management Council (Council) has transmitted Amendment 17 to the Pacific Coast Salmon Fishery Management Plan (FMP) for Secretarial review. Amendment 17 revises the maximum fishing mortality threshold (MFMT) for Quillayute fall coho, revises the FMP to correct typographical errors, updates reporting measures to reflect new technology, and updates or removes other obsolete or unnecessary language.

DATES: Comments on Amendment 17 must be received on or before January 8, 2013.

ADDRESSES: You may submit comments, identified by NOAA–NMFS–2012–0192, by any one of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal *http://www.regulations.gov.* To submit comments via the e-Rulemaking Portal, enter NOAA–NMFS–2011–0227 in the search box. Locate the document you wish to comment on from the resulting list and click on the ''Submit a Comment'' icon on the right of that line.
- *Mail:* William W. Stelle, Jr., Regional Administrator, Northwest Region, NMFS, 7600 Sand Point Way NE., Seattle, WA 98115–0070 or to Rod McInnis, Regional Administrator, Southwest Region, NMFS, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802–4213.
- *Fax:* 206–526–6736 Attn: Peggy Mundy, or 562–980–4047 Attn: Heidi Taylor.

Instructions: Comments must be submitted by one of the above methods to ensure that the comments are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *http://www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.)

submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter N/A in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

Electronic copies of the amendment may be obtained from the Council Web site at *http://pcouncil.org.*

FOR FURTHER INFORMATION CONTACT: Peggy Mundy at 206–526–4323, or Heidi Taylor at 562–980–4039.

SUPPLEMENTARY INFORMATION:

The ocean salmon fisheries in the exclusive economic zone off Washington, Oregon, and California are managed under a ''framework'' fishery management plan entitled the Pacific Coast Salmon Fishery Management Plan (FMP). The Magnuson-Stevens Fishery Conservation and Management Reauthorization Act of 2006 (MSRA) requires that each regional fishery management council submit any FMP or plan amendment it prepares to NMFS for review and approval, disapproval, or partial approval. The MSRA also requires that NMFS, upon receiving an FMP or amendment, immediately publish a notice that the FMP or amendment is available for public review and comment. NMFS will consider the public comments received during the comment period described above in determining whether to approve Amendment 17 to the FMP.

In 2011, the Council transmitted Salmon FMP Amendment 16 to NMFS (76 FR 57945, September 19, 2011). NMFS partially approved Amendment 16 in December 2011. NMFS disapproved the proposed maximum fishing mortality threshold (MFMT) for Quillayute coho. During the review of Amendment 16, a variety of other issues in the FMP were identified as needing revision, largely to correct typographical errors, update notification and reporting measures to reflect new technology, and remove an unnecessary post-final rule comment period from the schedule for annual management measures. Amendment 17 addresses the issue of MFMT for Quillayute coho and well as the other, largely editorial, revisions.

NMFS welcomes comments on the proposed FMP amendment through the end of the comment period. The Council also transmitted a proposed rule to implement Amendment 17 for Secretarial review and approval. NMFS expects to publish and request public review and comment on this rule in the near future. Public comments on the proposed rule must be received by the end of the comment period on the amendment to be considered in the approval/disapproval decision on the amendment. All comments received by the end of the comment period for the amendment, whether specifically directed to the amendment or the proposed rule, will be considered in the approval/disapproval decision.

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

Dated: November 5, 2012.

Emily H. Menashes,

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

[FR Doc. 2012–27473 Filed 11–8–12; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 77, No. 218
Friday, November 9, 2012

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Information Collection: Agricultural Foreign Investment Disclosure Act

AGENCY: Farm Service Agency, USDA.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on the extension of a currently approved information collection associated with the Agricultural Foreign Investment Disclosure Act (AFIDA) of 1978.

DATES: We will consider comments that we receive by January 8, 2013.

ADDRESSES: We invite you to submit comments on this notice. In your comments, include date, volume, and page number of this issue of the **Federal Register**. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.
- *Mail:* Lesa A. Johnson, Agricultural Foreign Investment Disclosure Act (AFIDA) Program Manager, Natural Resources Analysis Group, Economic and Policy Analysis Staff, USDA, FSA, STOP 0531, 1400 Independence Avenue SW., Washington, DC 20250–0531.
- *Email: lesa.johnson@wdc.usda.gov*.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Copies of the information collection may be requested by contacting Lesa A. Johnson at the above **ADDRESSES**.

FOR FURTHER INFORMATION CONTACT: Lesa A. Johnson, Agricultural Foreign Investment Disclosure Act (AFIDA) Program Manager, (202) 720–9223.

SUPPLEMENTARY INFORMATION:

Title: Agricultural Foreign Investment Disclosure Act Report.

OMB Control Number: 0560–0097.

Expiration Date of Approval: April 30, 2013.

Type of Request: Extension of a currently approved information collection.

Abstract: AFIDA requires foreign persons who hold, acquire, or dispose of any interest in U.S. agricultural land to report the transactions to FSA on an AFIDA report (FSA–153). The information collected is made available to States. Also, although not required by law, the information collected from the AFIDA reports is used to prepare an annual report to Congress and the President concerning the effect of foreign investment upon family farms and rural communities so that Congress may review the annual report and decide if further regulatory action is required.

Estimate of Average Time to Respond: 0.476 hours per response.

Respondents: Foreign investors, corporate employees, attorneys, or farm managers.

Estimated Number of Respondents: 5,525.

Estimated Number of Responses per Respondent: 1.

Estimated Number of Responses: 5,525.

Estimated Total Annual Burden on Respondents: 2,631.25 hours.

We are requesting comments on all aspects of this information collection to help us to:

(1) Determine whether the continued collection of information is still necessary for the proper performance of the functions of the FSA, including whether the information will have practical utility;

(2) Assess the accuracy of the FSA's estimate of burden 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.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission for the Office of Management and Budget approval.

Signed on September 20, 2012.

Carolyn B. Cooksie,

Acting Administrator, Farm Service Agency.

[FR Doc. 2012–27393 Filed 11–8–12; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Information Collection Request, Servicing Minor Program Loans

AGENCY: Farm Service Agency, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on an extension of a currently approved information collection to support the FSA Farm Loan Programs (FLP).

DATES: We will consider comments that we receive by January 8, 2013.

ADDRESSES: We invite you to submit comments on this notice. In your comments, include the date, volume, and page number of this issue of the **Federal Register**, the OMB control number and the title of the information collection. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Email: cindy.pawlikowski@wdc.usda.gov.*

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

FOR FURTHER INFORMATON CONTACT: Cindy Pawlikowski, Senior Loan Officer, (202) 720–0900.

SUPPLEMENTARY INFORMATION: *Title:* Servicing Minor Program Loans.

OMB Control Number: 0560–0230.

Expiration Date: March 31, 2013.

Type of Request: Extension.

Abstract: Section 331(b) of the Consolidated Farm and Rural

Development Act (CONTACT, 7 U.S.C. 1981(b)), in part, authorizes the Secretary of Agriculture to modify, subordinate and release terms of security instruments, leases, contracts, and agreements entered into by FSA. That section also authorizes transfers of security property, as the Secretary deems necessary, to carry out the purpose of the loan or protect the Government's financial interest. Section 335 of the CONACT (7 U.S.C. 1985), provides servicing authority for real estate security; operation or lease of realty; disposition of property; conveyance of real property interest of the United States; easements; and condemnations. The information collection relates to a program benefit recipient or loan borrower requesting action on security they own, which was purchased with FSA loan funds, improved with FSA loan funds or has otherwise been mortgaged to FSA to secure a Government loan. The information collected is primarily financial data not already on file, such as borrower asset values, current financial information and public use and employment data.

Estimate of Annual Burden: Public reporting burden for this collection of information is estimated to average .63 hours per response.

Respondents: Individuals, associations, partnerships, or corporations.

Estimated Number of Respondents: 58.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 37 hours.

We are requesting comments on all aspects of this information collection to help us to:

(1) Determine whether the continued collection of information is still necessary for the proper performance of the functions of the FSA, including whether the information will have practical utility;

(2) Assess the accuracy of the FSA's estimate of burden 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.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission for the Office of Management and Budget approval.

Signed on October 2, 2012.

Juan M. Garcia,

Administrator, Farm Service Agency.

[FR Doc. 2012–27395 Filed 11–8–12; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Forest Service

Sitka Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Sitka Resource Advisory Committee will meet in Sitka, Alaska. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) and in compliance with the Federal Advisory Committee Act. The purpose of this meeting, is to nominate a new Chairman, revise charter and discuss monitoring of projects.

DATES: The meetings will be held on November 20, 2012, and will begin at 4:00 p.m.

ADDRESSES: The meeting will be held at the Forest Service Building, Katlian Conference Room, 204 Siginaka Way, Sitka, Alaska. Written comments should be sent to Lisa Hirsch, Sitka Ranger District, 204 Siginaka Way, Sitka, Alaska 99835. Comments may also be sent via email to lisahirsch@fs.fed.us, or via facsimile to 907–747–4253.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Sitka Ranger District, 204 Siginaka Way, Sitka, Alaska. Visitors are encouraged to call ahead to 907–747–4214 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Lisa Hirsch, RAC coordinator, USDA, Tongass NF, Sitka Ranger District, 204 Siginaka Way, Sitka, Alaska 99835; 907–747–4214; Email *lisahirsch@fs.fed.us.*

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The following business will be conducted: (1) Introductions of all committee members, replacement members and Forest Service personnel. (2) Selection of a chairperson by the committee members. (3) Receive materials explaining the process for considering and recommending Title II projects; and (4) Public Comment. Persons who wish to bring related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting.

Dated: October 30, 2012.

Carol A. Goularte,

Designated Federal Officer.

[FR Doc. 2012–27272 Filed 11–8–12; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

RIN 0524–AA43

Solicitation of Input From Stakeholders Regarding the Veterinary Medicine Loan Repayment Program (VMLRP)

AGENCY: National Institute of Food and Agriculture, USDA.

ACTION: Notice of request for stakeholder input.

SUMMARY: The National Institute of Food and Agriculture (NIFA) is soliciting stakeholder input on the administration of the Veterinary Medicine Loan Repayment Program (VMLRP) authorized under section 1415A of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3151a). The purpose of this program is for the U.S. Department of Agriculture (USDA) to enter into agreements with veterinarians under which the veterinarians agree to provide, for a specific period of time as identified in the agreement, veterinary services in veterinarian shortage situations. As part of the stakeholder input process, NIFA is inviting comments regarding the current procedures and processes in place for the VMLRP. Input collected will be used to modify and improve processes for subsequent calls of shortage situation nominations and request for applications.

DATES: Written comments are invited from interested individuals and organizations. All comments must be received by close of business on December 10, 2012, to be considered.

ADDRESSES: You may submit comments, identified by NIFA–2013–0001, by any of the following methods:

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

Email: vmlrp@nifa.usda.gov. Include NIFA–2013–0001 in the subject line of the message.

Fax: 202–720–6486.

Mail: Paper, disk or CD–ROM submissions should be submitted to

VMLRP, Policy and Oversight Division, National Institute of Food and Agriculture, U.S. Department of Agriculture; STOP 2299, 1400 Independence Avenue SW., Washington, DC 20250–2299.

Hand Delivery/Courier: VMLRP; Policy and Oversight Division, National Institute of Food and Agriculture, U.S. Department of Agriculture, Room 2308, Waterfront Centre, 800 9th Street SW., Washington, DC 20024.

Instructions: All submissions received must include the agency name and NIFA–2013–0001. All comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided.

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

SUPPLEMENTARY INFORMATION:

Background and Purpose

The VMLRP helps qualified veterinarians offset a significant portion of the debt incurred in pursuit of their veterinary medicine degrees in return for their service in certain high-priority veterinary shortage situations. NIFA will enter into educational loan repayment agreements with veterinarians who agree to provide veterinary services in veterinarian shortage situations for a determined period of time. NIFA may repay up to $25,000 of a veterinarian's student loan debt per year if the veterinarian commits to at least three years to provide veterinary services in a designated veterinary shortage area. Loan repayment benefits are limited to payments of the principal and interest on government and commercial loans received for the attendance at an accredited college of veterinary medicine that result in a degree of Doctor of Veterinary Medicine or the equivalent.

In December 2003, the National Veterinary Medical Service Act (NVMSA) was passed into law adding section 1415A to the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (NARETPA). This law established a new Veterinary Medicine Loan Repayment Program (7 U.S.C. 3151a) authorizing the Secretary of Agriculture (secretary) to carry out a program of entering into agreements with veterinarians under which they agree to provide veterinary services in veterinarian shortage situations.

On October 1, 2009, CSREES became the NIFA as mandated by the Food, Conservation, and Energy Act of 2008, section 7511(f). Accordingly, the authority to administer the VMLRP transferred from CSREES to NIFA.

In FY 2010, VMLRP announced its first funding opportunity and received 257 applications from which NIFA issued 53 VMLRP awards totaling $5,185,970. In FY 2011, VMLRP opened its second funding opportunity and received 159 applications from which NIFA issued 75 VMLRP awards totaling $7,250,970. In FY 2012, VMLRP opened its third annual application cycle and received 139 applications from which 47 VMLRP award offers totaling $4,644,000 have been made. Each award offer is contingent upon submission of a signed contract, thereby executing the service agreement between the veterinarian and NIFA. Funding for future years is based on annual appropriations and balances, if any, remaining from prior years.

Section 7105 of the FCEA amended section 1415A to revise the determination of veterinarian shortage situations to consider (1) geographical areas that the Secretary determines have a shortage of veterinarians; and (2) areas of veterinary practice that the Secretary determines have a shortage of veterinarians, such as food animal medicine, public health, epidemiology, and food safety. This section also added that priority should be given to agreements with veterinarians for the practice of food animal medicine in veterinarian shortage situations.

NARETPA section 1415A requires the Secretary, when determining the amount of repayment for a year of service by a veterinarian, to consider the ability of USDA to maximize the number of agreements from the amounts appropriated and to provide an incentive to serve in veterinary service shortage areas with the greatest need. This section also provides that loan repayments may consist of payments of the principal and interest on government and commercial loans received by the individual for the attendance of the individual at an accredited college of veterinary medicine resulting in a degree of Doctor of Veterinary Medicine or the equivalent. This program is not authorized to provide repayments for any government or commercial loans incurred during the pursuit of another degree, such as an associate or bachelor degree. Loans eligible for repayment include educational loans made for one or more of the following: Loans for tuition expenses; other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the individual; and reasonable living expenses as determined by the Secretary. In addition, the Secretary is directed to make such additional payments to participants as the Secretary determines appropriate for the purpose of providing reimbursements to participants for individual tax liability resulting from participation in this program. The Secretary delegated the authority to carry out this program to NIFA.

NIFA is inviting stakeholder comments to use in improving the administration of the VMLRP. Written comments and suggestions on issues may be submitted to the NIFA Docket Clerk at the address above.

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

Sonny Ramaswamy,

Director, National Institute of Food and Agriculture.

[FR Doc. 2012–27396 Filed 11–8–12; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket Number 121010535–2575–01]

Annual Wholesale Trade Survey

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Notice of determination.

SUMMARY: The United States Department of Commerce's Bureau of the Census (Census Bureau) publishes this notice to announce that the Director of the Census Bureau has determined the need to conduct the 2012 Annual Wholesale Trade Survey (AWTS). The AWTS covers employer firms with establishments located in the United States and classified in the Wholesale Trade sector as defined by the 2007 North American Industry Classification System (NAICS). Through this survey, the Census Bureau will collect data covering annual sales, e-commerce sales, sales taxes, purchases, total and detailed operating expenses, year-end inventories held both inside and outside the United States, commissions, total operating revenue, and gross selling value, for three components of wholesale activity: wholesale distributors; manufacturers' sales branches and offices; and agents, brokers, and electronic markets. These data are collected to provide a sound statistical basis for the formation of

policy by various government agencies. Results will be available for use for a variety of public and business needs such as economic and market analysis, company performance, and forecasting future demand. The Census Bureau conducts the AWTS to provide continuing and timely national statistical data on wholesale trade. The 2012 AWTS is a separate collection from and is not part of the 2012 Economic Census.

ADDRESSES: The Census Bureau will provide report forms to businesses included in the survey. Additional copies are available upon written request to the Director, U.S. Census Bureau, Washington, DC 20233–0101.

FOR FURTHER INFORMATION CONTACT: Randy Moore, Service Sector Statistics Division, at (301) 763–7231 or by email at *randy.a.moore@census.gov.*

SUPPLEMENTARY INFORMATION: Sections 182, 224, and 225 of Title 13 of the United States Code (U.S.C.) authorize the Census Bureau to take surveys that are necessary to produce current data on the subjects covered by the major censuses. As part of this authorization, the Census Bureau conducts the AWTS to provide continuing and timely national statistical data on wholesale trade activity for the period between economic censuses and, for this year, during the economic census. The AWTS covers employer firms with establishments located in the United States and classified in the Wholesale Trade sector as defined by the 2007 NAICS. The 2012 AWTS will collect data for three components of wholesale activity: Wholesale distributors; manufacturers' sales branches and offices; and agents, brokers, and electronic markets. For wholesale distributors, the Census Bureau will collect data covering sales, sales taxes, e-commerce sales, year-end inventories held inside and outside theUnited States, purchases, total and detailed operating expenses. For manufacturers' sales branches and offices, the Census Bureau will collect data covering annual sales, sales taxes, e-commerce sales, year-end inventories held inside and outside the United States and total operating expenses. For agents, brokers, and electronic markets, the Census Bureau will collect data covering commissions, total operating revenue, gross selling value, and total operating expenses. The Census Bureau has determined that the conduct of this survey is necessary as these data are not available publicly on a timely basis from non-governmental or other government sources.

For the 2012 AWTS, we will request data for wholesale distributors on detailed operating expenses that were previously requested under a separate supplemental mailing (conducted every 5 years). The last supplemental mailing was conducted for the 2007 AWTS under OMB No. 0607–0942. While the wholesale portion of that program will be collapsed into the AWTS, we will continue to only ask the detailed expense questions to wholesale distributors every 5 years. Also for the 2012 AWTS, we will request data on sales taxes, which is asked as a part of the AWTS every 5 to 6 years. The last time we requested sales tax data was for the 2006 AWTS.

Firms were selected for the AWTS using a stratified random sample based on industry groupings and annual sales size. We will provide report forms to the firms covered by this survey in February 2013, and will require their responses within 50 days after receipt. Firms' responses to the AWTS are required by law (Title 13, U.S.C., Sections 182, 224, and 225).

The sample of firms selected will provide, with measurable reliability, statistics on annual sales, e-commerce sales, sales taxes, purchases, total and detailed operating expenses, year-end inventories held both inside and outside the Unites States, commissions, total operating revenue, and gross selling value, for 2012.

The data collected in this survey will be similar to that collected in the past and within the general scope and nature of those inquiries covered in the economic census. These data are collected to provide a sound statistical basis for the formation of policy by various government agencies. Results will be available for use for a variety of public and business needs such as economic and market analysis, company performance, and forecasting future demand.

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. In accordance with the PRA, 44 U.S.C. 3501–3521, OMB approved the AWTS under OMB control number 0607–0195.

Based upon the foregoing, I have directed that the annual survey be conducted for the purpose of collecting these data.

Dated: November 2, 2012.

Thomas L. Mesenbourg, Jr.,

Acting Director, Bureau of the Census.

[FR Doc. 2012–27446 Filed 11–8–12; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–932]

Certain Steel Threaded Rod From the People's Republic of China: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review; 2010–2011

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

SUMMARY: On May 8, 2012, the Department of Commerce (''Department'') published in the **Federal Register** the *Preliminary Results* of the second administrative review of the antidumping duty order on certain steel threaded rod from the People's Republic of China (''PRC'') for the period of review (''POR'') April 1, 2010, through March 31, 2011.[1] Based upon our analysis of the comments and information received, we continue to find that RMB Fasteners Ltd., and IFI & Morgan Ltd. (collectively ''RMB/IFI Group'') has sold subject merchandise at less than normal value.

DATES: *Effective Date:* November 9, 2012.

FOR FURTHER INFORMATION CONTACT: Jerry Huang, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: 202–482–4047.

SUPPLEMENTARY INFORMATION:

Background

On May 8, 2012, the Department published the *Preliminary Results.* In the *Preliminary Results,* the Department indicated its intent to rescind the review with respect to Gem-Year Industrial Co., Ltd. (''Gem-Year'') and Haiyan Julong Standard Part Co., Ltd. (''Haiyan Julong'') for lack of shipments.[2]

On June 8, 2012, the RMB/IFI Group submitted factor usage information that the Department requested for two control numbers that were not produced during the POR. On June 19, 2012, the

[1] *See Certain Steel Threaded Rod From the People's Republic of China: Preliminary Results of the Administrative Review, Intent To Rescind, and Rescission, in Part,* 77 FR 27022 (May 8, 2012) (''*Preliminary Results*'').

[2] *See Preliminary Results,* 77 FR at 27024.

RMB/IFI Group submitted additional surrogate value information for the final results. Interested parties were further provided an opportunity to comment on the *Preliminary Results.* Between July 17 and July 24, 2012, we received case and rebuttal briefs from interested parties. On August 24, 2012, the Department extended the time limit for these final results by 60 days.[3]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this review are addressed in the memorandum entitled, ''Issues and Decision Memorandum for the Final Results of the Second Administrative Review of Certain Steel Threaded Rod from the People's Republic of China'' (''I&D Memo''), which is dated November 5, 2012, and hereby adopted by this notice. A list of the issues that parties raised, and to which we respond in the I&D Memo is attached to this notice as Appendix I. The I&D Memo is a public document and is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and in the Central Records Unit (''CRU''), room 7046 of the main Department of Commerce building. In addition, a complete version of the I&D Memo can be accessed directly on the internet at *http://www.trade.gov/ia/.* The signed I&D Memo and the electronic versions of the I&D Memo are identical in content.

Changes Since the Preliminary Results

The Department has made changes to the preliminary margin calculation for the RMB/IFI Group. Specifically, we relied on factor usage information submitted after the *Preliminary Results* for the two control numbers that were not produced during the POR and updated the Thai import statistics used to value steel wire rod based on the specific carbon content reported by the RMB/IFI Group for its steel wire rod consumption.[4]

Scope of the Order

The merchandise covered by the order is steel threaded rod. Steel threaded rod is certain threaded rod, bar, or studs, of carbon quality steel, having a solid, circular cross section, of any diameter, in any straight length, that have been forged, turned, cold-drawn, cold-rolled, machine straightened, or otherwise cold-finished, and into which threaded grooves have been applied. Certain steel threaded rod subject to the order is currently classifiable in the Harmonized Tariff Schedule of the United States (''HTSUS'') at subheadings 7318.15.5051, 7318.15.5056, 7318.15.5090, and 7318.15.2095.[5] Although the subheadings are provided for convenience and customs purposes, the written product description, available in *Certain Steel Threaded Rod from the People's Republic of China: Notice of Antidumping Duty Order,* 74 FR 17154 (April 14, 2009), remains dispositive.

PRC-Wide Entity

As noted in the *Preliminary Results,* upon initiation of the administrative review, we provided an opportunity for all companies for which the review was initiated to complete either the separate rate application or certification.[6] The Department preliminarily determined that New Pole Power Systems Co., Ltd. (''New Pole'') failed to demonstrate eligibility for a separate rate and is thus properly considered not to be separate from the PRC-wide entity.[7] Further, in the *Preliminary Results* we assigned the PRC-wide entity a rate of 206.00 percent, the only rate ever determined for the PRC-wide entity in this proceeding.[8] No party submitted comments regarding this finding. Therefore, for these final results, we continue to assign the PRC-wide entity a rate of 206.00 percent.[9]

Final Partial Rescission

In the *Preliminary Results,* the Department indicated its intent to rescind this review with respect to Gem-Year and Haiyan Julong upon preliminarily determining that they had no shipments of subject merchandise to the United States during the POR.[10] Subsequent to the *Preliminary Results,* no information was submitted on the record indicating that they made sales to the United States of subject merchandise during the POR and no party provided written arguments regarding this issue. Thus, in accordance with 19 CFR 351.213(d)(3), and consistent with our practice,[11] we are rescinding this review with respect to Gem-Year and Haiyan Julong.

Final Results of Review

The dumping margins for the POR are as follows:

Exporter	Weighted-average margin (percent)
RMB Fasteners Ltd., and IFI & Morgan Ltd. (''RMB/IFI Group'')	19.68
PRC-wide Entity	206.00

The Department will disclose calculations performed for these final results to the parties within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Assessment

Upon issuance of the final results, the Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review. For any individually examined respondents whose weighted-average dumping margin is above *de minimis,* we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of antidumping duty calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[12] We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in the final results of this review is above *de minimis* (*i.e.,* 0.50 percent). Where either the respondent's

[3] *See* Department's Memorandum, re: ''Certain Steel Threaded Rod from the People's Republic of China: Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated August 24, 2012.

[4] *See* I&D Memo at Comments 1 and 3.

[5] As part of these final results, the Department has modified the language of the scope to reflect the fact that HTSUS subheading 7318.15.5050 has been deleted and replaced with subheadings 7318.15.5051 and 7318.15.5056. *See* I&D Memo at Comment 2.

[6] *See Preliminary Results,* 77 FR at 27024.

[7] *See id.*

[8] *See, e.g., Certain Steel Threaded Rod from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 74 FR 8907 (February 27, 2009).

[9] *See Certain Steel Threaded Rod from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 74 FR 8907, 8910 (February 27, 2009).

[10] *See Preliminary Results,* 77 FR at 27024.

[11] *See, e.g., Certain Tissue Paper Products from the People's Republic of China: Preliminary Results and Partial Rescission of Antidumping Duty Administrative Review,* 73 FR 18497, 18500 (April 4, 2008) (preliminarily rescinding review because of lack of reviewable entries), unchanged in *Certain Tissue Paper Products from the People's Republic of China: Final Results and Final Rescission, in Part, of Antidumping Duty Administrative Review,* 73 FR 58113 (October 6, 2008).

[12] In these final results, the Department applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Tariff Act of 1930, as amended, (''the Act''): (1) For the RMB/IFI Group, the cash deposit rate will be the rate established in the final results of review (except, if the rate is zero or *de minimis, i.e.,* less than 0.5 percent, a zero cash deposit rate will be required for that company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have a separate rate, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 206.00 percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that supplied that non-PRC exporter. The deposit requirements, when imposed, shall remain in effect until further notice.

Reimbursement of Duties

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

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under 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/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this administrative review and notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: November 5, 2012

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix I

Comment 1. Surrogate Country Selection
- A. Economic Comparability and Significant Producer
- B. Data Availability
- (1) Surrogate Value for Steel Inputs
- (2) Surrogate Value for Hydrochloric Acid
- (3) Surrogate Financial Ratios

Comment 2. Correcting the Harmonized Tariff Schedule Numbers Within the Scope

Comment 3. Factors of Production for Control Numbers Not Produced During the POR

[FR Doc. 2012–27438 Filed 11–8–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–933]

Frontseating Service Valves From the People's Republic of China; 2010–2011 Antidumping Duty Administrative Review; Final Results

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

SUMMARY: On May 4, 2012, the Department published its *Preliminary Results* in the antidumping duty administrative review of frontseating service valves from the People's Republic of China.[1] The period of review (''POR'') is April 1, 2010, through March 31, 2011. We have determined that neither Zhejiang DunAn Hetian Metal Co., Ltd. (''DunAn'') nor Zhejiang Sanhua Co., Ltd. (''Sanhua''), the only companies covered by this review, made sales in the United States at prices below normal value (''NV''). We invited interested parties to comment on our *Preliminary Results.* Based on our analysis of the comments received, we made changes to our margin calculations for DunAn and Sanhua. The final dumping margins for this review are listed in the ''Final Results Margins'' section below.

DATES: *Effective Date:* November 9, 2012.

FOR FURTHER INFORMATION CONTACT: Laurel LaCivita, Brooke Kennedy, or Eugene Degnan, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4243, (202) 482–3818, and (202) 482–0414, respectively.

Background

On May 4, 2012, the Department published its *Preliminary Results* in the antidumping duty administrative review of frontseating service valves from the People's Republic of China.[2] On June 1, 2012, Petitioner[3] requested a hearing for issues raised in the case and rebuttal briefs.[4] On June 1, 2011, DunAn submitted its 5th supplemental questionnaire response reporting factors of production (''FOPs'') for its unaffiliated brass tollers.[5]

On June 11, 2012, Petitioner and DunAn submitted publicly available surrogate value (''SV'') data to value respondents' factors of production.[6] On June 21, 2012, DunAn and Sanhua submitted rebuttal SV comments on the June 11, 2012 submissions.[7] We received case briefs from Petitioner and DunAn on July 12, 2012,[8] and rebuttal

---

[1] *See Frontseating Service Valves from the People's Republic of China: Preliminary Results of the 2010–2011 Antidumping Duty Administrative Review,* 77 FR 26489 (May 4, 2012).

[2] *See id.*

[3] Parker-Hannifin Corporation (''Parker-Hannifin''), Petitioner in the underlying investigation.

[4] *See* letter from Parker-Hannifin, ''Frontseating Service Valves from the People's Republic of China,'' dated June 1, 2012.

[5] *See* Letter from DunAn, ''DunAn's Fifth Supplemental Questionnaire Response; Second Administrative Review of the Antidumping Duty Order on Frontseating Service Valves from the People's Republic of China,'' dated June 1, 2012.

[6] *See* Letter from Petitioner, ''Petitioner's Submission of Surrogate Values for Final Results in the Second Administrative Review of Certain Frontseating Service Valves from the People's Republic of China: Case No. A–570–933,'' dated June 1, 2011; *see also,* Letter from DunAn, ''DunAn's Post-Preliminary Surrogate Value Submission: Second Administrative Review of the Antidumping Duty Order on Frontseating Service Valves from the People's Republic of China,'' dated June 11, 2012.

[7] *See* letter from DunAn, ''Post-Preliminary Surrogate Value Rebuttal Submission: Second Administrative Review of the Antidumping Duty Order on Frontseating Service Valves from the People's Republic of China,'' dated June 21, 2012; *see also* letter from Sanhua, ''Frontseating Service Valves from the People's Republic of China; A–570–933; Surrogate Value Rebuttal Comments for the Final Results by Zhejiang Sanhua Co., Ltd.,'' dated June 21, 2012.

[8] *See* letter from Parker-Hannifin, ''Frontseating Service Valves from the People's Republic of China: Petitioner's Case Brief,'' dated July 12, 2012; *see* letter from DunAn, ''Case Brief: Second

briefs from all parties on July 23, 2012.[9] On August 6, 2012, Petitioner withdrew its request for a hearing.[10]

On August 17, 2012, the Department originally extended the deadline for the final results of review to October 31, 2012.[11] As explained in the memorandum from the Assistant Secretary for Import Administration, the Department has exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from October 29, through October 30, 2012. Thus, all deadlines in this segment of the proceeding have been extended by two days. The revised deadline for the final results of this review is now Friday, November 2, 2012.[12]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs filed by parties in this review are addressed in the Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Import Administration, ''Frontseating Service Valves from the People's Republic of China: Issues and Decision Memorandum for the Final Results of the 2010–2011 Administrative Review (''Issues and Decision Memorandum''),'' dated concurrently with, and hereby adopted by, this notice. A list of the issues that parties raised and to which we responded in the Issues and Decision Memorandum follows as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and in the Central Records Unit (''CRU''), room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at *http://www.trade.gov/ia/*. The signed Issues and Decision Memorandum and the electronic versions of the Issues and Decision Memorandum are identical in content.

Period of Review

The POR is April 1, 2010, through March 31, 2011.

Scope of the Order

The merchandise covered by this order is frontseating service valves, assembled or unassembled, complete or incomplete, and certain parts thereof. Frontseating service valves are classified under subheading 8481.80.1095, and also have been classified under subheading 8415.90.80.85, of the Harmonized Tariff Schedule of the United States (''HTSUS''). It is possible for frontseating service valves to be manufactured out of primary materials other than copper and brass, in which case they would be classified under HTSUS subheadings 8481.80.3040, 8481.80.3090, or 8481.80.5090. In addition, if unassembled or incomplete frontseating service valves are imported, the various parts or components would be classified under HTSUS subheadings 8481.90.1000, 8481.90.3000, or 8481.90.5000. The HTSUS subheadings are provided for convenience and customs purposes, but the written description of the scope of this order, available in *Antidumping Duty Order: Frontseating Service Valves from the People's Republic of China,* 74 FR 19196 (April 28, 2009), remains dispositive.

Changes Since the Preliminary Results

Based on an analysis of the comments received, the Department has made the following changes in the margin calculation.

- We valued the surrogate value for brass scrap using the HTS number for brass bar and rod. *See* Comment 2 of the accompanying Issues and Decision Memorandum.
- The Department recalculated the surrogate financial ratios using the financial statements of FVC Philippines, Inc. and Makati Foundry, Inc. *See* Comment 4 of the accompanying Issues and Decision Memorandum.
- We revised Sanhua's reported scrap adjustment to ensure that the reported raw materials account fully for the reported weight of each FSV model sold. *See* Comment 7 of the accompanying Issues and Decision Memorandum.

Final Results Margin

We determine the weighted-average dumping margins for the period April 1, 2010, through March 31, 2011, to be:

FRONTSEATING SERVICE VALVES FROM THE PRC

Exporter	Weighted-average margin (percentage)
Zhejiang DunAn Hetian Metal Co. Ltd	0.00
Zhejiang Sanhua Co., Ltd	0.00

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Tariff Act of 1930, as Amended (''the Act'') and 19 CFR 351.212(b), the Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Where the weighted-average margin of dumping for the exporter or producer is determined to be zero or *de minimis,* no assessment rates will be calculated and the Department will instruct CBP to liquidate all imports from the exporter or producer without regard to antidumping duties. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For DunAn and Sanhua, the cash deposit rate will be the rate identified in the Final Results Margin section, as listed above; (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will continue to be the PRC-wide rate of 55.62 percent;[13] and (4) for all non-PRC

Administrative Review of the Antidumping Duty Order on Frontseating Service Valves from the People's Republic of China,'' dated July 12, 2012.

[9] *See* letter from Parker-Hannifin, ''Frontseating Service Valves from the People's Republic of China: Petitioner's Rebuttal Brief,'' dated July 23, 2012; *see* letter from DunAn, ''Rebuttal Case Brief: Second Administrative Review of the Antidumping Duty Order on Frontseating Service Valves from the People's Republic of China,'' dated July 23, 2012; and, *see* letter from Sanhua, ''Certain Frontseating Service Valves from the People's Republic of China; A–570–933; Rebuttal Brief of Zhejiang Sanhua Co., Ltd.,'' dated July 23, 2012.

[10] *See* letter from Petitioner, ''Frontseating Service Valves from the People's Republic of China: Request for Hearing,'' dated August 6, 2012.

[11] *See* Extension of the Deadline for Final Results.

[12] *See* Memorandum to the Record from Paul Piquado, AS for Import Administration, regarding ''Tolling of Administrative Deadlines As a Result of the Government Closure During the Recent Hurricane,'' dated October 31, 2012.

[13] This rate was established in the final results of the original investigation. *See Frontseating Service Valves from the People's Republic of China: Final Determination of Sales at Less Than Fair Value and*

Continued

exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that non-PRC exporter. The deposit requirements shall remain in effect until further notice.

Notification to Importers

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

Notification to Interested Parties

This notice also serves as a reminder to parties subject to administrative protective orders (''APOs'') of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Disclosure

We will disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

We are issuing and publishing the final results and notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 2, 2012.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix I—Issues for the Final Results

Comment 1: Surrogate Country Selection
Comment 2: Surrogate Value for Brass Bar and Rod
Comment 3: Surrogate Value for Brass Scrap
Comment 4: Financial Ratios
Comment 5: Brokerage and Handling for DunAn
Comment 6: Use of Historical FOPs for Models Produced Prior to the POR for DunAn
Comment 7: Sanhua's Brass Scrap Generation Is Overstated

[FR Doc. 2012–27424 Filed 11–8–12; 8:45 am]

BILLING CODE P

Final Negative Determination of Critical Circumstances, 74 FR 10886 (March 13, 2009).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–485–805]

Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe From Romania: Final Results of Antidumping Duty Administrative Review; 2010–2011

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

SUMMARY: On August 21, 2012, the Department of Commerce published the preliminary results of the administrative review of the antidumping duty order on certain small diameter carbon and alloy seamless standard, line and pressure pipe from Romania. The period of review is August 1, 2010, through July 31, 2011. We gave interested parties an opportunity to comment on the preliminary results, but we received no comments. The final weighted-average dumping margin for ArcelorMittal Tubular Products Roman S.A. is listed below in the ''Final Results of the Review'' section of this notice.

DATES: *Effective Date:* November 9, 2012.

FOR FURTHER INFORMATION CONTACT: Thomas Schauer, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–0410.

Background

On August 21, 2012, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on certain small diameter carbon and alloy seamless standard, line and pressure pipe from Romania. *See Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe From Romania: Preliminary Results of Antidumping Duty Administrative Review, 77 FR 50465 (August 21, 2012) (Preliminary Results).* We invited interested parties to comment on the *Preliminary Results,* but we received no comments.

The Department has conducted this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The products subject to the order are small diameter seamless carbon and alloy (other than stainless) steel standard, line, and pressure pipes and redraw hollows. The products are typically classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings: 7304.10.10.20, 7304.10.50.20, 7304.19.10.20, 7304.19.50.20, 7304.31.30.00, 7304.31.60.50, 7304.39.00.16, 7304.39.00.20, 7304.39.00.24, 7304.39.00.28, 7304.39.00.32, 7304.51.50.05, 7304.51.50.60, 7304.59.60.00, 7304.59.80.10, 7304.59.80.15, 7304.59.80.20, and 7304.59.80.25. Although the HTSUS subheadings are provided for convenience and customs purposes, the written product descriptions, available in *Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe From Romania,* 65 FR 48963 (August 10, 2000), remains dispositive.

Final Results of the Review

We have made no changes to our calculations announced in the *Preliminary Results.* As a result of our review, we determine that a weighted-average dumping margin of 0.00 percent exists for ArcelorMittal Tubular Products Roman S.A. for the period August 1, 2010, through July 31, 2011.

Assessment Rates

In accordance with the *Final Modification,* we will instruct U.S. Customs and Border Protection (CBP) to liquidate the entries covered by this review without regard to antidumping duties. *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012) (*Final Modification*).

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. This clarification will apply to entries of subject merchandise during the period of review produced by AMTP for which it did not know its merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. For a full discussion of this clarification, *see*

Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties, 68 FR 23954 (May 6, 2003).

The Department intends to issue assessment instructions directly to CBP 15 days after publication of these final results of review.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of this notice for all shipments of certain small diameter carbon and alloy seamless standard, line and pressure pipe from Romania entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(1) of the Act: (1) The cash deposit rate for ArcelorMittal Tubular Products Roman S.A. will be 0.00 percent; (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in the original less-than-fair-value investigation or previous reviews, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; (4) the cash deposit rate for all other manufacturers or exporters will continue to be 13.06 percent, the all-others rate established in *Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Small Diameter Carbon and Alloy Seamless Standard, Line and Pressure Pipe From Romania,* 65 FR 48963 (August 10, 2000). These cash deposit requirements shall remain in effect until further notice.

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 Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to the 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 notification of the 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.

We are issuing and publishing these results and this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 2, 2012.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2012–27439 Filed 11–8–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–904]

Certain Activated Carbon From the People's Republic of China; 2010–2011; Final Results of Antidumping Duty Administrative Review

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

SUMMARY: The Department of Commerce (''the Department'') published its *Preliminary Results* of the antidumping duty order on certain activated carbon from the People's Republic of China (''PRC'') on May 4, 2012,[1] and we gave interested parties an opportunity to comment on the *Preliminary Results.* Based upon our analysis of the comments and information received, we made changes to the margin calculations for these final results and partial rescission of antidumping duty administrative review. The final dumping margins are listed below in the ''Final Results of the Reviews'' section of this notice. The period of review (''POR'') is April 1, 2010, through March 31, 2011.

DATES: *Effective Date:* November 9, 2012.

FOR FURTHER INFORMATION CONTACT: Alan Ray, Javier Barrientos, or Emeka Chukwudebe, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5403, (202) 482–2243, or (202) 482–0219, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published the *Preliminary Results* on May 4, 2012.[2] The period of review (''POR'') is April 1, 2010, through March 31, 2011.[3] In accordance with 19 CFR 351.309(c)(1)(ii), we invited parties to comment on our *Preliminary Results.*[4] On June 13, 2012, we received case briefs from Cherishmet, DJAC, Jacobi, CAC, Bright Future, and Shanxi DMD.[5] On June 22, 2012, we received rebuttal briefs from Petitioners and Cherishmet.[6]

Scope of the Order

The merchandise subject to the order is certain activated carbon.[7] The products are currently classifiable under the Harmonized Tariff Schedule of the United States (''HTSUS'') subheading 3802.10.00. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the order remains dispositive.[8]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties are addressed in the ''Certain Activated Carbon from the People's Republic of China: Issues and Decision Memorandum for the Final Results of the Fourth Antidumping Duty Administrative Review,'' dated concurrently with this notice (''Issues & Decision Memo''). A list of the issues which parties raised is attached to this notice as Appendix I. The Issues & Decision Memo is a public document and is on file in the Central Records Unit (''CRU''), Room 7046 of the main Department of Commerce building, as well as electronically via Import Administration's Antidumping

[1] *See Certain Activated Carbon From the People's Republic of China: Preliminary Results of the Fourth Antidumping Duty Administrative Review, and Intent To Rescind in Part,* 77 FR 26496 (May 4, 2012) (''*Preliminary Results*'').

[2] *See id.*

[3] *See id.* at 26497.

[4] *See id.* at 26506.

[5] Beijing Pacific Activated Carbon Products Co., Ltd., Ningxia Guanghua Cherishmet Activated Carbon Co., Ltd., Ningxia Guanghua Activated Carbon Co., Ltd., (collectively, ''Cherishmet''); Datong Juqiang Activated Carbon Co., Ltd. (''DJAC''); Jacobi Carbons AB and its affiliates, Tianjin Jacobi International Trading Co. Ltd., Jacobi Carbons Industry (Tianjin) Co., Ltd., and Jacobi Carbons, Inc. (collectively, ''Jacobi''); Calgon Carbon Corp (''CAC''); Jilin Bright Future Chemicals Co., Ltd. (''Bright Future''); and Shanxi DMD Corporation (''Shanxi DMD'').

[6] *See* Petitioners' Rebuttal Brief, dated June 22, 2012 and Cherishmet's Rebuttal Brief, dated June 22, 2012.

[7] *See* Certain Activated Carbon from the People's Republic of China: Issues and Decision Memorandum for the Final Results of the Fourth Antidumping Duty Administrative Review,'' dated concurrently with this notice for a complete description of the Scope of the Order.

[8] *See Notice of Antidumping Duty Order: Certain Activated Carbon from the People's Republic of China,* 72 FR 20988 (April 27, 2007).

and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and in the CRU. In addition, a complete version of the Issues & Decision Memo can be accessed directly on the internet at *http://www.trade.gov/ia/.* The signed Issues & Decision Memo and the electronic version of the Issues & Decision Memo are identical in content.

Final Partial Rescission

In the *Preliminary Results,* the Department preliminarily rescinded the review with respect to Shanxi Dapu International Trade Co., Ltd. (''Dapu''). This company reported that it had no shipments of subject merchandise to the United States during the POR, and our examination of shipment data from U.S. Customs and Border Protection (''CBP'') confirmed that there were no entries of subject merchandise made by this company during the POR.[9] Subsequent to the *Preliminary Results,* the Department did not receive any comments or information indicating that Dapu made sales of subject merchandise to the United States during the POR. Therefore, pursuant to 19 CFR 351.213(d)(3), we are rescinding the administrative review with respect to Dapu.

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results,* we have made certain revisions to the margin calculations for Jacobi, DJAC, and Cherishmet. For the reasons explained in the Issues & Decision Memo at Comment I, we have selected the Philippines as the primary surrogate country. We have also made other changes to the margin calculations of Cherishmet, DJAC, and Jacobi.[10] Finally, the Surrogate Values Memo contains the further explanation of our changes to the surrogate values.[11]

Separate Rates

In our *Preliminary Results,* we determined that the following companies met the criteria for separate rate status: Bright Future; Datong Municipal Yunguang Activated Carbon Co., Ltd.; Ningxia Mineral; Shanxi Sincere Industrial Co., Ltd.; Shanxi Industry Technology Trading Co., Ltd.; Tangshan Solid; and Tianjin Maijin Industries Co., Ltd.[12] We have not received any information since the issuance of the *Preliminary Results* that provides a basis for reconsideration of these determinations. Therefore, the Department continues to find that the companies listed above meet the criteria for a separate rate.

Additionally, in the *Preliminary Results,* we also noted that CBP data reviewed by the Department does not show any reviewable entries of subject merchandise made during the POR by the third-country exporter, Adsorbent,[13] an Indian activated carbon company. For these final results, we continue to find that the CBP data does not show any reviewable entries of subject merchandise made by Adsorbent during the POR and intend to refer this matter to CBP to investigate whether Adsorbent's entries were entered properly.

Rate for Non-Selected Companies

In the *Preliminary Results,* and consistent with the Department's practice,[14] we assigned the separate rate companies a rate calculated using the ranged total sales quantities of the individually-reviewed respondents with margins above *de minimis* from the public versions of their submissions.[15] For the final results, we continue to find this approach to be consistent with the intent of section 735(c)(5)(A) of the Act and our use of section 735(c)(5)(A) of the Act as guidance when we establish the rate for respondents not examined individually in an administrative review.[16] *See* Decision Memo at Comment 3.

Because the calculated net U.S. sales values for the individually-reviewed respondents with margins above *de minimis* are business-proprietary figures, we find that 1.04 U.S. Dollars/kilogram (''USD/kg''), which we calculated using the publicly available figures of U.S. sales quantities for these firms, is the best reasonable proxy for the weighted-average margin based on the calculated U.S. sales quantities of these respondents.[17]

PRC-Wide Rate and PRC-Wide Entity

The Department used the PRC-Wide rate of 2.42 USD/kg in the most recently completed administrative review of this antidumping order.[18] Because we have not calculated a PRC-Wide rate greater than the PRC-Wide rate from previous reviews in this proceeding and nothing on the record of the instant review calls into question the reliability of the PRC-Wide rate, we find it appropriate to continue to apply the PRC-Wide rate of 2.42 USD/kg for the final results.[19]

In the *Preliminary Results,* the Department determined that those companies which did not demonstrate eligibility for a separate rate are properly considered part of the PRC-wide entity.[20] Since the *Preliminary Results,* none of the companies which did not file separate rate applications or certifications submitted comments regarding these findings. Therefore, we continue to treat these entities as part of the PRC-wide entity.

Final Results of the Review

The dumping margins for the POR are as follows:

[9] *See Preliminary Results,* 77 FR at 26498.

[10] *See* Comments II to VI of the Issues and Decision Memo and the company-specific analysis memoranda.

[11] *See* Memorandum to the File, through Matthew Renkey, Acting Program Manager, AC/CVD Operations, Office 9, from Javier Barrientos, Senior Case Analyst, Alan Ray, Senior Case Analyst, and Emeka Chukwudebe, Case Analyst, AD/CVD Operations, Office 9, Certain Activated Carbon from the People's Republic of China (''PRC''): Surrogate Values for the Final Results,'' (October 31, 2012).

[12] *See Preliminary Results* at 77 FR 26496.

[13] Adsorbent Carbons Pvt. Ltd., (''Adsorbent'').

[14] *See Certain Frozen Warmwater Shrimp From the Socialist Republic of Vietnam: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review,* 76 FR 56158, 56160 (September 12, 2011) (''*Vietnam Shrimp*''); *see also Galvanized Steel Wire From the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 77 FR 68407, 68415 (November 4, 2011) (''*Galvanized Wire LTFV*'').

[15] *See* Jacobi Section A questionnaire response (Public Version) dated September 13, 2011, at Exhibit 4; *see also* Guanghua Cherishmet Public Version of Exhibit SA–1 for the Section A Response, dated August 19, 2011.

[16] *See Vietnam Shrimp,* 76 FR at 56160; *see also Galvanized Wire LTFV,* 77 FR at 68415.

[17] *See* ''Memorandum to the File from Alan Ray, Case Analyst, Office 9, AD/CVD Operations, Re: Calculation of Separate Rate,'' dated concurrently with this notice.

[18] *See Certain Activated Carbon From the People's Republic of China: Final Results and Partial Rescission of Third Antidumping Duty Administrative Review,* 76 FR 67142, 67145 (October 31, 2011).

[19] *See Administrative Review of Certain Frozen Warmwater Shrimp From the People's Republic of China: Final Results and Partial Rescission of Antidumping Duty Administrative Review,* 76 FR 51940, 51942 (August 19, 2011) (where the Department used the PRC-Wide rate from the previous review).

[20] The PRC-Wide entity includes Hebei Foreign Trade and Advertising Corporation; Jilin Province Bright Future Industry and Commerce Co., Ltd.; and United Manufacturing International (Beijing) Ltd. *See Preliminary Results,* 77 FR at 26501.

[21] In the second administrative review of this order, the Department determined that it would calculate per-unit assessment and cash deposit rates for all future reviews. *See Certain Activated Carbon From the People's Republic of China: Final Results and Partial Rescission of Second Antidumping Duty Administrative Review,* 75 FR 70208, 70210 (November 17, 2010).

[22] In *Activated Carbon AR3,* the Department found Jacobi Carbons AB, Tianjin Jacobi International Trading Co. Ltd., and Jacobi Carbons Industry (Tianjin) are a single entity and, because there has been no change to this determination since the first administrative review, we continue to find these companies to be part of a single entity. Therefore, we will assign this rate to the companies in the single entity. *See Certain Activated Carbon*

Exporter	Margin (dollars per kilogram) [21]
Datong Juqiang Activated Carbon Co., Ltd.	0.00
Jacobi Carbons AB [22]	0.44
Ningxia Guanghua Cherishmet Activated Carbon Co., Ltd.[23]	2.11
Datong Municipal Yunguang Activated Carbon Co., Ltd.	1.04
Jilin Bright Future Chemicals Company, Ltd.	1.04
Ningxia Mineral and Chemical Limited	1.04
Shanxi DMD Corporation	1.04
Shanxi Sincere Industrial Co., Ltd.	1.04
Shanxi Industry Technology Trading Co., Ltd.	1.04
Tangshan Solid Carbon Co., Ltd.	1.04
Tianjin Maijin Industries Co., Ltd.	1.04
PRC-Wide Rate [24]	2.42

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b), the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of the final results of this administrative review.

For assessment purposes, we calculated importer (or customer)-specific assessment rates for merchandise subject to this review. As the Department stated in the most recent administrative review,[25] we will continue to direct CBP to assess importer-specific assessment rates based on the resulting per-unit (*i.e.,* per-kilogram) rates by the weight in kilograms of each entry of the subject merchandise during the POR. Specifically, we calculated importer-specific duty assessment rates on a per-unit rate basis by dividing the total dumping margins (calculated as the difference between normal value and export price or constructed export price) for each importer by the total sales quantity of subject merchandise sold to that importer during the POR. If an importer (or customer)-specific assessment rate is *de minimis* (*i.e.,* less than 0.50 percent), the Department will instruct CBP to assess that importer (or customer's) entries of subject merchandise without regard to antidumping duties, in accordance with 19 CFR 351.106(c)(2).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For Jacobi, DJAC, Cherishmet, and the Separate Rate Respondents, the cash deposit rate will be their respective rates established in the final results of this review, except if the rate is zero or *de minimis* no cash deposit will be required; (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-Wide rate of $2.42 per kilogram; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We will disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Notification to Importers Regarding The Reimbursement of Duties

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

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 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.

We are issuing and publishing this administrative review and notice in accordance with sections 751(a)(1) and 777(i) of the Act.

From the People's Republic of China: Final Results and Partial Rescission of the Third Antidumping Duty Administrative Review, 76 FR 67142, 67145 n.25 (October 31, 2011) (''*Activated Carbon AR3*'').

[23] In *Activated Carbon AR1,* the Department found Beijing Pacific Activated Carbon Products Co., Ltd., Ningxia Guanghua Cherishmet Activated Carbon Co., Ltd., and Ningxia Guanghua Activated Carbon Co., Ltd. are a single entity and, because there has been no change to this determination since the first administrative review, we continue to find these companies to be part of a single entity. Therefore, we will assign this rate to the companies in the single entity. *See Certain Activated Carbon From the People's Republic of China: Notice of Preliminary Results of the Antidumping Duty Administrative Review and Extension of Time Limits for the Final Results,* 74 FR 21317 (May 7, 2009), unchanged in *First Administrative Review of Certain Activated Carbon from the People's Republic of China: Final Results of Antidumping Duty Administrative Review,* 74 FR 57995, 57996 n.2 (November 10, 2009).

[24] As discussed above in this notice, the PRC-Wide entity includes Hebei Foreign Trade and Advertising Corporation; Jilin Province Bright Future Industry and Commerce Co., Ltd.; and United Manufacturing International (Beijing) Ltd.

[25] *Activated Carbon AR3,* 76 FR at 67145.

Dated: November 2, 2012.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix I—Issues & Decision Memorandum

General Issues

COMMENT I: SELECTION OF SURROGATE COUNTRY
- A. Economic Comparability
- B. Significant Producer of the Comparable Merchandise
- C. Data Considerations
  - A. Anthracite Coal
  - B. Bituminous Coal
  - C. Carbonized Material
  - D. Hydrochloric Acid
  - E. Labor
  - F. Financial Ratios

COMMENT II: CALCULATION OF THE SEPARATE RATE

COMMENT III: MISCELLANEOUS SURROGATE VALUES
- A. ELECTRICITY
- B. SALT
- C. BUCKLES

COMMENT IV: PER-UNIT ASSESSMENT/DUTY ABSORPTION

Company-Specific Issues

COMMENT V: VALUATION OF JACOBI'S CONSUMPTION OF BITUMINOUS COAL FOR HEATING

COMMENT VI: VALUATION OF JACOBI'S CONSUMPTION OF STEAM COAL INPUT

COMMENT VII: CALCULATION OF FREIGHT FOR CERTAIN PACKING INPUTS

COMMENT VIII: CALCULATION OF JACOBI'S TRANSPORT BAGS IN NORMAL VALUE

COMMENT IX: DO NOT USE AN ADJUSTMENT FOR DIRECT LABOR AND ELECTRICITY FOR CHERISHMET

[FR Doc. 2012–27423 Filed 11–8–12; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Fire Codes: Request for Comments on NFPA's Codes and Standards

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology (NIST) is publishing this notice on behalf of the National Fire Protection Association (NFPA) to announce the availability of and request comments on the technical reports that will be reporting in the NFPA's 2013 Fall Revision Cycle.

DATES: Sixteen First Draft Reports are published on the NFPA Web site at *http://www.nfpa.org/FDRSDR.* Comments received by 5:00 p.m. EST/EDST on November 16, 2012 will be considered by the respective NFPA Committees before final action is taken on the comments.

ADDRESSES: The 2013 Fall Revision Cycle First Draft Reports are available and downloadable from NFPA's Web site at *http://www/nfpa.org/FDRSDR.* Comments can be submitted online by going to link above.

FOR FURTHER INFORMATION CONTACT: Amy Beasley Cronin, Secretary, Standards Council, NFPA, 1 Batterymarch Park, Quincy, Massachusetts 02169–7471, (617) 770–3000. David F. Alderman, NIST, 100 Bureau Drive, MS 2100, Gaithersburg, MD 20899, email: *david.alderman@nist.gov* or by phone at 301–975–4019.

SUPPLEMENTARY INFORMATION: Since 1896, the National Fire Protection Association (NFPA) has accomplished its mission by advocating consensus codes and standards, research, training, and education for safety related issues. NFPA's *National Fire Codes®,* which holds over 295 documents, are administered by more than 240 Technical Committees comprised of approximately 7,600 volunteers and are adopted and used throughout the world. NFPA is a nonprofit membership organization with approximately 70,000 members from over 100 nations, all working together to fulfill the Association's mission.

The NFPA process provides ample opportunity for public participation in the development of its codes and standards. All NFPA codes and standards are revised and updated every three to five years in Revision Cycles that begin twice each year and take approximately two years to complete. Each Revision Cycle proceeds according to a published schedule that includes final dates for all major events in the process. The Code Revision Process contains four basic steps that are followed for developing new documents as well as revising existing documents. Step 1: Public Input Stage, which results in the First Draft Report (formerly ROP); Step 2: Comment Stage, which results in the Second Draft Report (formerly ROC); Step 3: the Association Technical Meeting at the NFPA Conference & Expo; and Step 4: Standards Council consideration and issuance of documents.

Note: Anyone wishing to make Amending Motions on the Second Draft Reports (formerly ROP and ROC) must signal his or her intention by submitting a Notice of Intent to Make a Motion by the Deadline of 5:00 p.m. EST/EDST on or before August 23, 2013. Certified motions will be posted by October 18, 2013. Documents that receive notice of proper Amending Motions (Certified Amending Motions) will be presented for action at the annual June 2014 Association Technical Meeting. Documents that receive no motions will be forwarded directly to the Standards Council for action on issuance.

For more information on these new rules and for up-to-date information on schedules and deadlines for processing NFPA Documents, check the NFPA Web site at *www.nfpa.org,* or contact NFPA Codes and Standards Administration.

The purpose of this notice is to request comments on the First Draft Report for the NFPA's 2013 Fall Revision Cycle. The publication of this notice by the National Institute of Standards and Technology (NIST) on behalf of NFPA is being undertaken as a public service; NIST does not necessarily endorse, approve, or recommend any of the standards referenced in the notice.

Background

The National Fire Protection Association (NFPA) develops building, fire, and electrical safety codes and standards. Federal agencies frequently use these codes and standards as the basis for developing Federal regulations concerning safety. Often, the Office of the Federal Register approves the incorporation by reference of these standards under 5 U.S.C. 552(a) and 1 CFR Part 51.

Request for Comments

Interested persons may participate in these revisions by submitting written data, views, or arguments to Amy Beasley Cronin, Secretary, Standards Council, NFPA, 1 Batterymarch Park, Quincy, Massachusetts 02169–7471. Commenters may go to the NFPA Web site at *http://www.nfpa.org/FDRSDR.* Each person submitting a comment should include his or her name and address, identify the notice, and give reasons for any recommendations. Comments received by 5:00 p.m. EST/EDST on November 16, 2012 for the 2013 Fall Revision Cycle First Draft Reports will be considered by the NFPA before final action is taken on the First Draft Reports.

Copies of all written comments received and the disposition of those comments by the NFPA committees will be published as the 2013 Fall Revision Cycle Second Draft Reports and will be available on the NFPA Web site at *http://www.nfpa.org/FDRSDR.*

2013 Fall Revision Cycle

First Draft Reports

(P = Partial revision; W = Withdrawal; N = New)

NFPA 37	Standard for the Installation and Use of Stationary Combustion Engines and Gas Turbines	P
NFPA 69	Standard on Explosion Prevention Systems	P
NFPA 82	Standard on Incinerators and Waste and Linen Handling Systems and Equipment	P
NFPA 730	Guide for Premises Security	P
NFPA 731	Standard for the Installation of Electronic Premises Security Systems	P
NFPA 750	Standard on Water Mist Fire Protection Systems	P
NFPA 921	Guide for Fire and Explosion Investigations	P
NFPA 1005	Standard for Professional Qualifications for Marine Fire Fighting for Land-Based Fire Fighters	P
NFPA 1192	Standard on Recreational Vehicles	P
NFPA 1194	Standard for Recreational Vehicle Parks and Campgrounds	P
NFPA 1521	Standard for Fire Department Safety Officer	P
NFPA 1561	Standard on Emergency Services Incident Management System	P
NFPA 1670	Standard on Operations and Training for Technical Search and Rescue Incidents	P
NFPA 1963	Standard for Fire Hose Connections	P
NFPA 1965	Standard for Fire Hose Appliances	P
NFPA 1975	Standard on Station/Work Uniforms for Emergency Services	P

Dated: November 5, 2012.

Willie E. May,

Associate Director for Laboratory Programs.

[FR Doc. 2012–27470 Filed 11–8–12; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC325

Endangered Species; File No. 15809

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Paul Jobsis, Ph.D., University of the Virgin Islands, Department of Biology, 2 John Brewers Bay, St Thomas, VI 00802, has applied in due form for a permit to take green (*Chelonia mydas*) and hawksbill (*Eretmochelys imbricata*) sea turtles for the purpose of scientific research.

DATES: Written, telefaxed, or email comments must be received on or before December 10, 2012.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the *Features* box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 15809 from the list of available applications.

These documents are also available upon written request or by appointment in the following offices:

Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376; and

Southeast Region, NMFS, 263 13th Avenue South, Saint Petersburg, FL 33701; phone (727) 824–5312; fax (727) 824–5309.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division

- By email to *NMFS.Pr1Comments@noaa.gov* (include the File No. in the subject line of the email),
- By facsimile to (301) 713–0376, or
- At the address listed above.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Kristy Beard or Amy Hapeman, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The applicant requests a 5-year permit to conduct research on green and hawksbill sea turtles around protected bays of St. Thomas and St. John, U.S. Virgin Islands. The purpose of the research is to assess the ecological movements of juvenile green and hawksbill sea turtles. Researchers would directly capture up to 40 adult, subadult, or juvenile green sea turtles using tangle nets and up to 40 juvenile and subadult hawksbill sea turtles by hand or using dip nets each year. No more than 40 total sea turtles (both species combined) would be captured in a year. The following procedures would be conducted on sea turtles: Count/survey, attach flipper and passive integrated transponder tags, attach acoustic transmitters using epoxy or a combination of wire and epoxy, measure, photograph, weigh, and sample tissue. Sea turtles would then be released within four hours of capture. Sea turtles might be unintentionally re-captured within a year.

Dated: November 5, 2012.

P. Michael Payne,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2012–27343 Filed 11–8–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC338

Fisheries of the South Atlantic; Southeast Data, Assessment and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 30 Assessment Process Webinar I for Caribbean blue tang and queen triggerfish.

SUMMARY: The SEDAR 30 assessments of the Caribbean blue tang and queen triggerfish will consist of a series of workshops and webinars. This notice is for a webinar associated with the Assessment portion of the SEDAR process. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 30 Assessment Webinar I will be held November 29, 2012 from 10 a.m. until approximately 12 p.m. Eastern Time (ET). The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from, or completed prior to, the time established by this notice.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator, 4055 Faber Place, Suite 201, North Charleston, SC 29405; telephone: (843) 571–4366; email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars and workshops; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species (HMS) Management Division, and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

SEDAR 30 Assessment Webinar I

Participants of the webinar will have an opportunity to review and comment on the draft assessment report and any additional assessment modeling work completed since the Assessment Workshop.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 10 business days prior to the meeting.

Dated: November 6, 2012.

Tracey L. Thompson,

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

[FR Doc. 2012–27375 Filed 11–8–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC339

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The North Pacific Fishery Management Council's (Council) Steller Sea Lion Mitigation Committee (SSLMC) will meet in Seattle, WA.

DATES: The meeting will be held November 28–29, 2012, from 8:30 a.m. through 5 p.m. AST.

ADDRESSES: The meeting will be held at the Alaska Fishery Science Center, 7600 Sand Point Way NE., Seattle, Washington.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Steve MacLean, North Pacific Fishery Management Council; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: At this meeting, the SSLMC will be reviewing proposals for alternatives to be considered in the 2012 Steller Sea Lion Protection Measures EIS currently being prepared by NMFS. The SSLMC will begin drafting one or more alternatives for recommendation to the Council in December, 2012. Proposals under consideration will be posted on the Council's Web site at *http://www.alaskafisheries.noaa.gov/npfmc/conservation-issues/ssl.html.* Please note that State or Federal ID will be required to enter the Federal Building in Juneau. Foreign nationals wishing to attend this meeting in person should contact the Council as soon as possible to expedite security clearance at the Federal Building in Juneau.

Additional information is posted on the Council Web site: *http://www.alaskafisheries.noaa.gov/npfmc/.*

The meeting will be webcast to allow the public to watch and hear presentations. Comments will not be accepted via webcast or teleconference.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen, (907) 271–2809, at least 5 working days prior to the meeting date.

Dated: November 6, 2012.

Tracey L. Thompson,

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

[FR Doc. 2012–27376 Filed 11–8–12; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

First Responder Network Authority Board Meeting

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of open public meetings.

SUMMARY: The National Telecommunications and Information Administration (NTIA) will convene open public meetings of the Board of the First Responder Network Authority (FirstNet).

DATES: The meetings will be held on December 11, 2012; April 23, 2013; August 13, 2013; and October 15, 2013, from 9 a.m. to 12:30 p.m. Eastern Time in Washington, DC.[1]

ADDRESSES: For the meetings in Washington, DC, Board members will meet in the Secretary's Conference Room, Room 5855, Herbert C. Hoover Building, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Uzoma Onyeije, Senior Advisor for Public Safety, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–0016; email *uonyeije@ntia.doc.gov.* Please direct media inquiries to NTIA's Office of Public Affairs, (202) 482–7002.

SUPPLEMENTARY INFORMATION: *Background:* The Middle Class Tax Relief and Job Creation Act of 2012 (Act), Public Law 112–96, 126 Stat. 156 (2012), created FirstNet as an independent authority within NTIA. The Act directs FirstNet to establish a single nationwide, interoperable public safety broadband network. The FirstNet Board is responsible for making strategic decisions regarding FirstNet's operations. The FirstNet Board held its first public meeting on September 25, 2012.

Matters To Be Considered: NTIA will post a detailed agenda on its Web site, *http://www.ntia.doc.gov/category/firstnet* prior to each meeting. The agenda topics are subject to change.

Time and Date: The meetings will be held on December 11, 2012; April 23, 2013; August 13, 2013; and October 15, 2013, from 9 a.m. to 12:30 p.m. Eastern Time. The times are subject to change. Please refer to NTIA's Web site at *http://www.ntia.doc.gov/category/firstnet* for the most current information.

Place: The meetings will be held in the Secretary's Conference Room, Room 5855, U.S. Department of Commerce, Herbert C. Hoover Building, 14th Street and Constitution Avenue NW., Washington, DC. The location of these meetings is subject to change. Please refer to NTIA's Web site at *http://www.ntia.doc.gov/category/firstnet* for the most current information.

Other Information: The meeting is open to the public and press. Given the space limitations of the Secretary's Conference Room where the Board will meet, members of the public wishing to attend the meeting in person will be directed to the Auditorium in the Herbert C. Hoover Building where they can observe the meeting by video. Due to security requirements and to facilitate entry into the building, U.S. nationals must present valid, government-issued photo identification upon arrival. Foreign nationals must contact Uzoma Onyeije at (202) 482–0016 or *uonyeije@ntia.doc.gov* at least five (5) business days prior to the meeting in order to provide the necessary clearance information, and must present valid, government-issued photo identification upon arrival.

The meetings are accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Uzoma Onyeije, Senior Advisor for Public Safety, at (202) 482–0016 or *uonyeije@ntia.doc.gov* at least five (5) business days before the meeting.

The meetings will also be webcast. Please refer to NTIA's Web site at *http://www.ntia.doc.gov/category/firstnet* for webcast instructions and other information. If you have technical questions regarding the webcast, please contact Charles Franz at *cfranz@ntia.doc.gov.* Access details for these meetings are subject to change. Please refer to NTIA's Web site at *http://www.ntia.doc.gov/category/firstnet* for the most current information.

Records: NTIA maintains records of all Board proceedings. Board minutes will be available at *http://www.ntia.doc.gov/category/firstnet.*

Dated: November 6, 2012.

Kathy D. Smith,

Chief Counsel.

[FR Doc. 2012–27435 Filed 11–8–12; 8:45 am]

BILLING CODE 3510–60–P

[1] Additional meetings will be held February 12, 2013, and December 17, 2013 in Boulder, Colorado; and June 11, 2012, in San Francisco, California. NTIA will publish separate **Federal Register** Notices for the Boulder and San Francisco meetings.

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to the Procurement List.

SUMMARY: The Committee is proposing to add a product and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

Comments Must Be Received on or Before: 12/10/2012.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

For Further Information or to Submit Comments Contact: Patricia Briscoe, 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 product and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following product and services are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Product

NSN: 5180–01–435–3502—Tool Kit, Multipurpose Plier
NPA: The Lighthouse for the Blind, St. Louis, MO
Contracting Activity: General Services Administration, Tools Acquisition Division I, Kansas City, Mo.
Coverage: B-List for the Broad Government Requirement as aggregated by the General Services Administration.

Services

Service Type/Location: Custodial and Grounds Maintenance Services, Rocky Mountain Metropolitan Airport (RMMA), Air Traffic Control Tower (ATCT) & Base Building, 11001 Control Tower Drive, Westminster, CO.
NPA: AspenPointe Employment, Colorado Springs, CO.
Contracting Activity: Dept of Transportation, Federal Aviation Administration, Renton, WA
Service Type/Location: Mess Attendant Services and Cook Support, Eielson AFB, AK.
NPA: Lakeview Center, Inc., Pensacola, FL.
Contracting Activity: Department of the Air Force (5700)/Eielson Air Force Base (FA 5004), Eielson AFB, AK.

The information is provided to further describe the Mess Attendant Services and Cook Support being proposed for addition to the Procurement List. For this project, the DOD contracting activity identified its requirement as Mess Attendants Service and Cook Support. The Mess Attendant and Cook Support tasks are: (1) Serving and replenishing food; (2) Cleaning facilities, equipment, pots, pans, and utensils; (3) Cleaning tables in the Dining Area; (4) Preparing vegetables and fruits for the salad bar and to be cooked; (5) Preparing hot and cold sandwiches; (6) Providing cashier services; (7) Maintaining quality control; and (8) Providing maintenance and housekeeping services for the facility.

Patricia Briscoe,

Deputy Director, Business Operations, (Pricing and Information Management).

[FR Doc. 2012–27374 Filed 11–8–12; 8:45 am]

BILLING CODE 6353–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting Notice

TIME AND DATE: Wednesday, November 14, 2012, 10:00 a.m.–12:00 p.m.

PLACE: Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Commission Meeting—Open to the Public.

MATTERS TO BE CONSIDERED:

Briefing Matters:

1. Bedside Sleepers—Notice of Proposed Rulemaking;
2. Handheld Carriers—Notice of Proposed Rulemaking.

A live webcast of the Meeting can be viewed at *www.cpsc.gov/webcast.*

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: November 6, 2012.

Todd A. Stevenson,

Secretary.

[FR Doc. 2012–27486 Filed 11–7–12; 11:15 am]

BILLING CODE 6355–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (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, and the impact of the requirement on respondents can be properly assessed.

Currently, CNCS is soliciting comments concerning its proposed recordkeeping requirement in 45 CFR 2540.205–.206. CNCS grantees and subgrantees must maintain records to demonstrate completion of National Service Criminal History Checks.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by January 8, 2013.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail sent to: Corporation for National and Community Service, Aaron Olszewski, Office of General Counsel; 1201 New York Avenue NW., Washington, DC 20525.

(2) By hand delivery or by courier to the CNCS mailroom at Room 8100 at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) By fax to: (202) 606–3467, Attention: Paperwork Reduction Act.

(4) Electronically, through www.regulations.gov. Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Aaron Olszewski, (202) 606–6709, or by email at aolszewski@cns.gov.

SUPPLEMENTARY INFORMATION: CNCS is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are expected to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronic submissions of responses).

Background

The Serve America Act requires CNCS grantees and subgrantees to conduct a National Service Criminal History Check. CNCS and its grantees must ensure that national service beneficiaries are protected from harm and the recordkeeping requirements of the final rule are critical to that responsibility.

Current Action

CNCS requests renewal of the recordkeeping requirement previously approved under an emergency clearance.

The requirements will be used in the same manner as the existing application. CNCS also seeks to continue using the current application until the revised application is approved by OMB. The current application is due to expire on March 31, 2013.

Type of Review: Renewal of Approved Recordkeeping Requirement.

Agency: Corporation for National and Community Service.

Title: National Service Criminal History Check Recordkeeping Requirement.

OMB Number: 3045–0145.

Agency Number: None.

Affected Public: CNCS Grantees and Subgrantees.

Total Respondents: 112,357.

Frequency: Three times per covered position.

Average Time per Response: Five minutes.

Estimated Total Burden Hours: 28,089 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval; they will also become a matter of public record.

Dated: November 5, 2012.

Valerie Green,

General Counsel.

[FR Doc. 2012–27349 Filed 11–8–12; 8:45 am]

BILLING CODE 6050–$$–P

DEPARTMENT OF DEFENSE

Final Environmental Impact Statement/ Environmental Impact Report (EIS/EIR) for the Clearwater Program

AGENCY: U.S. Army Corps of Engineers, Department of the Army.

ACTION: Notice of availability.

SUMMARY: The U.S. Army Corps of Engineers (Corps) in conjunction with the Sanitation Districts of Los Angeles County (Sanitation Districts) has completed a Final Environmental Impact Statement/Environmental Impact Report (EIS/EIR) for the Clearwater Program. The Clearwater Program is a comprehensive planning effort undertaken by the Sanitation Districts for the Joint Outfall System, a regional wastewater management system serving approximately 4.8 million people in 73 cities and unincorporated areas in Los Angeles County. A major component of the Clearwater Program is the evaluation of alternatives for construction of a new ocean outfall and rehabilitation of the existing ocean outfalls. Both activities would entail discharge of dredged and fill material in waters of the United States, work in navigable waters of the United States, and the transport of dredged material for ocean disposal. These activities would require authorization from the Corps pursuant to Section 404 of the Clean Water Act, Section 10 of the Rivers and Harbors Act, and Section 103 of the Marine Protection, Research, and Sanctuaries Act, respectively. The Draft EIS/EIR was circulated for a 57-day review period from February 13, 2012 through April 10, 2012. The Corps and the Sanitation Districts reviewed and provided responses to 19 agency comments and 33 public comments in preparing the Final EIS/EIR.

The Final EIS/EIR, including a Draft 404(b)(1) alternatives analysis, is available for a 31-day review period from November 9, 2012 through December 10, 2012. The document is accessible via the World-Wide Web at *www.ClearwaterProgram.org.* Alternatively, printed copies are available at the following locations: Sanitation Districts of Los Angeles County, 1955 Workman Mill Road, Whittier, California; Carson Regional Library, 151 East Carson Street, Carson, California; Los Angeles Public Library, San Pedro Branch, 931 South Gaffey Street, San Pedro, California; and Los Angeles Public Library, Wilmington Branch, 1300 North Avalon Boulevard., Wilmington, California. Written comments will be accepted until the close of public review on December 10, 2012.

For Additional Information Contact: Questions or comments concerning the Final EIS/EIR should be directed to Dr. Aaron O. Allen, U.S. Army Corps of Engineers, Los Angeles District, Regulatory Division, Ventura Field Office, 2151 Alessandro Drive, Suite 110, Ventura, CA 93001, (805) 585–2148.

Dated: October 29, 2012.

David J. Castanon,

Chief, Regulatory Division, Corps of Engineers.

[FR Doc. 2012–27448 Filed 11–8–12; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2012–ICCD–0050]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; 2013–2014 Federal Student Aid Application

AGENCY: Department of Education (ED), Federal Student Aid (FSA).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction 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 December 10, 2012.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2012–ICCD–0050 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 2E117, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: Electronically mail *ICDocketMgr@ed.gov.* Please do not send comments here.

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: 2013–2014 Federal Student Aid Application.

OMB Control Number: 1845–0001.

Type of Review: Revision of an existing information collection.

Respondents/Affected Public: Individuals or households.

Total Estimated Number of Annual Responses: 46,099,008.

Total Estimated Number of Annual Burden Hours: 25,959,853.

Abstract: Section 483 of the Higher Education Act of 1965, as amended (HEA), mandates that the Secretary of Education "* * *shall produce, distribute, and process free of charge common financial reporting forms as described in this subsection to be used for application and reapplication to determine the need and eligibility of a student for financial assistance* * *".

The determination of need and eligibility are for the following Title IV,

HEA, federal student financial assistance programs: The Federal Pell Grant Program; the Campus-Based programs (Federal Supplemental Educational Opportunity Grant (FSEOG), Federal Work-Study (FWS), and the Federal Perkins Loan Program); the William D. Ford Federal Direct Loan Program; the Teacher Education Assistance for College and Higher Education (TEACH) Grant; and the Iraq and Afghanistan Service Grant.

Federal Student Aid, an office of the U.S. Department of Education (hereafter ''the Department''), subsequently developed an application process to collect and process the data necessary to determine a student's eligibility to receive Title IV, HEA program assistance. The application process involves an applicant's submission of the *Free Application for Federal Student Aid* (FAFSA). After submission of the FAFSA, an applicant receives a *Student Aid Report* (SAR), which is a summary of the data they submitted on the FAFSA. The applicant reviews the SAR, and, if necessary, will make corrections or updates to their submitted FAFSA.

The Department seeks OMB approval of all application components as a single ''collection of information''. The aggregate burden will be accounted for under OMB Control Number 1845–0001. The specific application components, descriptions and submission methods for each are listed in Table 1.

TABLE 1—FEDERAL STUDENT AID APPLICATION COMPONENTS

Component	Description	Submission method
Initial Submission of FAFSA		
FAFSA on the Web (FOTW)	Online FAFSA that offers applicants a customized experience.	Submitted by the applicant via *www.fafsa.gov.*
FOTW—Renewal	Online FAFSA for applicants who have previously completed the FAFSA.	
FOTW—EZ	Online FAFSA for applicants who qualify for the Simplified Needs Test (SNT) or Automatic Zero (Auto Zero) needs analysis formulas.	
FOTW—EZ Renewal	Online FAFSA for applicants who have previously completed the FAFSA and who qualify for the SNT or Auto Zero needs analysis formulas.	
FAFSA on the Phone (FOTP)	The Federal Student Aid Information Center (FSAIC) representatives assist applicants by filing the FAFSA on their behalf through FOTW.	Submitted through *www.fafsa.gov* for applicants who call 1–800–4–FED–AID.
FOTP—EZ	FSAIC representatives assist applicants who qualify for the SNT or Auto Zero needs analysis formulas by filing the FAFSA on their behalf through FOTW.	
FAA Access	Online tool that a financial aid administrator (FAA) utilizes to submit a FAFSA	Submitted through *www.faaacess.ed.gov* by a FAA on behalf of an applicant.
FAA Access—Renewal	Online tool that a FAA can utilize to submit a Renewal FAFSA..	
FAA Access—EZ	Online tool that a FAA can utilize to submit a FAFSA for applicants who qualify for the SNT or Auto Zero needs analysis formulas.	
FAA Access—EZ Renewal	Online tool that a FAA can utilize to submit a FAFSA for applicants who have previously completed the FAFSA and who qualify for the SNT or Auto Zero needs analysis formulas.	
Electronic Other	This is a submission done by a FAA, on behalf of the applicant, using the Electronic Data Exchange (EDE).	The FAA may be using their mainframe computer or software to facilitate the EDE process.
PDF FAFSA or Paper FAFSA	The paper version of the FAFSA printed by the Department for applicants who are unable to access the Internet or the online PDF FAFSA for applicants who can access the Internet but are unable to complete the form using FOTW.	Mailed by the applicant.
Correcting Submitted FAFSA Information and Reviewing FAFSA Information		
FOTW—Corrections	Any applicant who has a Federal Student Aid PIN (FSA PIN)—regardless of how they originally applied—may make corrections using FOTW Corrections.	Submitted by the applicant via *www.fafsa.gov.*
Electronic Other—Corrections	With the applicant's permission, corrections can be made by a FAA using the EDE.	The FAA may be using their mainframe computer or software to facilitate the EDE process.
Paper SAR—This is a SAR and an option for corrections.	The full paper summary that is mailed to paper applicants who did not provide an e-mail address and to applicants whose records were rejected due to critical errors during processing. Applicants can write corrections directly on the paper SAR and mail for processing.	Mailed by the applicant.
FAA Access—Corrections	An institution can use FAA Access to correct the FAFSA	Submitted through *www.faaacess.ed.gov* by a FAA on behalf of an applicant.
Internal Department Corrections.	The Department will submit an applicant's record for system-generated corrections.	There is no burden to the applicants under this correction type as these are system-based corrections.
FSAIC Corrections	Any applicant, with their Data Release Number (DRN), can change the post-secondary institutions listed on their FAFSA or change their address by calling FSAIC.	These changes are made directly in the CPS system by a FSAIC representative.

TABLE 1—FEDERAL STUDENT AID APPLICATION COMPONENTS—Continued

Component	Description	Submission method
SAR Electronic (eSAR)	The eSAR is an online version of the SAR that is available on FOTW to all applicants with a PIN. Notifications for the eSAR are sent to students who applied electronically or by paper and provided an e-mail address. These notifications are sent by e-mail and include a secure hyperlink that takes the user to the FOTW site.	Cannot be submitted for processing.
SAR Acknowledgment	This is the condensed paper SAR that is mailed to applicants who applied electronically but did not provide an e-mail address and do not meet the criteria for a full paper SAR.	

This information collection also documents an estimate of the annual public burden as it relates to the application process for federal student aid. The Applicant Burden Model (ABM), measures applicant burden through an assessment of the activities each applicant conducts in conjunction with other applicant characteristics and in terms of burden, the average applicant's experience. Key determinants of the ABM include:

- The total number of applicants that will potentially apply for federal student aid;
- How the applicant chooses to complete and submit the FAFSA (e.g., by paper or electronically via FOTW);
- How the applicant chooses to submit any corrections and/or updates (e.g., the paper SAR or electronically via FOTW Corrections);
- The type of SAR document the applicant receives (eSAR, SAR acknowledgment, or paper SAR);
- The formula applied to determine the applicant's expected family contribution (EFC) (full need analysis formula, Simplified Needs Test or Automatic Zero); and
- The average amount of time involved in preparing to complete the application.

The ABM is largely driven by the number of potential applicants for the application cycle. The total application projection for 2013–2014 is based upon two factors—estimates of the total enrollment in all degree-granting institutions and the percentage change in FAFSA submissions for the last completed or almost completed application cycle. The ABM is also based on the application options available to students and parents. The Department accounts for each application component based on web trending tools, survey information, and other Department data sources.

For 2013–2014, the Department is reporting a net burden reduction of 3,398,000 hours. The reduction is a reflection of the effects of simplifying FAFSA on the Web, which is utilized by the majority of applicants who apply for aid. Simplification of the application is demonstrated by (1) the average completion times for initial submissions and; (2) fewer corrections being made to the application.

The projected average completion times for initial submissions has decreased by 11 minutes for 2013–14. In data reported in the 2012–2013 supporting statement, first-time filers using FOTW would take approximately 1.30 hours (78 minutes) to submit an application. The data from 2011–12 indicate that the same user would be able to submit their application in 1.12 hours (67 minutes), reducing their burden by .18 hours (11 minutes).

Corrections are also projected to decrease by 760,696 responses for 2013–14. Fewer corrections mean that more comprehensive and accurate data was captured in the initial submission of the application. Updated completion times were calculated for each component and have been used to estimate the burden, excluding the change in the applicant volume. The results demonstrate that the burden for all applicants would have decreased by almost 13 percent or 3,758,702 hours, if the application volume had remained constant.

If the Department had not simplified the application process, thus reducing the time required to complete the FAFSA, the new burden estimates would only need to account for the change in applicants. The 1.43% increase in applicants would result in an increase in burden of 347,945 hours.

Accounting for both the increase in total applicants and the decrease in individual applicant burden, the net change is an overall decrease of almost 12 percent or 3,398,000 hours. The following Table shows the net burden change and total cost for applicants. The change in total annual responses is also listed in the Table. Total annual responses include the original FAFSA submission and corrections.

TABLE 2—NET BURDEN CHANGE

	2012–2013	2013–2014	Change	% Change	Burden disposition
		Accounting for change in applicant burden and change in applicants.			
Total Applicants	24,705,864	25,053,809	+347,945	+1.41	Net decrease in burden.
Total Applicant Burden	29,357,853	25,959,853	−3,398,000	−11.6	The 1.41% increase in applicants is offset by the results of the simplification changes implemented by the Department. This has resulted in an overall decrease in burden of 11.57% or 3,397,545 hours.
Total Annual Responses	46,447,024	46,099,007	−348,017	−.75	
Cost for All Applicants	$234,804.24	$190,224.76	$44,579.48	−18.99	

The Department takes pride in the continued efforts to simplify the FAFSA submission process and the continued decrease in burden associated with the application process, even as the Department serves more students each year. The results confirm the significant improvements that have been made to the application process. The Department

believes that these changes will lead to more students completing the FAFSA and will assist more students with their pursuit of postsecondary education through access to Title IV, HEA program assistance.

Dated: November 5, 2012.

Darrin A. King,

Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2012–27449 Filed 11–8–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Privacy Act of 1974; System of Records—Alternative Dispute Resolution (ADR) Center Case Tracking System

AGENCY: Office of Management (OM), Alternative Dispute Resolution Center, Department of Education.

ACTION: Notice of altered systems of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, 5 U.S.C. 552a (Privacy Act), the Department of Education (Department) publishes this notice proposing to revise the system of records entitled ''Grievances Filed Informally Through the Informal Dispute Resolution Center'' (IDR Center) (18–05–12), including revising the title to ''Alternative Dispute Resolution (ADR) Center Case Tracking System.''

DATES: Submit your comments on this proposed altered system of records on or before December 10, 2012.

The Department has filed a report describing the altered system of records covered by this notice with the Chair of the Senate Committee on Homeland Security and Governmental Affairs, the Chair of the House Committee on Oversight and Government Reform, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on November 6, 2012. This altered system of records will become effective on the later date of: (1) The expiration of the 40-day period for OMB review on December 17, 2012, unless OMB waives 10 days of the 40-day review period for compelling reasons shown by the Department; or (2) December 10, 2012, unless the systems of records needs to be changed as a result of public comment or OMB review.

ADDRESSES: Address all comments about the ADR Center Case Tracking system of records to Debra A. Bennett, Director, Alternative Dispute Resolution Center, Office of Management, U.S. Department of Education, Capitol Place Building, 80 F Street NW., Room 408C/Mail Stop 4000, Washington, DC 20001–1528. If you prefer to send comments through the Internet, use the following address: *comments@ed.gov.*

You must include the term ''ADR Center System of Records'' in the subject line of your electronic message. During and after the comment period, you may inspect all public comments about this notice at the U.S. Department of Education in room 410–F, 80 F Street NW., Room 410C/Mail Stop 4000, Washington, DC 20001–1528, between the hours of 8:00 a.m. and 4:30 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Debra A. Bennett, Director, Alternative Dispute Resolution Center, Office of Management, U.S. Department of Education, Capitol Place Building, 80 F Street NW., Room 408C/Mail Stop 4000, Washington, DC 20001–1528. Telephone number: 202–401–0693. If you use a telecommunications device for the deaf (TDD), or text telephone (TTY), you may call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Introduction

The ADR Center Case Tracking System is a web-based J2EE application that is platform independent and captures all information relating to Alternative Dispute Resolution case processing. It tracks, manages, and reports on all data, events, and procedures related to pre-grievances (administrative and negotiated), pre-Equal Employment Opportunity (EEO) complaints, formal EEO complaints, and other workplace issues. The ADR Center Case Tracking System provides a reporting module that collects data for tracking, managing, and reporting purposes, including, but not limited to, management reports, statistical analysis, and case status reports.

The ADR Center Case Tracking System will be a standalone system of records that will no longer be located in the OM, Office of Hearings and Appeals, but instead will be located in the OM, Alternative Dispute Resolution Center. These records will be maintained, not only in paper files in filing cabinets, but will now also be maintained electronically on a computerized tracking system, as well as in an email system. They will now be maintained electronically to improve efficiency and functionality, particularly with regard to tracking. The ADR Center Case Tracking System will collect the same data as previously collected on current and former non-bargaining unit employees of the Department and applicants.

The Department published the original system of records on June 4, 1999, in the **Federal Register**. (64 FR 30106, 30137–30139). This notice adds the category of individuals whose records are maintained to include current and former bargaining-unit employees of the Department. It also revises the purpose for which the information is used in the system of records to indicate that it will be used: (1) To track, manage, and report on all data, events, and procedures related to pre-grievances (administrative or negotiated); (2) to track, manage, and report on all data, events, and procedures related to pre-Equal EEO complaints referred to the ADR Center for alternative dispute resolution; (3) to track, manage, and report on all data, events, and procedures related to formal EEO complaints referred to the ADR Center for alternative dispute resolution; (4) to track, manage, and report on all data, events, and procedures related to Department employees filing any workplace issue; (5) to collect, analyze, and report data pertinent to the particular claim being asserted to include some Personally Identifiable Information (PII) for periodic reports and analysis; (6) to maintain a record of the data provided by employees requesting assistance; (7) to act as a source for information necessary to fulfill OM, Equal Employment Opportunity Services' alternative dispute resolution reporting requirements; and (8) to enable complaint resolution partners to review and analyze the data of their formal grievance/complaint population. In addition, the authority for maintenance of the ADR Center Case Tracking system of records has been updated to include applicable sources of authority.

In addition, the Department proposes to revise the routine uses. We propose

to revise routine use (3)(a)(iii) ''Litigation and Alternative Dispute Resolution (ADR) Disclosures'' to permit the Department to disclose certain records from this system to the parties described in routine use paragraphs (3)(b) ''Disclosure to the Department of Justice (DOJ),'' (3)(c) ''Administrative Disclosures,'' and (3)(d) ''Parties, Counsel, Representatives, and Witnesses'' for any Department employee in his or her individual capacity if the DOJ has been requested to provide or arrange for representation of the employee.

The Department proposes to also revise routine use (6) ''Labor Organization Disclosure'' to permit the Department to disclose records from this system to an arbitrator to resolve disputes under a negotiated grievance procedure or to officials of labor organizations recognized under 5 U.S.C. chapter 71 when relevant and necessary to their duties of exclusive representation. In addition, the Department also proposes to revise routine use (7) ''Freedom of Information Act (FOIA) and Privacy Act Advice Disclosure'' to permit the Department to disclose records from this system to the Department of Justice and OMB if the Department concludes that disclosure is desirable or necessary in determining whether particular records are required to be disclosed under the FOIA or the Privacy Act.

Finally, the Department proposes to add a new, routine use (13) ''Disclosure in the Course of Responding to a Breach of Data'' to permit the Department to disclose records from this system to appropriate agencies, entities, and persons when: (a) The Department suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (b) the Department has determined that as a result for the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

The notice also revises the policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system (particularly the retention and disposal of records in the system), the safeguards that protect the records in the system, and updates the system manager and address. The retention and disposal policy has been updated to comply with the General Records Schedule approved by the National Archives and Records Administration. The description of safeguards has been updated to include additional security measures that have been put in place, including monitoring by security personnel and the testing of the system's security posture.

The Privacy Act requires the Department to publish in the **Federal Register** this notice of an altered system of records (5 U.S.C. 552a(e)(4) and (11)). The Department's regulations implementing the Privacy Act are contained in part 5b of title 34 of the Code of Federal Regulations (CFR).

The Privacy Act applies to any record about an individual containing individually identifying information that is retrieved from a system of records by a unique identifier associated with each individual, such as a name or social security number. The information about each individual is called a ''record,'' and the system, whether manual or computer-based, is called a ''system of records.''

The Privacy Act requires each agency to publish notices of systems of records in the **Federal Register** and to prepare reports to OMB and Congress whenever the agency publishes a new system of records or makes a significant change to an established system of records.

Each agency is also required to send copies of the report to the Chair of the Senate Committee on Homeland Security and Governmental Affairs and the Chair of the House Committee on Oversight and Government Reform. These reports are included to permit an evaluation of the probable effect of the proposal on the privacy rights of individuals.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the contact person listed in this section.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of the Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: November 6, 2012.

Winona H. Varnon,

Principal Deputy Assistant Secretary for Management, Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary for Management.

For the reasons discussed in the introduction, the Principal Deputy Assistant Secretary for Management, U.S. Department of Education (Department) publishes a notice of altered system of records to read as follows:

SYSTEM NUMBER: 18–05–12

SYSTEM NAME:

Alternative Dispute Resolution (ADR) Center Case Tracking System

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Alternative Dispute Resolution Center, Office of Management, U.S. Department of Education, Capitol Place Building, 80 F Street, NW., Room 408C/ Mail Stop 4000, Washington, DC 20001–1528.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system contains records about current and former Department employees or applicants who have contacted the ADR Center within 45 calendar days of becoming aware of an incident or work-related dispute needing resolution. A work-related dispute can include a pre-grievance (administrative or negotiated), pre-Equal Employment Opportunity (EEO) complaint, or formal EEO complaint that involves various labor and employment laws and regulations pertaining to informal workplace dispute resolution.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records produces an Alternative Dispute Resolution Center case file that contains personally identifying information that is pertinent to the particular claim (e.g., non-selection, disciplinary action, performance problem) being asserted, including, but not limited to, documents that contain the employee's name, sex, date of birth, home address, and

telephone number. This system of records does not include records covered by the Department's system of records notices entitled ''Discrimination Complaints Records System'' 18–05–04 or the Equal Employment Opportunity Commission (EEOC)/GOVT-1 System of Records Notice entitled ''Equal Employment Opportunity in the Federal Government Complaint and Appeal Records'' and ''Grievances Filed Formally Under the Administrative Grievance Procedure'' 18–05–05'' or ''Grievance Records Filed Under Procedures Established by Labor Management Negotiations'' 18–05–06.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The system is authorized under the Administrative Dispute Resolution Act of 1996 (ADRA), 5 U.S.C. 571 et seq.; Age Discrimination in Employment Act of 1967, as amended (ADEA), 29 U.S.C. 621 et seq.; EEOC regulations, 29 CFR part 1614; Title VII of the Civil Rights Act of 1964, 42 U.S.C. 2000e et seq.; Sections 501 and 505 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 791 et seq.; the Equal Pay Act, 29 U.S.C. 206(d); the Genetic Information Nondiscrimination Act, 42 U.S.C. 2000ff et seq.; Department of Education, Personnel Management Instruction 771–1-Employee Grievances; and, the Department of Education's Collective Bargaining Agreement, Article 42-Grievance Procedure.

PURPOSE(S):

The information in this system is used: (1) To track, manage, and report on all data, events, and procedures related to pre-grievances (administrative or negotiated); (2) to track, manage, and report on all data, events, and procedures related to pre-EEO complaints referred to the ADR Center for alternative dispute resolution; (3) to track, manage, and report on all data, events, and procedures related to formal EEO complaints referred to the ADR Center for alternative dispute resolution; (4) to track, manage, and report on all other data, events, and procedures related to any workplace issue; (5) to collect, analyze, and report data pertinent to the particular claim being asserted to include some Personally Identifiable Information (PII) for periodic reports and analysis; (6) to maintain a record of the data provided by employees requesting assistance; (7) to act as a source for information necessary to fulfill Equal Employment Opportunity Services' alternative dispute resolution reporting requirements; and (8) to enable complaint resolution partners to review and analyze the data of their formal grievance/complaint population.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The Department may disclose information contained in a record in this system of records under the routine uses listed in the system of records without the consent of the individual, if the disclosure is compatible with the purposes for which the record was collected. These disclosures may be made on a case-by-case basis or, if the Department has complied with the computer matching requirements of the Privacy Act of 1974, as amended (Privacy Act), under a computer matching agreement.

(1) *Disclosure for Use by Other Law Enforcement Agencies.* The Department may disclose information to any Federal, State, local, or foreign agency or other public authority responsible for enforcing, investigating, or prosecuting violations of administrative, civil, or criminal law or regulation if that information is relevant to any enforcement, regulatory, investigative, or prosecutorial responsibility within the receiving entity's jurisdiction.

(2) *Enforcement Disclosure.* In the event that information in this system of records indicates, either on its face or in connection with other information, a violation or potential violation of any applicable statute, regulation, or order of a competent authority, the Department may disclose the relevant records to the appropriate agency, whether foreign, Federal, State, Tribal, or local, charged with the responsibility of investigating or prosecuting that violation or charged with enforcing or implementing the statute, Executive order, rule, regulation, or order issued pursuant thereto.

(3) *Litigation and ADR Disclosures.*

(a) *Introduction.* In the event that one of the parties listed below is involved in litigation or ADR, or has an interest in litigation ADR, the Department may disclose certain records to the parties described in paragraphs (b), (c) and (d) of this routine use under the conditions specified in those paragraphs:

(i) The Department, or any of its components; or

(ii) Any Department employee in his or her official capacity; or

(iii) Any Department employee in his or her individual capacity if the Department of Justice (DOJ) has agreed to or has been requested to provide or arrange for representation of the employee;

(iv) Any Department employee in his or her individual capacity where the Department has agreed to represent the employee; or

(v) The United States where the Department determines that the litigation is likely to affect the Department or any of its components.

(b) *Disclosure to the DOJ.* If the Department determines that disclosure of certain records to the DOJ is relevant and necessary to litigation or ADR, the Department may disclose those records as a routine use to the DOJ.

(c) *Adjudicative Disclosures.* If the Department determines that disclosure of certain records to an adjudicative body before which the Department is authorized to appear, an individual or entity designated by the Department or otherwise empowered to resolve or mediate disputes is relevant and necessary to the litigation or ADR, the Department may disclose those records as a routine use to the adjudicative body, individual, or entity.

(d) *Parties, Counsel, Representatives, and Witnesses.* If the Department determines that disclosure of certain records to a party, counsel, representative, or witness is relevant and necessary to the litigation or ADR, the Department may disclose those records as a routine use to the party, counsel, representative, or witness.

(4) *Employment, Benefit, and Contracting Disclosure.*

(a) *For Decisions by the Department.* The Department may disclose a record to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement or other pertinent records, or to another public authority or professional organization, if necessary to obtain information relevant to a Department decision concerning the hiring or retention of an employee or other personnel action, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

(b) *For Decisions by Other Public Agencies and Professional Organizations.* The Department may disclose a record to a Federal, State, local, or foreign agency or other public authority or professional organization, in connection with the hiring or retention of an employee or other personnel action, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit, to the extent that the record is relevant and necessary to the receiving entity's decision on the matter.

(5) *Employee Grievance, Complaint or Conduct Disclosure.* The Department may disclose a record in this system of records to another agency of the Federal

Government if the record is relevant to one of the following proceedings regarding a present or former employee of the Department: A complaint, a grievance, or a disciplinary or competence determination proceeding. The disclosure may only be made during the course of the proceeding.

(6) *Labor Organization Disclosure.* The Department may disclose records from this system to an arbitrator to resolve disputes under a negotiated grievance procedure or to officials of labor organizations recognized under 5 U.S.C. chapter 71 when relevant and necessary to their duties of exclusive representation.

(7) *Freedom of Information Act (FOIA) and Privacy Act Advice Disclosure.* The Department may disclose records to the DOJ and the Office of Management and Budget if the Department concludes that disclosure is desirable or necessary in determining whether particular records are required to be disclosed under the FOIA or the Privacy Act.

(8) *Disclosure to the DOJ.* The Department may disclose records to the DOJ to the extent necessary for obtaining DOJ advice on any matter relevant to an audit, inspection, or other inquiry related to the programs covered by this system.

(9) *Contract Disclosure.* If the Department contracts with an entity for the purposes of performing any function that requires disclosure of records in this system to employees of the contractor, the Department may disclose the records to those employees. Before entering into such a contract, the Department shall require the contractor to maintain Privacy Act safeguards as required under 5 U.S.C. 552a(m) with respect to the records in the system.

(10) *Research Disclosure.* The Department may disclose records to a researcher if an appropriate official of the Department determines that the individual or organization to which the disclosure would be made is qualified to carry out specific research related to functions or purposes of this system of records. The official may disclose records from this system of records to that researcher solely for the purpose of carrying out that research related to the functions or purposes of this system of records. The researcher shall be required to maintain Privacy Act safeguards with respect to the disclosed records.

(11) *Congressional Member Disclosure.* The Department may disclose records to a member of Congress from the record of an individual in response to an inquiry from the member made at the written request of that individual. The member's right to the information is no greater than the right of the individual who requested it.

(12) *Disclosure to the OMB for Credit Reform Act (CRA) Support.* The Department may disclose records to OMB as necessary to fulfill CRA requirements.

(13) *Disclosure in the Course of Responding to a Breach of Data.* The Department may disclose records from this system to appropriate agencies, entities, and persons when: (a) The Department suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (b) the Department has determined that as a result for the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Not applicable to this notice.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in paper files in filing cabinets and electronically on a computerized tracking system, and in an email system.

RETRIEVABILITY:

Records are indexed by case tracking number and can be retrieved by the name of the non-Government party, whether applicant or employee.

SAFEGUARDS:

Access to and use of the hard-copy records and the electronic system is limited to those persons with a ''need-to-know'' and whose official duties require such access. Hard-copy records are stored in file cabinets in an office location that is kept locked after the close of the business day. Personnel screening is employed to prevent unauthorized disclosure. Computers are password protected. The system is designed with security measures to control an individual user's ability to access and alter records.

RETENTION AND DISPOSAL:

The records in this system are maintained in accordance with the General Records Schedule 1, item 27 Alternative Dispute Resolution (ADR) Files. The General Files, such as, general correspondence and copies of statutes, regulations, meeting minutes, reports, statistical tabulations, evaluations of the ADR program, and other records relating to the Department's overall ADR program will be destroyed when 3 years old. A longer retention is authorized if records are needed for agency business. (N1–GRS–03–2 item a).

The Case Files cover records documenting ADR proceedings and may include an agreement to use ADR, documentation of the settlement or discontinuance of the ADR case, parties' written evaluations of the process and/or the neutral third party mediator, and related correspondence. The Case Files will be destroyed 3 years after settlement is implemented or the case is discontinued. (N1–GRS–03–2 item b).

SYSTEM MANAGER(S) AND ADDRESS:

Director, Alternative Dispute Resolution Center, Office of Management, U.S. Department of Education, Capitol Place Building, 80 F. Street, NW., Room 408C/Mail Stop 4000, Washington, DC 20001–1528.

NOTIFICATION PROCEDURE:

If you wish to determine whether a record exists regarding you in this system of records, contact the system manager. Requests must meet the requirements in the regulations at 34 CFR 5b.5, including proof of identity.

RECORD ACCESS PROCEDURES:

If you wish to gain access to a record in this system, contact the system manager. Requests by an individual for access to a record must meet the requirements the regulations at 34 CFR 5b.5, including proof of identity.

CONTESTING RECORD PROCEDURES:

If you wish to contest the content of a record regarding you in this system of records, contact the system manager. Your request must meet the requirements of the Act regulations at 34 CFR 5b.7, including proof of identity.

RECORD SOURCE CATEGORIES:

Information in this system of records is supplied from the following sources: Directly by the individual filing a request for resolution of an EEO pre-complaint, EEO formal complaint or pre-grievance, from information supplied by the individual, or by testimony of witnesses, employee

representatives, or Department employees/officials.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2012–27431 Filed 11–8–12; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13287–004]

City of New York; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Major project, existing dam.

b. *Project No.:* 13287–004.

c. *Date filed:* February 29, 2012.

d. *Applicant:* City of New York.

e. *Name of Project:* Cannonsville Hydroelectric Project.

f. *Location:* On the West Branch of the Delaware River, near the Township of Deposit, Delaware County, New York. The project does not occupy any federal lands.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Anthony J. Fiore, Chief of Staff—Operations, New York City Department of Environmental Protection, 59–17 Junction Blvd., Flushing, NY 11373–5108, (718) 595–6529 or *afiore@dep.nyc.gov.*

i. *FERC Contact:* John Mudre, (202) 502–8902 or *john.mudre@ferc.gov.*

j. *Deadline for filing comments, recommendations, terms and conditions, and prescriptions:* 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

All documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted and is now ready for environmental analysis.

l. *Project facilities would include:* (1) An existing 2,800-foot-long, 45-foot-wide earthen embankment dam with a crest elevation of 1,175.0 feet above mean sea level; (2) an existing 800-foot-long stone masonry spillway; (3) an existing 12-mile-long, 4,670-acre impoundment (Cannonsville Reservoir); (4) four proposed penstocks branching from an existing 12-foot-diameter intake; (5) a proposed 168-foot-long by 54-foot-wide powerhouse containing four horizontal shaft Francis generating units; (6) a proposed tailrace occupying approximately one acre; (7) a proposed transmission system consisting of a 150-foot-long underground and 1,200-foot-long overhead 12.47-kilovolt (kV) line, a substation, and a 460-foot-long overhead 46-kV line; and (8) appurtenant facilities. The project would have a total installed capacity of 14.08 megawatts and would generate approximately 42,281 megawatt-hours of electricity annually.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

All filings must (1) bear in all capital letters the title ''COMMENTS'', ''REPLY COMMENTS'', ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), and 385.2010.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

o. A license applicant must file no later than 60 days following the date of issuance of this notice: (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

Dated: November 2, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27407 Filed 11–8–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13739–002]

Lock+ Hydro Friends Fund XLII, LLC; Notice of Application Accepted for Filing and Soliciting 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:* Major Original License

b. *Project No.:* 13739–002

c. *Date filed:* September 17, 2012

d. *Applicant:* Lock+ Hydro Friends Fund XLII, LLC

e. *Name of Project:* Braddock Locks and Dam Hydroelectric Project

f. *Location:* At the existing U.S. Army Corps of Engineers' Braddock Locks and Dam on the Monongahela River, in Allegheny County, Pennsylvania. The project would occupy about 0.19 acre of federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 USC 791(a)–825(r).

h. *Applicant Contact:* Mr. Mark R. Stover, Lock+™ Hydro Friends Fund XLII, LLC, c/o Hydro Green Energy, LLC, 900 Oakmont Lane, Suite 310, Westmont, IL 60559; (877) 556–6566 ext. 711; email—*mark@hgenergy.com.*

i. *FERC Contact:* John Mudre at (202) 502–8902; or email at *john.mudre@ferc.gov.*

j. *Deadline for filing motions to intervene and protests:* 60 days from the issuance date of this notice.

All documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The Commission's Rules of Practice and Procedures require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing, but is not ready for environmental analysis at this time.

l. *The proposed project would utilize the existing U.S. Army Corps of Engineers' Braddock Locks and Dam and the Braddock Pool, and would consist of the following new facilities:* (1) A new powerhouse with five turbine-generators having a total installed capacity of 3,750 kilowatts; (2) a new approximately 3,450-foot-long, 23-kilovolt electric distribution line; (3) a switchyard and control room; and (4) appurtenant facilities. The average annual generation is estimated to be 25,020 megawatt-hours.

The proposed project would deploy hydropower turbines within a patented ''Large Frame Module'' (LFM) that would be deployed on the south (river left) side of the dam, opposite the location of the existing navigational locks and at the upstream face of the existing left closure weir. The proposed modular, low environmental impact powerhouse would be approximately 60.4 feet long, 16.6 feet wide, and 40 feet high, and constructed of structural-grade steel. The powerhouse will bear on a concrete foundation on rock that is anchored to the existing left closure weir. A trash rack with 6-inch openings would be placed at the powerhouse intake to increase safety and protect the turbines from large debris.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified intervention deadline date, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified intervention deadline date. Applications for preliminary permits will not be accepted in response to this notice.

A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit a development application. A notice of intent must be served on the applicant(s) named in this public notice.

Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

When the application is ready for environmental analysis, the Commission will issue a public notice requesting comments, recommendations, terms and conditions, or prescriptions.

All filings must (1) bear in all capital letters the title ''PROTEST'' or ''MOTION TO INTERVENE,'' ''NOTICE OF INTENT TO FILE COMPETING APPLICATION,'' or ''COMPETING APPLICATION;'' (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. 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.

Dated: November 2, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27410 Filed 11–8–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1484–005.

Applicants: Shell Energy North America (U.S.), L.P.

Description: Shell Energy North America (U.S.), L.P. submits updated market power analysis for the Northeast region.

Filed Date: 10/31/12.
Accession Number: 20121031–5397.
Comments Due: 5 p.m. ET 11/21/12.

Docket Numbers: ER13–266–000.
Applicants: Duke Energy Carolinas, LLC.
Description: Amendment to Rate Schedule No. 318–2013 Confirmation to be effective 1/1/2013.
Filed Date: 11/1/12.
Accession Number: 20121101–5017.
Comments Due: 5 p.m. ET 11/23/12.

Docket Numbers: ER13–269–000.
Applicants: PJM Interconnection, L.L.C.
Description: Original Service Agreement No. 3403; Queue No. U3–004 to be effective 9/28/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5055.
Comments Due: 5 p.m. ET 11/23/12.

Docket Numbers: ER13–270–000.
Applicants: New England Power Pool Participants Committee, ISO New England Inc.
Description: Elimination of Internal Bilateral Transactions for Regulation to be effective 1/1/2013.
Filed Date: 11/1/12.
Accession Number: 20121101–5067.
Comments Due: 5 p.m. ET 11/23/12.

Docket Numbers: ER13–271–000.
Applicants: Alabama Power Company.
Description: Cancellation of Rate Schedule MUN–1 to be effective 1/1/2013.
Filed Date: 11/1/12.
Accession Number: 20121101–5083.
Comments Due: 5 p.m. ET 11/23/12.

Docket Numbers: ER13–272–000.
Applicants: Startrans IO, LLC.
Description: Startrans IO Proposed Decrease in Base Transmission Revenue Requirement to be effective 1/1/2013.
Filed Date: 11/1/12.
Accession Number: 20121101–5084.
Comments Due: 5 p.m. ET 11/23/12.

Docket Numbers: ER13–273–000.
Applicants: Northern States Power Company, a Wisconsin corporation.
Description: Northern States Power Company, a Wisconsin corporation submits a Notice of Cancellation of the Restated Interconnection and Power and Energy Supply Agreement with the City of Barron, Wisconsin.
Filed Date: 10/31/12.
Accession Number: 20121031–5398.
Comments Due: 5 p.m. ET 11/21/12.

Docket Numbers: ER13–274–000.
Applicants: Northern States Power Company, a Wisconsin corporation.
Description: Northern States Power Company, a Wisconsin corporation submits a Notice of Cancellation of the Restated Interconnection and Power and Energy Supply Agreement with the Village of Cadott, Wisconsin.
Filed Date: 10/31/12.
Accession Number: 20121031–5401.
Comments Due: 5 p.m. ET 11/21/12.

Docket Numbers: ER13–275–000.
Applicants: Northern States Power Company, a Wisconsin corporation.
Description: Northern States Power Company, a Wisconsin corporation submits a Notice of Cancellation of the Restated Interconnection and Power and Energy Supply Agreement with the City of Bloomer, Wisconsin.
Filed Date: 10/31/12.
Accession Number: 20121031–5407.
Comments Due: 5 p.m. ET 11/21/12.

Docket Numbers: ER13–276–000.
Applicants: Northern States Power Company, a Wisconsin corporation.
Description: Northern States Power Company, a Wisconsin corporation submits a Notice of Cancellation of the Restated Interconnection and Power and Energy Supply Agreement with the City of Cornell, Wisconsin.
Filed Date: 10/31/12.
Accession Number: 20121031–5408.
Comments Due: 5 p.m. ET 11/21/12.

Docket Numbers: ER13–277–000.
Applicants: The Detroit Edison Company.
Description: Update Seller Category Status to be effective 11/2/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5098.
Comments Due: 5 p.m. ET 11/23/12.

Docket Numbers: ER13–278–000.
Applicants: Northern States Power Company, a Wisconsin corporation.
Description: Northern States Power Company, a Wisconsin corporation submits a Notice of Cancellation of the Restated Interconnection and Power and Energy Supply Agreement with the City of Wakefield, Wisconsin.
Filed Date: 10/31/12.
Accession Number: 20121031–5410.
Comments Due: 5 p.m. ET 11/21/12.

Docket Numbers: ER13–279–000.
Applicants: Northern States Power Company, a Wisconsin corporation.
Description: Northern States Power Company, a Wisconsin corporation submits a Notice of Cancellation of the Restated Interconnection and Power and Energy Supply Agreement with the City of Spooner, Wisconsin.
Filed Date: 10/31/12.
Accession Number: 20121031–5411.
Comments Due: 5 p.m. ET 11/21/12.

Docket Numbers: ER13–280–000.
Applicants: Northern States Power Company, a Wisconsin corporation.
Description: Northern States Power Company, a Wisconsin corporation submits a Notice of Cancellation of the Restated Interconnection and Power and Energy Supply Agreement with the Village of Trempealeau, Wisconsin.
Filed Date: 10/31/12.
Accession Number: 20121031–5412.
Comments Due: 5 p.m. ET 11/21/12.

Docket Numbers: ER13–281–000.
Applicants: Star Energy Partners LLC.
Description: Star Energy Partners Market Based Rate Tariff to be effective 11/20/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5102.
Comments Due: 5 p.m. ET 11/23/12.

Docket Numbers: ER13–282–000.
Applicants: Wabash Valley Power Association, Inc.
Description: Rate Schedule Amendments—November 2012 to be effective 7/6/2010.
Filed Date: 11/1/12.
Accession Number: 20121101–5104.
Comments Due: 5 p.m. ET 11/23/12.

Docket Numbers: ER13–283–000.
Applicants: Public Service Company of Colorado.
Description: 2012–11–1-Annual FP2P Rate Filing to be effective 1/1/2013.
Filed Date: 11/1/12.
Accession Number: 20121101–5105.
Comments Due: 5 p.m. ET 11/23/12.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES11–40–002.
Applicants: Entergy Services, Inc., Entergy Arkansas, Inc., Entergy Gulf States Louisiana, L.L.C., Entergy Louisiana, LLC, Entergy Mississippi, Inc., Entergy New Orleans, Inc., Entergy Texas, Inc.
Description: Joint Application for Temporary Modification of Existing Authorizations under Section 204 of the Federal Power Act of Entergy Services, Inc., et al.
Filed Date: 10/31/12.
Accession Number: 20121031–5413.
Comments Due: 5 p.m. ET 11/21/12.

Take notice that the Commission received the following land acquisition reports:

Docket Numbers: LA12–3–000.
Applicants: Bluegrass Generation Company, L.L.C., Blythe Energy, LLC, Calhoun Power Company, LLC, Cherokee County Cogeneration Partners, LLC, DeSoto County Generating Company, LLC, Doswell Limited Partnership, Las Vegas Power Company, LLC, LS Power Marketing, LLC, LSP Safe Harbor Holdings, LLC, LSP University Park, LLC, Renaissance Power, L.L.C., Riverside Generating Company, L.L.C., Rocky Road Power, LLC, Tilton Energy LLC, University Park Energy, LLC, and Wallingford Energy LLC, LLC.

Description: Quarterly Land Acquisition Report of the LS Power Development, LLC MBR Sellers.
Filed Date: 10/31/12.
Accession Number: 20121031–5409.
Comments Due: 5 p.m. ET 11/21/12.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH13–3–000.
Applicants: DTE Energy Company.
Description: DTE Energy Company submits Form 65 and Form 65–B Notice of Change.
Filed Date: 10/31/12.
Accession Number: 20121031–5400.
Comments Due: 5 p.m. ET 11/21/12.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 1, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–27388 Filed 11–8–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: CP13–11–000.
Applicants: Peoples TWP LLC.
Description: Application for Limited Jurisidiction Blanket Certificate of Peoples TWP LLC.
Filed Date: 10/31/12.
Accession Number: 20121101–0003.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–243–000.
Applicants: Crossroads Pipeline Company.
Description: PFSA Cleanup to be effective 12/1/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5042.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–244–000.
Applicants: Columbia Gas Transmission, LLC.
Description: PFSA Clean Up to be effective 12/1/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5047.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–245–000.
Applicants: Central Kentucky Transmission Company.
Description: PFSA Cleanup to be effective 12/1/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5053.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–246–000.
Applicants: Hardy Storage Company, LLC.
Description: PFSA Cleanup Filing to be effective 12/1/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5056.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–247–000.
Applicants: ANR Storage Company.
Description: J. Aron FS Agmt to be effective 11/1/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5057.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–248–000.
Applicants: Columbia Gulf Transmission Company.
Description: PFSA Cleanup to be effective 12/1/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5059.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–249–000.
Applicants: ANR Pipeline Company.
Description: Nexen_Integrys Agmts to be effective 11/1/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5100.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–250–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Brooklyn Union Gas Company Releases November 2012 Ramapo to be effective 11/1/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5101.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–252–000.
Applicants: CenterPoint Energy Gas Transmission Comp.
Description: CEGT LLC—Neg Rate Filing—November 2012 to be effective 11/1/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5147.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–253–000.
Applicants: Northern Border Pipeline Company.
Description: Ameren Illinois Rate Change to be effective 11/1/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5151.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–254–000.
Applicants: Millennium Pipeline Company, LLC.
Description: Negotiated Rate Service Agmts No. 5582, 135770 to be effective 11/1/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5160.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–255–000.
Applicants: Granite State Gas Transmission, Inc.
Description: Non-Conforming Contracts to be effective 11/1/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5164.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–256–000.
Applicants: Equitrans, L.P.
Description: Equitrans, L.P. submits Operational Purchases and Sales Report for the twelve month period ended August 31, 2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5184.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–257–000.
Applicants: Destin Pipeline Company, L.L.C.
Description: Fuel Retention Adjustment to be effective 12/1/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5187.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–258–000.
Applicants: Alliance Pipeline L.P.
Description: November 6–15 2012 Auction to be effective 11/6/2012.
Filed Date: 11/2/12.
Accession Number: 20121102–5151.
Comments Due: 5 p.m. ET 11/14/12.

Docket Numbers: RP13–259–000.
Applicants: ANR Pipeline Company.
Description: BP Energy_Exploration to be effective 11/1/2012.
Filed Date: 11/2/12.
Accession Number: 20121102–5195.
Comments Due: 5 p.m. ET 11/14/12.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP12–610–001.
Applicants: Columbia Gas Transmission, LLC.
Description: South Jersey Compliance Filing—Inservice.
Filed Date: 11/1/12.
Accession Number: 20121101–5159.
Comments Due: 5 p.m. ET 11/13/12.

Docket Numbers: RP13–218–001.
Applicants: Carolina Gas Transmission Corporation.
Description: BG Negotiated Rate Filing Amendment to be effective 11/1/2012.
Filed Date: 11/1/12.
Accession Number: 20121101–5124.
Comments Due: 5 p.m. ET 11/13/12.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 5, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–27386 Filed 11–8–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC13–26–000.
Applicants: Ohio Power Company, AEP Generation Resources Inc.
Description: Application for Authorization to Transfer Jurisdictional Assets under Section 203 of the Federal Power Act of Ohio Power Company and AEP Generation Resources Inc.
Filed Date: 10/31/12.
Accession Number: 20121031–5336.
Comments Due: 5 p.m. e.t. 11/30/12.

Docket Numbers: EC13–27–000.
Applicants: Appalachian Power Company, Wheeling Power Company.
Description: Application for Authorization to Transfer Jurisdictional Assets under Section 203 of the Federal Power Act of Appalachian Power Company and Wheeling Power Company.
Filed Date: 10/31/12.
Accession Number: 20121031–5337.
Comments Due: 5 p.m. e.t. 12/17/12.

Docket Numbers: EC13–28–000.
Applicants: Appalachian Power Company, Kentucky Power Company, AEP Generation Resources Inc.
Description: Application for Authorization to Transfer Jurisdictional Assets under Section 203 of the Federal Power Act of Appalachian Power Company, Kentucky Power Company and AEP Generation Resources Inc.
Filed Date: 10/31/12.
Accession Number: 20121031–5339.
Comments Due: 5 p.m. e.t. 12/17/12.

Docket Numbers: EC13–29–000.
Applicants: Kiowa Power Partners, LLC, Tenaska Energy, Inc., Tenaska Energy Holdings, LLC, Tenaska Oklahoma, Inc., Diamond Pittsburg, LP, Diamond Oklahoma, LP.
Description: Kiowa Power Partners, LLC, et al. Joint Application For Approval Under Section 203 of the Federal Power Act and Request for Shortened Comment Period and Expedited Action.
Filed Date: 10/31/12.
Accession Number: 20121031–5387.
Comments Due: 5 p.m. e.t. 11/21/12.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–2780–007.
Applicants: Safe Harbor Water Power Corporation.
Description: Notice of Change in Status of Safe Harbor Water Power Corporation.
Filed Date: 10/31/12.
Accession Number: 20121031–5353.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER12–60–003; ER10–1632–003; ER10–1616–001; ER10–1585–001; ER10–1594–001; ER10–1617–001; ER10–1628–001.
Applicants: New Covert Generating Company, LLC, Tenaska Power Services Co., Tenaska Power Management, LLC, Alabama Electric Marketing, LLC, California Electric Marketing, LLC, New Mexico Electric Marketing, LLC, Texas Electric Marketing, LLC.
Description: Updated Market Power Analysis for the Central Region on behalf of Tenaska Power Management, LLC, et al.
Filed Date: 10/31/12.
Accession Number: 20121031–5351.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER12–569–001; 1920–002; ER10–1928–002; ER12–895–001; ER10–2720–002; ER11–4428–002; ER10–1971–006.
Applicants: Blackwell Wind, LLC, FPL Energy Oklahoma Wind, LLC, FPL Energy Sooner Wind, LLC, Minco Wind Interconnection Services, LLC, Minco Wind, LLC, Minco Wind II, LLC, NextEra Energy Power Marketing, LLC.
Description: Notification of Non-material Change in Status of the NextEra Resource Entities.
Filed Date: 10/31/12.
Accession Number: 20121031–5393.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER12–2291–000.
Applicants: New England Power Company.
Description: Refund Report of New England Power Company in Docket No. ER12–2291 to be effective N/A.
Filed Date: 10/31/12.
Accession Number: 20121031–5268.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER12–2304–002.
Applicants: Green Mountain Power Corporation, ISO New England Inc.
Description: Green Mountain Power Notice of Effective Date Schedule 21 and Schedule 20A to be effective 10/1/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5030.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–150–001.
Applicants: Northern Indiana Public Service Company, Midwest Independent Transmission System Operator, Inc.
Description: 10–31–12 NIPSCO Amendment to be effective 1/1/2013.
Filed Date: 10/31/12.
Accession Number: 20121031–5259.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–226–000.
Applicants: Southern California Edison Company.
Description: 2013 TRBAA Update Filing to be effective 1/1/2013.
Filed Date: 10/31/12.
Accession Number: 20121031–5003.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–227–000.
Applicants: Southern California Edison Company.
Description: 2013 RSBAA Update Filing to be effective 1/1/2013.
Filed Date: 10/31/12.
Accession Number: 20121031–5014.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–228–000.
Applicants: Pacific Gas and Electric Company.
Description: CCSF IA—39th Quarterly Filing of Facilities Agreements to be effective 9/30/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5016.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–229–000.

Applicants: Green Mountain Power Corporation, ISO New England Inc.
Description: GMP—Notice of Succession for Service Agreement No. 69 to be effective 10/1/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5029.
Comments Due: 5 p.m. e.t. 11/21/12.
Docket Numbers: ER13–230–000.
Applicants: Northern Iowa Windpower II LLC.
Description: Corrected Tariff Revisions to be effective 6/30/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5066.
Comments Due: 5 p.m. e.t. 11/21/12.
Docket Numbers: ER13–231–000.
Applicants: Northern States Power Company, a Minnesota corporation.
Description: 2012–10–31-Ada-Kasota-Intercon-Agmnts to be effective 12/31/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5067.
Comments Due: 5 p.m. e.t. 11/21/12.
Docket Numbers: ER13–232–000.
Applicants: AEP Generation Resources Inc.
Description: Ohio Power Supply Agreement to be effective 1/1/2014.
Filed Date: 10/31/12.
Accession Number: 20121031–5096.
Comments Due: 5 p.m. e.t. 11/30/12.
Docket Numbers: ER13–233–000.
Applicants: Appalachian Power Company.
Description: Power Coordination Agreement and Bridge Agreement to be effective 1/1/2014.
Filed Date: 10/31/12.
Accession Number: 20121031–5097.
Comments Due: 5 p.m. e.t. 11/30/12.
Docket Numbers: ER13–234–000.
Applicants: Kentucky Power Company.
Description: Power Coordination Agreement and Bridge Agreement Concurrence to be effective 1/1/2014.
Filed Date: 10/31/12.
Accession Number: 20121031–5098.
Comments Due: 5 p.m. e.t. 11/30/12.
Docket Numbers: ER13–235–000.
Applicants: Indiana Michigan Power Company.
Description: Power Coordination Agreement and Bridge Agreement Concurrence to be effective 1/1/2014.
Filed Date: 10/31/12.
Accession Number: 20121031–5101.
Comments Due: 5 p.m. e.t. 11/30/12.
Docket Numbers: ER13–236–000.
Applicants: AEP Generation Resources Inc.
Description: Bridge Agreement Concurrence to be effective 1/1/2014.
Filed Date: 10/31/12.
Accession Number: 20121031–5104.
Comments Due: 5 p.m. e.t. 11/30/12.
Docket Numbers: ER13–237–000.
Applicants: Ohio Power Company.
Description: Bridge Agreement Concurrence to be effective 1/1/2014.
Filed Date: 10/31/12.
Accession Number: 20121031–5105.
Comments Due: 5 p.m. e.t. 11/30/12.
Docket Numbers: ER13–238–000.
Applicants: Appalachian Power Company.
Description: Sporn and Mitchell Operating Agreements to be effective 1/1/2014.
Filed Date: 10/31/12.
Accession Number: 20121031–5106.
Comments Due: 5 p.m. e.t. 12/17/12.
Docket Numbers: ER13–239–000.
Applicants: Kentucky Power Company.
Description: Mitchell Operating Agreement Concurrence to be effective 1/1/2014.
Filed Date: 10/31/12.
Accession Number: 20121031–5107.
Comments Due: 5 p.m. e.t. 12/17/12.
Docket Numbers: ER13–240–000.
Applicants: AEP Generation Resources Inc.
Description: Sporn Operating Agreement Concurrence to be effective 1/1/2014.
Filed Date: 10/31/12.
Accession Number: 20121031–5109.
Comments Due: 5 p.m. e.t. 12/17/12.
Docket Numbers: ER13–241–000.
Applicants: PJM Interconnection, L.L.C.
Description: Original SA No. 3410; Queue No. W4–029 & Y1–075 (Reeves South) to be effective 10/12/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5117.
Comments Due: 5 p.m. e.t. 11/21/12.
Docket Numbers: ER13–242–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: SA 2013 G586 Amended GIA to be effective 11/1/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5118.
Comments Due: 5 p.m. e.t. 11/21/12.
Docket Numbers: ER13–243–000.
Applicants: PJM Interconnection, L.L.C.
Description: Original SA No. 3411; Queue No. W4–029 & Y1–075 (Reeves North) to be effective 10/12/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5123.
Comments Due: 5 p.m. e.t. 11/21/12.
Docket Numbers: ER13–244–000.
Applicants: Green Mountain Power Corporation.
Description: Notice of Succession and Establishment of New eTariff Database to be effective 10/31/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5125.
Comments Due: 5 p.m. e.t. 11/21/12.
Docket Numbers: ER13–245–000.
Applicants: Green Mountain Power Corporation, Central Vermont Public Service Corporation.
Description: Cancellation of Central Vermont eTariff Database to be effective 10/31/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5136.
Comments Due: 5 p.m. e.t. 11/21/12.
Docket Numbers: ER13–246–000.
Applicants: Southern California Edison Company.
Description: SCE 2013 Update ETC Reliability Services Rate to be effective 1/1/2013.
Filed Date: 10/31/12.
Accession Number: 20121031–5165.
Comments Due: 5 p.m. e.t. 11/21/12.
Docket Numbers: ER13–247–000.
Applicants: NV Energy, Inc.
Description: Transmission Rate Case—SPPC to be effective 1/1/2013.
Filed Date: 10/31/12.
Accession Number: 20121031–5179.
Comments Due: 5 p.m. e.t. 11/21/12.
Docket Numbers: ER13–249–000.
Applicants: Southwest Power Pool, Inc.
Description: 1313R6 Oklahoma Gas & Electric NITSA NOA to be effective 10/1/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5195.
Comments Due: 5 p.m. e.t. 11/21/12.
Docket Numbers: ER13–250–000.
Applicants: Luminescent Systems, Inc.
Description: Cancellation of Tariff to be effective 11/1/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5218.
Comments Due: 5 p.m. e.t. 11/21/12.
Docket Numbers: ER13–251–000.
Applicants: Arizona Public Service Company.
Description: APS Service Agreement No. 327-Azusa Simultaneous Exchange to be effective 1/1/2013.
Filed Date: 10/31/12.
Accession Number: 20121031–5222.
Comments Due: 5 p.m. e.t. 11/21/12.
Docket Numbers: ER13–252–000.
Applicants: Entergy Gulf States Louisiana, L.L.C.
Description: EGSL–SRMPA Extension of Interim Agreement to be effective 1/1/2013.
Filed Date: 10/31/12.
Accession Number: 20121031–5229.
Comments Due: 5 p.m. e.t. 11/21/12.
Docket Numbers: ER13–253–000.
Applicants: Entergy Arkansas, Inc.
Description: EAI Filing of Unexecuted Reimbursement Agreement with AECC to be effective 1/1/2013.

Filed Date: 10/31/12.
Accession Number: 20121031–5235.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–254–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: 10–31–12 ATC Attachment FF to be effective 12/30/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5243.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–255–000.
Applicants: NV Energy, Inc.
Description: Transmission Rate Case—NPC to be effective 1/1/2013.
Filed Date: 10/31/12.
Accession Number: 20121031–5246.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–256–000.
Applicants: Exelon Energy Company.
Description: Exelon Energy Company, Notice of Cancellation to be effective 11/1/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5250.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–257–000.
Applicants: PJM Interconnection, L.L.C.
Description: Queue Position V2–028; Original Service Agreement No. 3413 to be effective 9/28/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5251.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–258–000.
Applicants: California Independent System Operator Corporation.
Description: 2012–10–31 CAISO Amendment 7 to the PLA with CDWR to be effective 11/1/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5255.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–259–000.
Applicants: Oklahoma Gas and Electric Company.
Description: Revisions to Depreciation Rates to be effective 8/2/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5256.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–260–000.
Applicants: Dynegy Oakland, LLC.
Description: Annual RMR Section 205 Filing and RMR Schedule F Informational Filing to be effective 1/1/2013.
Filed Date: 10/31/12.
Accession Number: 20121031–5260.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–261–000.
Applicants: California Power Exchange Corporation.
Description: Rate Filing for Rate Period 22 to be effective 1/1/2013.
Filed Date: 10/31/12.
Accession Number: 20121031–5273.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–262–000.
Applicants: Central Maine Power Company.
Description: Warren Interconnection Agreement to be effective 11/1/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5277.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–263–000.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: 10–31–12 to be effective 1/1/2013.
Filed Date: 10/31/12.
Accession Number: 20121031–5279.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–264–000.
Applicants: Oklahoma Gas and Electric Company.
Description: Revisions to Formula Rate to be effective 8/2/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5280.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–265–000.
Applicants: Nevada Power Company.
Description: Rate Schedule No. 134 Interim Balancing Area Services Agreement-VEA to be effective 11/1/2012.
Filed Date: 10/31/12.
Accession Number: 20121031–5281.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–267–000.
Applicants: Northern States Power Company, a Minnesota corporation, Northern States Power Company, a Wisconsin corporation.
Description: Northern States Power Company, a Minnesota corporation, et al. submit a Notice of Cancellation of the Restated Electric Service Agreement with Rice Lake, Wisconsin.
Filed Date: 10/31/12.
Accession Number: 20121031–5366.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ER13–268–000.
Applicants: Northern States Power Company, a Wisconsin corporation.
Description: Northern States Power Company, a Wisconsin corporation submits a Notice of Cancellation of the Restated Interconnection and Power and Energy Supply Agreement with the Village of Bangor, Wisconsin.
Filed Date: 10/31/12.
Accession Number: 20121031–5391.
Comments Due: 5 p.m. e.t. 11/21/12.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES13–5–000.
Applicants: ITC Arkansas LLC, ITC Louisiana LLC, ITC Mississippi LLC, ITC Texas LLC.
Description: Application under Section 204 of the Federal Power Act for Authorization to Issue Debt Securities of ITC Arkansas LLC, ITC Louisiana LLC, ITC Mississippi LLC and ITC Texas LLC.
Filed Date: 10/31/12.
Accession Number: 20121031–5386.
Comments Due: 5 p.m. e.t. 11/21/12.

Docket Numbers: ES13–6–000.
Applicants: Entergy Services, Inc., Transmission Company Arkansas, LLC, Transmission Company Louisiana I, LLC, Transmission Company Louisiana II, LLC, Transmission Company Mississippi, LLC, Transmission Company New Orleans, LLC, Transmission Company Texas, LLC.
Description: Application under Section 204 of the Federal Power Act for Authorization to Issue Debt Securities of Transmission Company Arkansas, LLC, et al.
Filed Date: 10/31/12.
Accession Number: 20121031–5390.
Comments Due: 5 p.m. e.t. 11/21/12.

Take notice that the Commission received the following land acquisition reports:

Docket Numbers: LA12–3–000.
Applicants: Ashtabula Wind, LLC, Ashtabula Wind II, LLC, Ashtabula Wind III, LLC, Backbone Mountain Windpower LLC, Badger Windpower, LLC, Baldwin Wind, LLC, Bayswater Peaking Facility, LLC, Blackwell Wind, LLC, Butler Ridge Wind Energy Center, LLC, Crystal Lake Wind, LLC, Crystal Lake Wind II, LLC, Crystal Lake Wind III, LLC, Day County Wind, LLC, Diablo Winds, LLC, Elk City Wind, LLC, Elk City II Wind, LLC, Ensign Wind, LLC, ESI Vansycle Partners, L.P., Florida Power & Light Co., FPL Energy Burleigh County Wind, LLC, FPL Energy Cabazon Wind, LLC, FPL Energy Cape, LLC, FPL Energy Cowboy Wind, LLC, FPL Energy Green Power Wind, LLC, FPL Energy Hancock County Wind, LLC, FPL Energy Illinois Wind, LLC, FPL Energy Maine Hydro LLC, FPL Energy Marcus Hook, L.P., FPL Energy MH50 L.P., FPL Energy Montezuma Wind, LLC, FPL Energy Mower County, LLC, FPL Energy New Mexico Wind, LLC, FPL Energy North Dakota Wind, LLC, FPL Energy North Dakota Wind II, LLC, FPL Energy Oklahoma Wind, LLC, FPL Energy Oliver Wind I, LLC, FPL Energy Oliver Wind II, LLC, FPL Energy Sooner Wind, LLC, FPL Energy South Dakota Wind, LLC, FPL Energy Stateline II, Inc., FPL Energy Vansycle, LLC, FPL Energy Wyman, LLC, FPL Energy Wyman IV, LLC, FPL Energy Wyoming, LLC, Garden Wind, LLC, Gray County Wind Energy, LLC, Hatch Solar Energy Center I, LLC, Hawkeye Power Partners, LLC,

High Majestic Wind Energy Center, LLC, High Winds, LLC, High Majestic Wind II, LLC, Jamaica Bay Peaking Facility, LLC, Lake Benton Power Partners II, LLC, Langdon Wind, LLC, Limon Wind, LLC, Limon Wind II, LLC, Logan Wind Energy LLC, Meyersdale Windpower LLC, Mill Run Windpower, LLC, Minco Wind, LLC, Minco Wind II, LLC, Minco Wind III, LLC, Minco Wind Interconnection Services, LLC, NEPM II, LLC, NextEra Energy Duane Arnold, LLC, NextEra Energy Montezuma II Wind, LLC, NextEra Energy Power Marketing, LLC, NextEra Energy Point Beach, LLC, NextEra Energy Seabrook, LLC, NextEra Energy Services Massachusetts, LLC, Northeast Energy Associates, A Limited Partnership, North Jersey Energy Associates, A Limited Partnership, North Sky River Energy, LLC, Northern Colorado Wind Energy, LLC, Osceola Windpower, LLC, Osceola Windpower II, LLC, Paradise Solar Urban Renewal, L.L.C., Peetz Table Wind Energy, LLC, Pennsylvania Windfarms, Inc., Perrin Ranch Wind, LLC, Red Mesa Wind, LLC, Sky River LLC, Somerset Windpower, LLC, Story Wind, LLC, Tuscola Bay Wind, LLC, Vasco Winds, LLC, Victory Garden Phase IV, LLC, Waymart Wind Farm, L.P., Wessington Wind Energy Center, LLC, White Oak Energy LLC, Wilton Wind II, LLC, Windpower Partners 1993, L.P.

Description: Quarterly Land Acquisition Report of the NextEra Energy Companies.

Filed Date: 10/31/12.

Accession Number: 20121031–5385.

Comments Due: 5 p.m. e.t. 11/21/12.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 1, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–27387 Filed 11–8–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12965–002]

Wickiup Hydro Group, LLC, Oregon; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC's) regulations, 18 Code of Federal Regulations (CFR) Part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed Wickiup Hydro Group, LLC's application for an original license for the Wickiup Dam Hydroelectric Project (FERC Project No. 12965–002), which would be constructed at the existing Bureau of Reclamation Wickiup Dam on the Deschutes River in Deschutes County near the city of La Pine, Oregon. The proposed project, if licensed, would occupy 1.02 acres of federal lands jointly managed by the U.S. Department of the Interior, Bureau of Reclamation, and the U.S. Forest Service.

The final environmental assessment (EA) contains staff's analysis of the potential environmental effects of licensing the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the final EA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's web site at *www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, 202–502–8659.

You may also register online at *www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

For further information, contact Matt Cutlip by telephone at 503–552–2762 or by email at *matt.cutlip@ferc.gov.*

Dated: November 2, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27408 Filed 11–8–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–311–000]

MP2 Energy IL 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 MP2 Energy IL 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 November 26, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC.

There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 5, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–27391 Filed 11–8–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–291–000]

EnergyMark, 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 EnergyMark, 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 November 26, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 5, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–27389 Filed 11–8–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER13–310–000]

MP2 Energy NJ 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 MP2 Energy NJ 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 November 26, 2012.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 5, 2012.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2012–27390 Filed 11–8–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13511–001]

Igiugig Village Council; Notice of Successive Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On October 1, 2012, Igiugig Village Council (IVC) filed an application for a successive preliminary permit, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of the Igiugig RISEC Water Power Project (Igiugig Project or project), to be located on the Kvichak River in the Lake and Peninsula Borough, Alaska. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) Up to 8 proposed RISEC kinetic energy-to-electrical energy conversion devices having a total installed capacity of 40 kilowatts; (2) a proposed transmission line that will either connect directly to the IVC diesel power plant or a 1,000-foot-long transmission line interconnecting with the Iguigig Village electric distribution system (depending on the location of the RISEC devices); and (3) appurtenant facilities. The proposed project would have an estimated average annual generation of 250 megawatt-hours.

Applicant Contact: AlexAnna Salmon, Iguigig Village Administrator, P.O. Box 4008, Iguigig, AK 99613; phone: (907) 533–3211.

FERC Contact: Jennifer Harper; phone: (202) 502–6136.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–13511) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: November 5, 2012.

Kimberly D. Bose,

Secretary.

[FR Doc. 2012–27409 Filed 11–8–12; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2010–0674; FRL–9750–8]

Request for Information To Inform Hydraulic Fracturing Research Related to Drinking Water Resources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for information.

SUMMARY: EPA is inviting the public to submit data and scientific literature to inform EPA's research on the potential impacts of hydraulic fracturing on drinking water resources.

DATES: EPA will accept data and literature in response to this request until April 30, 2013.

ADDRESSES: Using the online method is preferred for submitting information. Follow the online instructions at *http://www.regulations.gov,* and identify your submission with Docket ID No. EPA–HQ–ORD–2010–0674.

Additional methods for submission are:

- *Email:* Send information by electronic mail (email) to: *ord.docket@epa.gov,* Attention Docket ID No. EPA–HQ–ORD–2010–0674.
- *Fax:* Fax information to: (202) 566–9744, Attention Docket ID No. EPA–HQ–ORD–2010–0674.
- *Mail:* Send information by mail to: U.S. Environmental Protection Agency, EPA Docket Center, Mail Code: 28221T, 1200 Constitution Ave. NW., Washington, DC 20460, Attention Docket ID No. EPA–HQ–ORD–2010–0674.
- *Hand Delivery or Courier:* Deliver information to: EPA Docket Center, EPA West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC, Attention Docket ID No. EPA–HQ–ORD–2010–0674. Deliveries are only accepted during the docket's normal hours of operation, between 8:30 a.m. and 4:30 p.m. (Eastern), Monday through Friday, excluding legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your information to Docket ID No. EPA–HQ–ORD–2010–0674. EPA's policy is that all information received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit information electronically, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. Information on a CD ROM should be formatted as a MS Word, Rich Text or Adobe Acrobat PDF file. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/dockets.*

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 EPA Docket Center, EPA 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. (Eastern), Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the ORD Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: For further information contact Lisa Matthews, Mail Code 8101R, Office of Research and Development, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; via phone/voice mail at: (202) 564–6669; via fax at: (202) 565–2430; or via email at: *matthews.lisa@epa.gov.*

SUPPLEMENTARY INFORMATION:

Background

In response to public concern, the U.S. Congress urged EPA to conduct scientific research to examine the relationship between hydraulic fracturing and drinking water resources. EPA is undertaking a study to understand the potential impacts of hydraulic fracturing on drinking water resources, if any, and to identify the driving factors that may affect the severity and frequency of such impacts.

The scope of the study includes the full hydraulic fracturing water lifecycle—from water acquisition, through the mixing of chemicals and injection of fracturing fluids, to the post-fracturing stage, including the management of flowback and produced water and its ultimate treatment and disposal. The study will include a review of the published literature, analysis of existing data, scenario evaluation and modeling, laboratory studies and case studies.

To ensure that EPA is up-to-date on evolving hydraulic fracturing practices and technologies, EPA is soliciting public involvement in identifying relevant data and scientific literature specific to inform EPA's research study on the potential impacts of hydraulic fracturing on drinking water resources. While EPA conducts a thorough literature search, there may be studies or other primary technical sources that are not available through the open literature. EPA would appreciate receiving information from the public to help inform current and future research and ensure a robust record of scientific information. Consistent with our commitment to using the highest quality information, EPA prefers information which has been peer reviewed. Interested persons may provide scientific analyses, studies and other pertinent scientific information. EPA will consider all submissions but will give preference to peer reviewed data and literature sources.

Dated: November 5, 2012.

E. Ramona Trovato,

Associate Assistant Administrator, Office of Research and Development.

[FR Doc. 2012–27452 Filed 11–8–12; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9005–9]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/*.

Weekly Receipt of Environmental Impact Statements

Filed 10/29/2012 Through 11/02/2012 Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html*.

SUPPLEMENTARY INFORMATION: As of October 1, 2012, EPA will not accept paper copies or CDs of EISs for filing purposes; all submissions on or after October 1, 2012 must be made through e-NEPA.

While this system eliminates the need to submit paper or CD copies to EPA to meet filing requirements, electronic submission does not change requirements for distribution of EISs for public review and comment. To begin using e-NEPA, you must first register with EPA's electronic reporting site—*https://cdx.epa.gov/epa_home.asp.*

EIS No. 20120352, Final EIS, USFS, UT, Chicken Creek Gypsum Mine, Proposed Plan of Operations to Conduct Mining Operations, San Pitch Mountains, Sanpete Ranger District, Manti-La Sal National Forest, Juab County, UT, Review Period Ends: 12/10/2012, Contact: Karl Boyer 435–637–2817.

EIS No. 20120353, Final EIS, FHWA, IL, TIER 2—Elgin O'Hare—West Bypass, Extending the Planning Period from 2030 to 2040, Federal Approvals and Funding, Cook and DuPage Counties, IL, Review Period Ends: 12/10/2012, Contact: Norman Stoner 217–492–4600 The U.S. Department of Transportation's Federal Highway Administration and Federal Aviation Administration are joint lead agencies for this project.

EIS No. 20120354, Draft EIS, FRA, 00, Chicago to Council Bluffs—Omaha Regional Passenger Rail System Planning Study Tier 1 Service Level, from Chicago, Illinois through Iowa and Omaha, NE., Comment Period Ends: 12/26/2012, Contact: Andrea Martin 202–493–6201.

EIS No. 20120355, Final EIS, FRA, 00, Chicago to St. Louis High Speed Rail Program Tier 1, Improvements, Several Counties, IL and St. Louis County, MO, Review Period Ends: 12/10/2012, Contact: Andrea Martin 202–493–6201.

EIS No. 20120356, Draft EIS, BLM, AZ, Sun Valley to Morgan 500/230kV Transmission Line Project and Draft Resource Management Plan Amendment, Maricopa County, AZ, Comment Period Ends: 02/08/2013, Contact: Joe Incardine 801–560–7135.

EIS No. 20120357, Final Supplement, USFWS, CA, Translocation of Southern Sea Otters (Enhydra lutris nereis) Program, New and Updated Information, Santa Barbara, Ventura, Los Angeles, Orange, and San Diego Counties, CA, Review Period Ends: 12/10/2012, Contact: Lilian Carswell 805–644–1766.

EIS No. 20120358, Draft Supplement, BOEM, 00, Gulf of Mexico Outer Continental Shelf (OCS) Oil and Gas Lease Sales: 2013–2014 Western Planning Area Lease Sales 233: Central Planning Area Lease Sales 231, Comment Period Ends: 12/24/2012, Contact: Gary D. Goeke 504–736–3233.

EIS No. 20120359, Final EIS, USACE, CA, Clearwater Program, Master Facilities Plan, To Meet the Wastewater Management Needs of the Joint Outfall System (JOS) Through the Year 2050, Los Angeles County, CA, Review Period Ends: 12/10/2012, Contact: Aaron O. Allen 805–585–2148.

EIS No. 20120360, Final EIS, BLM, 00, PROGRAMMATIC—Allocation of Oil Shale and Tar Sands Resources on Lands Administered, Propose to Amend 10 Land Use Plans in Colorado, Utah, and Wyoming, Review Period Ends: 12/10/2012, Contact: Sherri Thompson 303–239–3758.

Amended Notices

EIS No. 20120294, Draft EIS, USN, OR, Naval Weapons Systems Training Facility Boardman, Military Readiness Activities, OR, Comment Period Ends: 12/06/2012, Contact: Amy Burt 360–396–0924.

Dated: November 6, 2012.

Cliff Rader,

Director, NEPA Compliance Division, Office of Federal Activities,

[FR Doc. 2012–27404 Filed 11–8–12; 8:45 am]

BILLING CODE 6560–50–P

EXPORT–IMPORT BANK

[Public Notice: 2012–0539]

Application for Final Commitment for a Long-Term Loan or Financial Guarantee in Excess of $100 Million; 25 Day Comment Period

AGENCY: Export-Import Bank of the United States.

ACTION: Notice of 25 day comment period regarding an application for final commitment for a long-term loan or financial guarantee in excess of $100 million.

Reason for Notice: This Notice is to inform the public, in accordance with Section 3(c)(10) of the Charter of the Export-Import Bank of the United States (''Ex-Im Bank''), that Ex-Im Bank has received an application for final commitment for a long-term loan or financial guarantee in excess of $100 million (as calculated in accordance with Section 3(c)(10) of the Charter). Comments received within the comment period specified below will be presented to the Ex-Im Bank Board of Directors prior to final action on this Transaction.

Reference: AP086754XX, AP087318XX, and AP087407XX.

Purpose and Use:

Brief description of the purpose of the transaction:

To support the export of mining trucks and bulldozers to Ukraine.

Brief non-proprietary description of the anticipated use of the items being exported:

To mine iron ore in Ukraine

To the extent that Ex-Im Bank is reasonably aware, the item(s) being exported are not expected to produce exports or provide services in competition with the exportation of goods or provision of services by a United States industry.

Parties:

Principal Supplier: Caterpillar Inc.

Obligors: OJSC Ferrexpo Poltava Mining, Ukraine; OJSC Ferrexpo Yeristovo Mining, Ukraine; OJSC Ferrexpo Belanovo Mining, Ukraine.

Guarantor(s): Ferrexpo AG, Switzerland.

Description of Items Being Exported:

Caterpillar mining trucks and bulldozers.

Information on Decision: Information on the final decision for this transaction will be available in the ''Summary Minutes of Meetings of Board of Directors'' on *http://www.exim.gov/articles.cfm/board%20minute.*

Confidential Information: Please note that this notice does not include confidential or proprietary business information; information which, if disclosed, would violate the Trade Secrets Act; or information which would jeopardize jobs in the United States by supplying information that competitors could use to compete with companies in the United States.

DATES: Comments must be received on or before *December 4, 2012* to be assured of consideration before final consideration of the transaction by the Board of Directors of Ex-Im Bank.

ADDRESSES: Comments may be submitted through *WWW.REGULATIONS.GOV.*

Sharon A. Whitt,

Agency Clearance Officer.

[FR Doc. 2012–27380 Filed 11–8–12; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

Sunshine Act Meeting

Notice of a Partially Open Meeting of the Board of Directors of the Export-Import Bank of the United States.

TIME AND PLACE: Monday, November 19, 2012 at 9:30 a.m. The meeting will be held at Ex-Im Bank in Room 321, 811 Vermont Avenue NW., Washington, DC 20571.

OPEN AGENDA ITEMS: Item No. 1: Proposed Economic Impact Procedures and Methodological Guidelines. Documentation including the proposed Economic Impact Procedures and Methodological Guidelines as well as the public comment can be accessed at the following location: *http://www.exim.gov/generalbankpolicies/economicimpact/proposed-economic-impact-procedures.cfm*

PUBLIC PARTICIPATION: The meeting will be open to public observation for Item No. 1 only.

FURTHER INFORMATION: The Bank requests that members of the public who wish to attend the meeting call Joyce Stone, Office of the Secretary, 811 Vermont Avenue NW., Washington, DC 20571 at (202) 565–3336 by close of business Wednesday, November 14, 2012.

Lisa V. Terry,

Assistant General Counsel.

[FR Doc. 2012–27421 Filed 11–7–12; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 12–1620]

Notice of Suspension and Commencement of Proposed Debarment Proceedings; Schools and Libraries Universal Service Support Mechanism

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The Enforcement Bureau (the ''Bureau'') gives notice of Ms. Denisa Babcock's suspension from the schools and libraries universal service support mechanism (or ''E-Rate Program''). Additionally, the Bureau gives notice that debarment proceedings are commencing against her. Ms. Babcock, or any person who has an existing contract with or intends to contract with her to provide or receive services in matters arising out of activities associated with or related to the schools and libraries support, may respond by filing an opposition request, supported by documentation to Joy Ragsdale, Federal Communications Commission, Enforcement Bureau, Investigations and Hearings Division, Room 4–C330, 445 12th Street SW., Washington, DC 20554.

DATES: Opposition requests must be received by 30 days from the receipt of the suspension letter or December 10, 2012, whichever comes first. The Bureau will decide any opposition request for reversal or modification of suspension or debarment within 90 days of its receipt of such requests.

ADDRESSES: Federal Communications Commission, Enforcement Bureau, Investigations and Hearings Division, Room 4–C330, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Joy Ragsdale, Federal Communications Commission, Enforcement Bureau, Investigations and Hearings Division, Room 4–C330, 445 12th Street SW., Washington, DC 20554. Joy Ragsdale may be contacted by phone at (202) 418–1697 or email at *Joy.Ragsdale@fcc.gov*. If Ms. Ragsdale is unavailable, you may contact Ms. Theresa Cavanaugh, Chief, Investigations and Hearings Division, by telephone at (202) 418–1420 and by email at *Terry.Cavanaugh@fcc.gov*.

SUPPLEMENTARY INFORMATION: The Bureau has suspension and debarment authority pursuant to 47 CFR 54.8 and 47 CFR 0.111(a)(14). Suspension will help to ensure that the party to be suspended cannot continue to benefit from the schools and libraries mechanism pending resolution of the debarment process. Attached is the suspension letter, DA 12–1620, which was mailed to Ms. Babcock and released on October 10, 2012. The complete text of the notice of suspension and initiation of debarment proceedings is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portal II, 445 12th Street SW., Room CY–A257, Washington, DC 20554, In addition, the complete text is available on the FCC's Web site at

http://www.fcc.gov. The text may also be purchased from the Commission's duplicating inspection and copying during regular business hours at the contractor, Best Copy and Printing, Inc., Portal II, 445 12th Street SW., Room CY–B420, Washington, DC 20554, telephone (202) 488–5300 or (800) 378–3160, facsimile (202) 488–5563, or via email *http://www.bcpiweb.com*.

Federal Communications Commission.

Dated: October 10, 2012.

Theresa Z. Cavanaugh,

Chief, Investigations and Hearings Division, Enforcement Bureau.

DA 12–1620

SENT VIA CERTIFIED MAIL, RETURN RECEIPT REQUESTED AND EMAIL

Ms. Denisa Babcock, c/o Leon Fred Spies, Mellon & Spies, 312 E. College Street, Suite 216, Iowa City, IA 52240

Re: Notice of Suspension and Initiation of Debarment Proceedings FCC File No. EB–12–IH–1396

Dear Ms. Babcock: The Federal Communications Commission (Commission) has received notice of your conviction, under 18 U.S.C. 666(a)(1)(A) and (b), for theft of, among other amounts, funds associated with the federal schools and libraries universal service support mechanism (E-Rate program).[1] Consequently, pursuant to 47 CFR 54.8, this letter constitutes official notice of your suspension from the E-Rate program. In addition, the Enforcement Bureau (Bureau) hereby notifies you that the Bureau will commence E-Rate program debarment proceedings against you.[2]

I. Notice of Suspension

The Commission has established procedures to prevent persons who have ''defrauded the government or engaged in similar acts through activities associated with or related to the [E-Rate program]'' from receiving the benefits associated with that program.[3] The Commission's rules are designed to ensure that all E-Rate funds are used for their intended purpose.[4]

On May 11, 2011, you pled guilty to converting more than $1,000,000 belonging to various school districts for your personal use from November 2005 through December 2009.[5] That amount included approximately $49,000 in E-Rate checks that had been payable to school districts you represented through your E-Rate consulting company, Camanche Consulting Services (CCS).[6] According to your Plea Agreement, you knowingly deposited E-Rate checks payable to these school districts into your personal bank accounts without the authority to do so.[7] Along with the other funds stolen from the various school districts, you used these stolen E-Rate funds to help pay off your home mortgage, fund retirement plans, and purchase vehicles, real property, a boat, travel, and personal items.[8]

On October 14, 2011, the United States District Court for the Southern District of Iowa sentenced you to serve 64 months in prison followed by a three-year period of supervised release.[9] In addition, the court ordered you to pay $1,330,215.96 in restitution and a $100 special assessment.[10]

Pursuant to § 54.8(b) of the Commission's rules,[11] upon your conviction for theft of E-Rate funds, the Bureau is required to suspend you from participating in any activities associated with or related to the E-Rate program, including the receipt of funds or discounted services through the E-Rate program, or consulting with, assisting, or advising applicants or service providers regarding the E-Rate program.[12] Your suspension becomes effective upon either your receipt of this letter or its publication in the **Federal Register**, whichever comes first.[13]

In accordance with the Commission's suspension and debarment rules, you may contest this suspension or the scope of this suspension by filing arguments, with any relevant documents, within thirty (30) calendar days of your receipt of this letter or [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], whichever comes first.[14] Such requests, however, will not ordinarily be granted.[15] The Bureau may reverse or limit the scope of a suspension only upon a finding of extraordinary circumstances.[16] The Bureau will decide any request to reverse or modify a suspension within ninety (90) calendar days of its receipt of such request.[17]

II. Initiation of Debarment Proceedings

In addition to requiring your immediate suspension from the E-Rate program, your conviction is cause for debarment as defined in § 54.8(c) of the Commission's rules.[18] Therefore,

[1] Any further reference in this letter to ''your conviction'' refers to your guilty plea in *United States v. Babcock,* Criminal Docket No. 3:10–cr–00074–RP–TJS–1, Plea Agreement (S.D. Iowa, May 11, 2011) (*Plea Agreement*).

[2] *See* 47 CFR 0.111 (delegating to the Bureau authority to resolve universal service suspension and debarment proceedings). The Commission adopted debarment rules for the E-Rate program in 2003. *See Schools and Libraries Universal Service Support Mechanism,* Second Report and Order and Further Notice of Proposed Rulemaking, 18 FCC Rcd 9202 (2003) (*Second Report and Order)* (adopting § 54.521 to suspend and debar parties from the E-Rate program). In 2007, the Commission extended the debarment rules to apply to all federal universal service support mechanisms. *Comprehensive Review of the Universal Service Fund Management, Administration, and Oversight; Federal-State Joint Board on Universal Service; Schools and Libraries Universal Service Support Mechanism; Rural Health Care Support Mechanism; Lifeline and Link Up; Changes to the Board of Directors for the National Exchange Carrier Association, Inc.,* Report and Order, 22 FCC Rcd 16372, 16410–12 (2007) (*Program Management Order*) (renumbering § 54.521 of the universal service debarment rules as § 54.8 and amending subsections (a)(1), (a)(5), (c), (d), (e)(2)(i), (e)(3), (e)(4), and (g)).

[3] *Second Report and Order,* 18 FCC Rcd at 9225, para. 66; *Program Management Order,* 22 FCC Rcd at 16387, para. 32. The Commission's debarment rules define a ''person'' as ''[a]ny individual, group of individuals, corporation, partnership, association, unit of government or legal entity, however organized.'' 47 CFR 54.8(a)(6).

[4] *NEC-Business Network Solutions, Inc.,* Notice of Debarment and Order Denying Waiver Petition, 21 FCC Rcd 7491, 7493, para. 7 (2006).

[5] *Plea Agreement* at 1, 17–18; *see also United States Attorney's Office, Southern District of Iowa,* News, *Former Clinton Community School District Employee Pleads Guilty to Theft of Federal Funds,* May 11, 2011, *at http://www.justice.gov/usao/ias/news/2011/Babcock%20-%20plea%20-%20media%20release%20-%205-10-11.pdf (Press Release).*

[6] *Plea Agreement* at 17.

[7] *Id.*

[8] *Id.* at 18.

[9] *United States v. Babcock,* Criminal Docket No. 3:10–cr–00074–RP–TJS–1, Amended Judgment at 2 (S.D. Iowa, entered Jan. 23, 2012) (*Amended Judgment*).

[10] *Amended Judgment* at 4–5. This restitution order includes: $8,061.77 payable to Bement Community School District Five; $2,231.28 payable to the Chester Area School District; $21,789.40 payable to the Lena-Winslow School District; $17,933.80 payable to North Boone School District 200; $1,852.03 payable to Oldham Public Library; and $4,270.64 payable to West Carroll Community School District No. 314. *Id.* at 4. In addition, you were ordered to forfeit, among other items, E-Rate checks that FBI agents had seized from your residence. Plea Agreement at 6–7.

[11] 47 CFR 54.8(a)(4); *see Second Report and Order,* 18 FCC Rcd at 9225–27, paras. 67–74.

[12] 47 CFR 54.8(a)(1), (d).

[13] *Second Report and Order,* 18 FCC Rcd at 9226, para. 69; 47 CFR 54.8(e)(1).

[14] 47 CFR 54.8(e)(4).

[15] *Id.*

[16] 47 CFR 54.8(f).

[17] *Second Report and Order,* 18 FCC Rcd at 9226, para. 70; 47 CFR 54.8(e)(5), (f).

[18] ''Causes for suspension and debarment are conviction of or civil judgment for attempt or commission of criminal fraud, theft, embezzlement, forgery, bribery, falsification or destruction of records, making false statements, receiving stolen property, making false claims, obstruction of justice and other fraud or criminal offense arising out of activities associated with or related to the schools and libraries support mechanism, the high-cost support mechanism, the rural healthcare support mechanism, and the low-income support mechanism.'' 47 CFR. 54.8(c). Associated activities ''include the receipt of funds or discounted services through [the federal universal service] support mechanisms, or consulting with, assisting, or advising applicants or service providers regarding [the federal universal service] support mechanisms.'' *Id.* 54.8(a)(1).

pursuant to § 54.8(b) of the Commission's rules, your conviction requires the Bureau to commence debarment proceedings against you.[19]

As with the suspension process, you may contest the proposed debarment or the scope of the proposed debarment by filing arguments and any relevant documentation within thirty (30) calendar days of receipt of this letter or its publication in the **Federal Register**, whichever comes first.[20] The Bureau, in the absence of extraordinary circumstances, will notify you of its decision to debar within ninety (90) calendar days of receiving any information you may have filed.[21] If the Bureau decides to debar you, its decision will become effective upon either your receipt of a debarment notice or publication of the decision in the **Federal Register**, whichever comes first.[22]

If and when your debarment becomes effective, you will be prohibited from participating in activities associated with or related to the E-Rate program for three years from the date of debarment.[23] The Bureau may set a longer debarment period or extend an existing debarment period if necessary to protect the public interest.[24]

Please direct any response, if sent by messenger or hand delivery, to Marlene H. Dortch, Secretary, Federal Communications Commission, 445 12th Street SW., Room TW–A325, Washington, DC 20554 and to the attention of Joy M. Ragsdale, Attorney Advisor, Investigations and Hearings Division, Enforcement Bureau, Room 4–C330, Federal Communications Commission, 445 12th Street SW., Washington, DC 20554 with a copy to Theresa Z. Cavanaugh, Division Chief, Investigations and Hearings Division, Enforcement Bureau, Room 4–C330, Federal Communications Commission, 445 12th Street SW., Washington, DC 20554. All messenger or hand delivery filings must be submitted without envelopes.[25] If sent by commercial overnight mail (other than U.S. Postal Service (USPS) Express Mail and Priority Mail), the response must be sent to the Federal Communications Commission, 9300 East Hampton Drive, Capitol Heights, Maryland 20743. If sent by USPS First Class, Express Mail, or Priority Mail, the response should be addressed to Joy Ragsdale, Attorney Advisor, Investigations and Hearings Division, Enforcement Bureau, Federal Communications Commission, 445 12th Street SW., Room 4–C330, Washington, DC 20554, with a copy to Theresa Z. Cavanaugh, Chief, Investigations and Hearings Division, Enforcement Bureau, Federal Communications Commission, 445 12th Street SW., Room 4–C330, Washington, DC 20554. You shall also transmit a copy of your response via email to Joy M. Ragsdale, *Joy.Ragsdale@fcc.gov* and to Theresa Z. Cavanaugh, *Terry.Cavanaugh@fcc.gov*.

If you have any questions, please contact Ms. Ragsdale via U.S. postal mail, email, or by telephone at (202) 418–1697. You may contact me at (202) 418–1553 or at the email address noted above if Ms. Ragsdale is unavailable.

Sincerely yours,
Theresa Z. Cavanaugh,
Chief, Investigations and Hearings Division, Enforcement Bureau

cc: Johnnay Schrieber, Universal Service Administrative Company (via email); Rashann Duvall, Universal Service Administrative Company (via email); Maureen McGuire, United States Attorney's Office, Southern District of Iowa (via email); Richard Westphal, United States Attorney's Office, Southern District of Iowa (via email)

[FR Doc. 2012–27348 Filed 11–8–12; 8:45 am]

BILLING CODE 6712–01–P

[19] *Id.* 54.8(b).

[20] *Second Report and Order,* 18 FCC Rcd at 9226, para. 70; 47 CFR § 54.8(e)(3).

[21] *Second Report and Order,* 18 FCC Rcd at 9226, para. 70; 47 CFR. § 54.8(e)(5).

[22] 47 CFR 54.8(e)(5). The Commission may reverse a debarment, or may limit the scope or period of debarment, upon a finding of extraordinary circumstances, following the filing of a petition by you or an interested party or upon motion by the Commission. *Id.* 54.8(f).

[23] *Second Report and Order,* 18 FCC Rcd at 9225, para. 67; 47 CFR 54.8(d), (g).

[24] 47 CFR 54.8(g).

[25] *See FCC Public Notice,* DA 09–2529 for further filing instructions (rel. Dec. 3, 2009).

FEDERAL MARITIME COMMISSION

Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov*.

Agreement No.: 201157–002.

Title: USMX–ILA Master Contract between United States Maritime Alliance, Ltd. and International Longshoremen's Association.

Parties: United States Maritime Alliance, Ltd., on behalf of Management, and the International Longshoremen's Association, AFL–CIO.

Filing Parties: William M. Spelman, Esq.; The Lambos Firm; 29 Broadway, 9th Floor; New York, NY 10006 and Andre Mazzola, Esq.; Marrinan & Mazzola Mardon, P.C.; 26 Broadway, 17th Floor; New York, NY 10004.

Synopsis: The amendment extends the terms and conditions of USMX–ILA Master Contract to December 29, 2012, without any changes by USMX and the ILA.

By Order of the Federal Maritime Commission.

Dated: November 6, 2012.

Karen V. Gregory,
Secretary.

[FR Doc. 2012–27392 Filed 11–8–12; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than November 27, 2012.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *G. Jeffrey Records, Jr.,* Oklahoma City, Oklahoma; as trustee, of the Martha E. Records 2009 GST Exempt Family Trust; the Martha E. Records 2009 Non-Exempt Family Trust; the Kathryn R. Ryan 2007 GST Exempt Family Trust; the Kathryn R. Ryan 2007 Non-Exempt Family Trust; and the George J. and Nancy J. Records 1990 Irrevocable Trust, all in Oklahoma City, Oklahoma, to acquire voting shares of Midland Financial Co., and thereby indirectly acquire voting shares of MidFirst Bank, both in Oklahoma City, Oklahoma.

Board of Governors of the Federal Reserve System, November 6, 2012.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2012–27411 Filed 11–8–12; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Docket 2012–0076; Sequence 34; OMB Control No. 9000–0088]

Federal Acquisition Regulation; Information Collection; Travel Costs

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding the extension of a previously existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning Travel Costs.

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

DATES: Submit comments on or before January 8, 2013.

ADDRESSES: Submit comments identified by *Information Collection 9000–0088, Travel Costs* by any of the following methods:

- Regulations.gov: *http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0088, Travel Costs''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0088, Travel Costs'' on your attached document.
- Fax: 202–501–4067.
- Mail: General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417. ATTN: Hada Flowers/IC 9000–0088, Travel Costs.

Instructions: Please submit comments only and cite Information Collection 9000–0088, Travel Costs, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Edward Chambers, Procurement Analyst, Office of Acquisition Policy, GSA, (202) 501–3221 or via email at *Edward.chambers@gsa.gov.*

A. Purpose

FAR 31.205–46, Travel Costs, requires that, except in extraordinary and temporary situations, costs incurred by a contractor for lodging, meals, and incidental expenses shall be considered to be reasonable and allowable only to the extent that they do not exceed on a daily basis the per diem rates in effect as of the time of travel as set forth in the Federal Travel Regulations for travel in the conterminous 48 United States, the Joint Travel Regulations, Volume 2, Appendix A, for travel is Alaska, Hawaii, the Commonwealth of Puerto Rico, and territories and possessions of the United States, and the Department of State Standardized Regulations, section 925, ''Maximum Travel Per Diem Allowances for Foreign Areas.'' The burden generated by this coverage is in the form of the contractor preparing a justification whenever a higher actual expense reimbursement method is used.

B. Annual Reporting Burden

Respondents: 3,598.

Responses per Respondent: 10.

Total Responses: 35,980.

Hours per response: .25.

Total Burden Hours: 8,995.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0088, Travel Costs, in all correspondence.

Dated: November 1, 2012.

William Clark,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2012–27397 Filed 11–8–12; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Docket 2012–0076; Sequence 31; OMB Control No. 9000–0077]

Federal Acquisition Regulation; Information Collection; Quality Assurance Requirements

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning quality assurance requirements.

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

DATES: Submit comments on or before January 8, 2013.

ADDRESSES: Submit comments identified by *Information Collection 9000–0077, Quality Assurance Requirements,* by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by

searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0077, Quality Assurance Requirements''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0077, Quality Assurance Requirements'' on your attached document.

- Fax: 202–501–4067.
- Mail: General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417. ATTN: Hada Flowers/IC 9000–0077, Quality Assurance Requirements.

Instructions: Please submit comments only and cite Information Collection 9000–0077, Quality Assurance Requirements, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Curtis E. Glover, Sr., Procurement Analyst, Contract Policy Division, GSA (202) 501–1448 or email *Curtis.glover@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Supplies and services acquired under Government contracts must conform to the contract's quality and quantity requirements. FAR Part 46 prescribes inspection, acceptance, warranty, and other measures associated with quality requirements. Standard clauses related to inspection require the contractor to provide and maintain an inspection system that is acceptable to the Government; give the Government the right to make inspections and test while work is in process; and require the contractor to keep complete, and make available to the Government, records of its inspection work. The

B. Annual Reporting Burden

An upward adjustment is being made to the previously approved estimated annual burden. The change is based on calculating the burden for each clause in FAR Part 46 associated with this information collection requirement. In addition, the Government considered the information collected under this requirement to be records kept as a part of a contractor's normal business operations, and the Government will only request to see the records a limited number of times per year for each contractor.

Respondents: 176,286.

Responses per Respondent: 1.0186344.

Total Responses: 179,571.

Hours per Response: 82246.

Total Burden Hours: 147,690.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0077, Quality Assurance Requirements, in all correspondence.

Dated: November 1, 2012.

William Clark,

Acting Director, Federal Acquisition Policy, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2012–27399 Filed 11–8–12; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Physical Activity Guidelines Mid-Course Report Availability and Public Comment Period

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

Authority: 15 U.S.C. 3719.

SUMMARY: The U.S. Department of Health and Human Services (HHS) announces the availability of the Physical Activity Guidelines for Americans (PAG) Mid-course Report and solicits written comments on the draft report. A subcommittee of the President's Council on Fitness, Sports and Nutrition (PCFSN) was convened to complete the PAG Mid-course Report. The subcommittee was tasked with reviewing the evidence on intervention strategies that have been shown to be effective in increasing physical activity among youth ages 3–17. The report is a review-of-reviews which highlights research from a variety of settings in which physical activity can successfully be implemented for youth, including school, community, preschool/childcare, home/family, and primary care settings. In addition, the report identifies areas for future research.

The intent of this report is to serve as a complement to the *Physical Activity Guidelines for Americans, 2008* which recommends that youth ages 6–17 engage in at least 60 minutes of physical activity each day and provides strategies for increasing physical activity in youth toward meeting the PAG. Although the PAG did not include specific recommendations for youth younger than age 6, the PAG Mid-course Report includes intervention strategies in the preschool/childcare setting. This is a response to new science on physical activity among young children and supports HHS' efforts through Healthy People 2020 to promote physical activity in childcare settings. The subcommittee has completed its draft report and is soliciting public comment before the report is presented to PCFSN for deliberation, and subsequent submission to the Secretary, HHS.

DATES: Written comments on the PAG Mid-course Report can be submitted by email or mail and must be received on or before December 10, 2012 at 9:00 a.m. EST.

ADDRESSES: The PAG Mid-course Report is available for review electronically at *www.health.gov/PAguidelines.* Comments may be either emailed to *PhysicalActivityGuidelines@hhs.gov* or mailed to Katrina Butner, Office of Disease Prevention and Health Promotion, Department of Health and Human Services, 1101 Wootton Parkway, Suite LL100, Rockville, MD 20852. For those submitting written comments of more than 5 pages in length, please provide a 1-page summary of key points related to the comments submitted.

FOR FURTHER INFORMATION CONTACT: Katrina L. Butner, Ph.D., RD, ACSM CES, Coordinator, Physical Activity Guidelines for Americans Mid-course Report, Physical Activity and Nutrition Advisor, Office of Disease Prevention and Health Promotion, Department of Health and Human Services, 1101 Wootton Parkway, LL100, Rockville, MD 20852. Email: *Katrina.Butner@hhs.gov.* Phone: (240) 453–8271.

SUPPLEMENTARY INFORMATION: A subcommittee of the President's Council on Fitness, Sports and Nutrition (PCFSN) was created with approval of the Secretary, HHS. The subcommittee is comprised of ten experts in physical activity from both federal and non-federal sectors and is chaired by Council member, Dr. Risa Lavizzo-Mourey. The PAG Mid-course Report will serve as a complement to the *Physical Activity Guidelines for Americans, 2008* and is expected to be released in 2013.

The PAG Mid-course Report is available electronically at *www.health.gov/PAguidelines.* Hard copies may be obtained by contacting

the individual named within the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Dated: September 24, 2012.

Don Wright,

Director, Office of Disease Prevention and Health Promotion.

[FR Doc. 2012–27425 Filed 11–8–12; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9075–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July through September 2012

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

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July through September 2012, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone No.
I CMS Manual Instructions	Ismael Torres	(410) 786–1864
II Regulation Documents Published in the **Federal Register**	Terri Plumb	(410) 786–4481
III CMS Rulings	Tiffany Lafferty	(410) 786–7548
IV Medicare National Coverage Determinations	Wanda Belle	(410) 786–7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786–6877
VI Collections of Information	Mitch Bryman	(410) 786–5258
VII Medicare-Approved Carotid Stent Facilities	Sarah J. McClain	(410) 786–2294
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	JoAnna Baldwin, MS	(410) 786–7205
IX Medicare's Active Coverage-Related Guidance Documents	Lori Ashby	(410) 786–6322
X One-Time Notices Regarding National Coverage Provisions	Lori Ashby	(410) 786–6322
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786–8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	JoAnna Baldwin, MS	(410) 786–7205
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	JoAnna Baldwin, MS	(410) 786–7205
XIV Medicare-Approved Bariatric Surgery Facilities	Kate Tillman, RN, MAS	(410) 786–9252
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786–8564
All Other Information	Annette Brewer	(410) 786–6580

I. Background

Among other things, the Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) Furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, State governments, State Medicaid agencies, State survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Revised Format for the Quarterly Issuance Notices

While we are publishing the quarterly notice required by section 1871(c) of the Act, we will no longer republish duplicative information that is available to the public elsewhere. We believe this approach is in alignment with CMS' commitment to the general principles of the President's Executive Order 13563 released January 2011entitled ''Improving Regulation and Regulatory Review,'' which promotes modifying and streamlining an agency's regulatory program to be more effective in achieving regulatory objectives. Section 6 of Executive Order 13563 requires agencies to identify regulations that may be ''outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand or repeal them in accordance with what has been learned.'' This approach is also in alignment with the President's Open Government and Transparency Initiative that establishes a system of transparency, public participation, and collaboration.

Therefore, this quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS Web site or the appropriate data registries that are used as our resources. This information is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the Web site list provides more timely access for beneficiaries, providers, and suppliers. We also believe the Web site offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and ''real time'' accessibility. In addition, many of the Web sites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the Web site. These listservs avoid the need to check the Web site, as notification of

updates is automatic and sent to the subscriber as they occur. If assessing a Web site proves to be difficult, the contact person listed can provide information.

III. How To Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at *http://www.cms.gov/manuals.*

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, Program No. 93.774, Medicare—Supplementary Medical Insurance Program, and Program No. 93.714, Medical Assistance Program)

Dated: November 5, 2012.

Kathleen Cantwell,

Director, Office of Strategic Operations and Regulatory Affairs.

BILLING CODE 4120–01–P

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: December 16, 2011 (76 FR 78267), February 21, 2012 (77 FR 9931), May 18, 2012 (77 FR 29648) and August 17, 2012 (77 FR 49799). For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (July through September 2012)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: http://cms.gov/manuals.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the Medicare National Coverage Determination publication titled Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) use CMS-Pub. 100-03, Transmittal No. 144.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual. For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
79	January 2013 Quarterly Updates to the CMS Standard File for Reason Codes for the Fiscal Intermediary Shared System (FISS)
Medicare Benefit Policy (CMS-Pub. 100-02)	
00	None
Medicare National Coverage Determination (CMS-Pub. 100-03)	
144	Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)
145	National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR)
146	Liver Transplantation for Patients with Malignancies Transcatheter Aortic Valve Replacement (TAVR) Adult Liver Transplantation
Medicare Claims Processing (CMS-Pub. 100-04)	
2494	Pharmacy Billing for Drugs Provided "Incident To" a Physician Service This CR rescinds and fully replaces CR 7109.
2495	Validation of Payment Group Codes for Prospective Payment Systems (PPS)

	Based on Patient Assessments Systematic Validation of Claims Information Using Patient Assessments
2496	New Waived Tests
2497	Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and the Hospice Prices for FY 2013
2498	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2499	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2500	Clarification of the Use of the Electronic Claim Format to Indicate Where a Service Was Performed Payment Jurisdiction Among Local B/MACs for Services Paid Under the Physician Fee Schedule and Anesthesia Claims Processing Instructions for Payment Jurisdiction Conditional Data Element Requirements for A/B MACs and DMEMACs
2501	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2502	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2503	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2504	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2505	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2506	Extracorporeal Photopheresis (ICD-10)
2507	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System (PPS) Pricer Update FY 2013
2508	Claim Status Category and Claim Status Codes Update
2509	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2510	Payment of Global Surgical Split Care in a Method II Critical Access Hospital (CAH) Submitted with Modifier 54 and/or 55
2511	Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)
2512	National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) Transcatheter Aortic Valve Replacement (TAVR) Furnished on or After May 1, 2012 Coding Requirements for Requirements for Transcatheter Aortic Valve Replacement (TAVR) Services Furnished On or After May 1, 2012 Claims Processing Requirements for TAVR Services on Professional Claims Claims Processing Requirements for TAVR Services on Inpatient Hospital Claim
2513	Liver Transplantation for Patients with Malignancies Liver Transplants
2514	October 2012 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files Notification for Beneficiaries Exceeding Financial Limitations
2515	Handling Form CMS-1500 Hard Copy Claims Where an ICD-9-CM "E" Code or Where an ICD-10 V00-Y99 Code is Reported as the First Diagnosis on the Claim Conditional Data Element Requirements for A/B MACs and DMEMACs Consolidated Claims Crossover Process Claims Crossover Disposition and Coordination of Benefits Agreement By-Pass Indicators
2516	New Non- Physician Specialty Code for Centralized Flu Nonphysician Practitioner, Supplier, and Provider Specialty Codes
2517	Medicare Claims Processing Pub. 100-04 Chapter 24 Update for Security Requirements
2518	Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment System (PPS) Pricer Changes for FY 2013 Payment Provisions Under IRF PPS
2519	New Fiscal Intermediary Shared System (FISS) Consistency Edit to Validate Attending Physician NPI
2520	Update-Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS) Fiscal Year (FY) 2013 Annual Update
2521	Claim Adjustment Reason Code (CARC), Remittance Advice Remark Code (RARC), and Medicare Remit Easy Print (MREP) and PC Print Update
2522	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2523	Revised Medicare Summary Notice (MSN) Message Regarding Outpatient Therapy Caps
2524	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2525	October 2012 Update of the Ambulatory Surgical Center Payment System (ASC)
2526	Annual Update for the Health Professional Shortage Area (HPSA) Bonus Payments
2527	Issued to a specific audience, not posted to Internet/Intranet/ due to Sensitivity of Instruction
2528	Instructions for Downloading the Medicare ZIP Code File for January 2013
2529	Healthcare Common Procedure Coding System (HCPCS) Annual Update Reminder
2530	October Update to the CY 2012 Medicare Physician Fee Schedule Database (MPFSDB)
2531	October 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS) Transitional Outpatient Payments (TOPs) for CY 2010 through CY 2012 Fiscal Intermediary Billing Requirements
2532	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2533	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2534	Healthcare Provider Taxonomy Codes (HPTC) Update, October 2012
2535	Chapter 24 Update to Remove Outdated Information FIs, Carriers, RHHIs, A/B MACs, and CEDI HIPAA Claim Level Edits Institutional Implementation Guide (IG) Edits Institutional Implementation Guide and Direct Data Entry Edits

2536	Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2012
2537	Expiration of 2012 Therapy Cap Revisions and User-Controlled Mechanism to Identify Legislative Effective Dates S
2538	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2539	Fiscal Year (FY) 2013 Inpatient Prospective Payment System (IPPS), Long Term Care Hospital (LTCH) PPS Changes Medicare Code Editor (MCE) Disproportionate Share Hospital (DSH) Policy Changes Effective for Cost Reporting Periods beginning on or after October 1, 2009 Disproportionate Share Hospital (DSH) Policy Changes Effective for Cost Reporting Periods beginning on or after October 1, 2012 Repeat Admissions Outpatient Services Treated as Inpatient Services Replaced Devices Offered Without Cost or With a Credit Addenda A-Provider Specific File
2540	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2541	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
2542	2013 Annual Update of Healthcare Common Procedure Coding System (HCPCS) Codes for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Update
2543	Extracorporeal Photopheresis (ICD-10) Billing Requirements for Extracorporeal Photopheresis Healthcare Common Procedural Coding System (HCPCS), Applicable Diagnosis Codes and Procedure Code Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RAs) and Claim Adjustment Reason Code
2544	Contractor and Common Working File (CWF) Additional Instructions Related to Change Request (CR) 7633 - Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse
2545	Issued to a specific audience, not posted to Internet/ Intranet due to Confidentiality of Instruction
2546	Instructions for Retrieving the 2013 Pricing and HCPCS Data Files through CMS' Mainframe Telecommunications Systems
2547	Claim Status Category and Claim Status Codes Update
Medicare Secondary Payer (CMS-Pub. 100-05)	
87	Clarification of Medicare Conditional Payment Policy and Billing Procedures for Liability, No-Fault and Workers' Compensation Medicare Secondary Payer (MSP) Claims.
88	Expanding the Coordination of Benefits (COB) Contractor Numbers to include 11139 and 11142 for the Common Working File (CWF) Definition of MSP/CWF Terms
89	Expanding the Coordination of Benefits (COB) Contractor Numbers to include 11139 and 11142 for the Common Working File (CWF)
Medicare Financial Management (CMS-Pub. 100-06)	
211	Notice of New Interest Rate for Medicare Overpayments and Underpayments – 4th Notification for FY 2011
212	New Non- Physician Specialty Code for Centralized Flu Claims Processing
	Timeliness - All Claims Part E/Interest Payment Data Non-Physician Practitioner/Supplier Specialty Codes
210	Validation of Recovery Audit Program New Issues
Medicare State Operations Manual (CMS-Pub. 100-07)	
82	CMS Certification Numbers for Medicaid-Only Hospitals and New State Code for Foreign Countries
Medicare Program Integrity (CMS-Pub. 100-08)	
00	None
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
00	None
Medicare Quality Improvement Organization (CMS-Pub. 100-10)	
00	None
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
00	None
Medicare Managed Care (CMS-Pub. 100-16)	
108	This is the initial release of New Chapter 21, Compliance Program Guidelines
109	This is the initial release of New Chapter 21, Compliance Program Guidelines
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
00	None
Demonstrations (CMS-Pub. 100-19)	
84	Revisions to the Method of Cost Settlement for Inpatient Services for Rural Hospitals Participating Under Demonstration Authorized by Section 410A of the Medicare Modernization Act. Sections 3123 and 10313 of the Affordable Care Act authorizes an expansion of the demonstration and an extension for an additional 5-year period. This CR makes revisions to CR 7505, which gives instructions for the additional 5-year period.
One Time Notification (CMS-Pub. 100-20)	
1101	Reporting of Recoupment for Overpayment on the Remittance Advice (RA) with Patient Control Number
1102	Direction to Modify Institutional Reason Code 39012
1103	Health Insurance Portability and Accountability Act (HIPAA) 5010 and D.0 Execution of the Annual Recertification Program
1104	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1105	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
1106	Posting the Limiting Charge after Applying the e-Prescribing (eRx) Negative Adjustment
1107	The Medicare Secondary Payer Payment Module (MSPPAY) to be Maintained by the Shared System Maintainers for all Future Enhancements
1108	Fee For Service Common Eligibility Services (FFS CES) - Common Working File (CWF) Detail Analysis, Design and Requirements
1109	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
1110	Revision of Medicare Summary Notice (MSN) for Non-Competitive Bid Claims
1111	Expand Place of Service Address to Include Full Address

1112	Health Insurance Portability and Accountability Act (HIPAA) 5010 837 Institutional (8371) Edits and 5010 837 Professional (837P) Edits January 2012
1113	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1114	New Field Established within FISS and MCS
1115	Implement Fraud Prevention Predictive Modeling Prepayment Edits for Shared Systems (xref CR7787)
1116	Implement Fraud Prevention Predictive Modeling Prepayment Edits for Shared Systems (xref CR7787)
1117	Manual Medical Review of Therapy Services
1118	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
1119	Implementation of the Award for the Jurisdiction 5 Part A and Part B Medicare Administrative Contractor (J5 A/B MAC) Reprocurment Including a New Workload Number for the Remaining WPS Legacy Workload
1120	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
1121	None
1122	International Classification of Diseases (ICD)-10 Conversion from ICD-9 and Related Code Infrastructure of the Medicare Shared Systems as They Relate to CMS National Coverage Determinations (NCDs) (CR 1 of 3) (ICD-10)

Addendum II: Regulation Documents Published in the Federal Register (July through September 2012)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register,** contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at http://www.gpoaccess.gov/fr/index.html. The following Website http://www.archives.gov/federal-register/ provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our Website at: http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-3Q12QPU.pdf

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at http://www.cms.gov/Rulings/CMSR/list.asp#TopOfPage. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (July through September 2012)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we list only the specific updates that have occurred in the 3-month period. This information is available on our website at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Liver Transplantation for Malignancies	NCD 260.1	R146NCD	08/03/2012	07/13/2012
Transcutaneous Electrical Nerve Stimulation (TENS) Chronic Low Back Pain	NCD 160.27	R144NCD	08/03/2012	06/08/2012

Transcatheter Aortic Valve Replacement (TAVR)	NCD 20.32	R145NCD	08/03/2012	05/01/2012

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 2012)

Addendum V includes listings of the FDA-approved investigational device exemption (IDE) numbers that the FDA assigns. The listings are organized according to the categories to which the devices are assigned (that is, Category A or Category B), and identified by the IDE number. For the purposes of this quarterly notice, we list only the specific updates to the Category B IDEs as of the ending date of the period covered by this notice and a contact person for questions or additional information. For questions or additional information, contact John Manlove (410-786-6877).

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more information about the classes or categories, please refer to the notice published in the April 21, 1997 **Federal Register** (62 FR 19328).

IDE	Device	Start Date
BB15140	Magellan System	07/06/12
G100021	Stentys Coronary Stent System	09/12/12
G110112	Formula Balloon-Expandable Stent	07/18/12
G110162	Solace Intra Vesical Bladder Control System	08/09/12
G110186	Spinal Modulation Neurostimulator System	09/19/12
G110217	Unify Quadra MP CRT-DS Device	08/08/12
G110221	Siello S Pacing Leads	09/12/12
G110223	Consulta CRT-P Device	09/12/12
G110227	Ingevity Active Fixation and Passive Fixation Pace	07/13/12
G110229	Surpass Intracranial Embolization System	07/11/12
G120008	Pulmonx Zephyr Endobronchial Valve	07/19/12
G120010	NEO Baroreflex Activation Therapy	08/24/12
G120021	Intuitive Surgical Davinci	08/07/12
G120030	Nucleus Cochlear Implant System	07/19/12
G120075	Vercise Deep Brain Stimulation	07/25/12
G120076	Samurai Clinical Study	08/16/12
G120077	Reliance 4-Front Clinical Study	07/10/12
G120092	Non-Invasive Reduction of Fat in the Inner Thighs with the Zeltiq Cool Sculpting System	07/12/12
G120104	Robot-Assisted MRI-Guided Prostate Biopsy	08/09/12
G120133	Allegretto Wave Eye-Q Excimer Laser System	07/03/12
G120135	Deviate-AF	07/06/12
G120136	Zenith P-Branch	07/11/12
G120141	Embosphere Microspheres	09/11/12
G120142	Solitaire FR Revascularization Device	07/18/12
G120143	Michi Neuroprotection System	07/18/12
G120144	Supera Veritas Peripheral Sten System	07/18/12
G120146	Subqstim Study	07/20/12
G120147	Rescue-VT	07/19/12
G120149	Tria Beauty Fan Precision Device	07/18/12
G120150	Implantable Myoelectric Sensors for Upper Extremity Prosthetic Control in Transradial Amputees	07/25/12
G120151	Star S4 Excimer Laser System	07/24/12
G120152	Lifevest Wearable Cardioverter Defibrillator (WDC)	07/25/12
G120155	Prevent	07/26/12
G120162	Star SR IR Excimer Laser System and IDesign Advanced Wavescan Studio for Wavefront-Guided Lasik Treatment of Mixed Astig	08/08/12
G120164	Star SR IR Excimer Laser System and IDesign Advanced Wavescan Studio for Wavefront-Guided Lasik Treatment of Hyperopia	08/08/12
G120166	Ulthera System Model 8850-0001	08/15/12
G120169	Surtavi	08/15/12
G120171	Medtronic Reveal XT Isertable Cardiac Monitor Model 9529	08/24/12
G120175	Native Outflow Tract TPV System	08/30/12
G120176	B-Tevar Device	08/24/12
G120181	Intra-Articular Hyaluronan	08/29/12
G120183	C-Met Immunohistochemistry	09/05/12
G120188	Pulmonary Artery Repair with Covered Cheatham Platinum Stent	09/12/12
G120191	The Lone AFIB Trial	09/19/12
G120194	Nucleus 24 Auditory Brainstem Implant	09/21/12
G120195	The Moe Plasma Treatment System	09/17/12

Addendum VI: Approval Numbers for Collections of Information (July through September 2012)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact Mitch Bryman (410-786-5258).

Addendum VII: Medicare-Approved Carotid Stent Facilities, (July through September 2012)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing

carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available on our website at:
http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage
For questions or additional information, contact Sarah J. McClain (410-786-2294).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
Carlsbad Medical Center 2430 W. Pierce Street Carlsbad, NM 88220	320065	07/11/2012	NM
Denver Health Medical Center 777 Bannock Street, MC0960 Denver, CO 80204	060011	07/11/2012	CO
Galion Community Hospital 269 Portland Way South Galion, OH 44833	1215907522	07/18/2012	OH
Beaumont Health System – Troy 44201 Dequindre Road Troy, MI 48085	1306825997	07/25/2012	MI
Texoma Medical Center 5016 South US Hwy 75 Denison, TX 75020	1851390967	07/25/2012	TX
McLaren-Lapeer Region 1375 North Main Street Lapeer, MI 48446-1350	230193	08/06/2012	MI
Lutheran Medical Center 150 55th Street Brooklyn, NY 11220-2574	330306	08/20/2012	NY
Southside Regional Medical Center 200 Medical Park Boulevard Petersburg, VA 23805	490067	08/29/2012	VA
Saint Agnes Hospital 900 Caton Avenue Baltimore, MD 21229	210011	09/10/2012	MD
Mercy Hospital Washington 901 E 5th Street Washington, MO 63090	260052	09/13/2012	MO
St. Joseph Regional Medical Center 415 6th Street Lewiston, ID 83501	1225090954	09/24/2012	ID
Editorial changes (shown in bold) were made to the facilities listed below.			
From: Dakota Specialty Institute **To: Innovis Health dba Essentia Health** 3000 32nd Avenue SW Fargo, ND 58104	350070	06/05/2007	ND
Franciscan St. Anthony Health – Michigan City 301 West Homer Street Michigan City, IN 46360	150015	**07/06/2006**	IN
From: Kaleida Health, Millard Fillmore Hospital **3 Gates Circle Buffalo, NY 14209** **To: Buffalo General Medical Center** **100 High Street Buffalo, NY 14203**	330005	05/03/2005	NY
Galichia Heart Hospital 2610 N. Woodlawn Boulevard Wichita, KS 67220-2729	**170123**	05/16/2005	KS
From: Saint Joseph Medical Center **To: Alegent Creighton Health Creighton University Medical Center** 601 North 30th Street Omaha, NE 68131-2197	280030	06/27/2005	NE
The following facility has been removed from the listings of Medicare-approved carotid stent facilities.			
Saint Anthony Memorial 301 W. Homer Street Michigan City, IN 46360	150015	07/06/2006	IN

Addendum VIII:
American College of Cardiology's National Cardiovascular Data Registry Sites (July through September 2012)

Addendum VIII includes a list of the American College of Cardiology's National Cardiovascular Data Registry Sites. We cover implantable cardioverter defibrillators (ICDs) for certain clinical indications, as long as information about the procedures is reported to a central registry. Detailed descriptions of the covered indications are available in the NCD. In January 2005, CMS established the ICD Abstraction Tool through the Quality Network Exchange (QNet) as a temporary data collection mechanism. On October 27, 2005, CMS announced that the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) ICD Registry satisfies the data reporting requirements in the NCD. Hospitals needed to transition to the ACC-NCDR ICD Registry by April 2006.

Effective January 27, 2005, to obtain reimbursement, Medicare NCD policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. Details of the clinical indications that are covered by Medicare and their respective data reporting requirements are available in the Medicare NCD Manual, which is on the CMS Website at
http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the FDA or in the ACC-NCDR ICD registry. Therefore, for a beneficiary to receive a Medicare-covered ICD implantation for primary prevention, the beneficiary must receive the scan in a facility that participates in the ACC-NCDR ICD registry. The entire list of facilities that participate in the ACC-NCDR ICD registry can be found at www.ncdr.com/webncdr/common

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available by accessing our website and clicking on the link for the American College of Cardiology's National Cardiovascular Data Registry at: www.ncdr.com/webncdr/common. For questions or additional information, contact Joanna Baldwin, MS (410-786-7205).

Facility Name	City	State
The following facilities are new listings for this quarter.		
Children's Mercy Hospital	Kansas City	MO
Norwegian American Hospital	Chicago	IL
Lake Wales Medical Center	Lake Wales	FL
Thomas Hospital	Fairhope	AL
Ephraim McDowell Regional Medical Center	Danville	KY
Ponca City Medical Center	Ponca City	OK
Northwestern Lake Forest Hospital	Lake Forest	IL
Wentworth-Douglass Hospital	Dover	NH
Oro Valley Hospital	Ora Valley	AZ
Seton Medical Center Harker Heights	Harker Heights	TX
Jupiter Medical Center	Jupiter	FL
Hendricks Regional Health	Danville	IN
St. Anthony's Hospital	Houston	TX
Maine General Medical Center	Augusta	ME
Southeast Georgia Health System	Brunswick	GA
Central Vermont Medical Center Inc	Berlin	VT
Opelousas General Health System	Opelousas	LA
Lodi Memorial Hospital	Lodi	CA
Memorial Hospital of Tampa	Tampa	FL
San Francisco Heart and Vascular Institute	Daly City	CA
Feather River Hospital	Paradise	CA
Mercy Memorial Hospital	Monroe	MI
Palestine Regional Medical Center	Palestine	TX
University Medical Center	Lubbock	TX

Addendum IX: Active CMS Coverage-Related Guidance Documents (July through September 2012)

There were no CMS coverage-related guidance documents published in the July through September 2012 quarter. To obtain full-text copies of these documents, visit the CMS Coverage website at http://www.cms.gov/mcd/index_list.asp?list_type=mcd_1 and click on the archives link. For questions or additional information, contact Lori Ashby (410-786-6322).

Addendum X:
List of Special One-Time Notices Regarding National Coverage Provisions (July through September 2012)

There were no special one-time notices regarding national coverage provisions published in the July through September 2012 quarter. This information is available at www.cms.hhs.gov/coverage. For questions or additional information, contact Lori Ashby (410-786-6322).

Addendum XI: National Oncologic PET Registry (NOPR) (July through September 2012)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no updates to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the July through September 2012 quarter. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage.

For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564)

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (July through September 2012)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred to the list of Medicare-approved facilities that meet our standards in the 3-month period. This information is available on our website at http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Facility	Provider Number	Date Approved	State
The following facilities are new listings for this quarter.			
Abington Memorial Hospital 1200 Old York Road Abington, PA 19001	390231	07/10/2012	PA
Froedtert Memorial Lutheran Hospital 9200 West Wisconsin Avenue Milwaukee, WI 53226	520177	08/01/2012	Wi
Maimonides Medical Center 4802 Tenth Avenue Brooklyn, NY 11219	330194	08/24/2012	NY

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (July through September 2012)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commision on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There were no additions to the listing of facilities for lung volume reduction surgery published in the July through September 2012 quarter. This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (July through September 2012)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

For the purposes of this quarterly notice, we list only the specific updates to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery and have been certified by ACS and/or ASMBS in the 3-month period. This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For

questions or additional information, contact Kate Tillman, RN, MAS (410-786-9252).

Facility	Provider Number	Date Approved	State
The following facilities are new listings for this quarter.			
Greater Baltimore Medical Center (GBMC) Comprehensive Obesity Management Program 6535 North Charles Street Physicians Pavilion North, Suite 125 Baltimore, MD 21204	1396774238	06/07/12	MD
The Bryn Mawr Hospital 130 South Bryan Mawr Avenue Bryn Mawr, PA 19010	24371	03/16/12	PA
Hurley Medical Center One Hurley Plaza Flint, MI 48503-5993	230132	04/14/12	MI
Surgical Weight Loss Program at Eastern Maine Medical Center 905 Union Street, Suite 11 Bangor, ME 4401	1790789147	06/10/12	ME
Saint Vincent Hospital 123 Summer Street Worcester, MA 01608	220176	06/10/10	MA
Mount Sinai Hospital 5 East 98th Street, 15th Floor New York, NY 10029	1932103413	07/15/11	NY
Editorial changes (shown in bold) were made to the facilities listed below.			
St. Francis Hospital & Health Centers 1600 Albany Street Beech Grove, IN 46107	**1386749893**	05/30/2007	IN
MetroWest Medical Center, Leonard Morse Hospital 67 Union Street, Fair 4 Natick, MA01760	**220175**	07/14/2010	MA
SSM DePaul Health Center 12266 DePaul Drive, Suite 310 Bridgeton, MO 63044	**260104**	02/24/2006	MO
Silver Cross Hospital and Medical Centers **1900 Silver Cross Boulevard New Lenox, IL. 60451-9508**	140213	03/10/2006	IL
Brigham and Women's Hospital 75 Francis Street ASBII-3 Boston, MA 02115-619	MPI-1790717650; PI-220110	**08/14/2012**	MA
Albany Medical Center 47 New Scotland Avenue Albany, NY 12208	330013	**06/02/2012**	NY
The following facilities are no longer participants as of this notice.			
Northeast Alabama Regional Medical Center 400 East 10th Street Anniston, AL 36207	010078	07/30/2007	AL
Parkway Medical Center 1854 Beltline Road SW Decatur, AL 35601	01-0054	12/18/2009	AL
Allegheny General Hospital 320 East North Avenue Pittsburgh, PA 15212	390050	11/21/2006	PA

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (July through September 2012)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the July through September 2012 quarter.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

[FR Doc. 2012–27422 Filed 11–08–12; 8:45 am]
BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–1057]

Draft Guidance for Industry and Food and Drug Administration Staff; Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices.'' This draft guidance is to provide industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of highly multiplexed microbiological/medical countermeasures in vitro nucleic acid based diagnostic devices (HMMDs) intended to simultaneously detect and identify multiple pathogen nucleic acids extracted from a single appropriate human specimen or culture. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 7, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John Hobson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5555, Silver Spring, MD 20993–0002, 301–796–5892.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is to provide industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of HMMDs intended to simultaneously detect and identify multiple pathogen nucleic acids extracted from a single appropriate human specimen or culture. For the purposes of this draft guidance document the multiplex level that is used to define HMMDs is the capability to detect ≥20 different organisms/targets, in a single reaction, using a nucleic acid based technology and involves testing multiple targets through a common process of specimen preparation, amplification and/or detection, and result interpretation. HMMDs are used to aid in the diagnosis of infection.

The scope of this draft guidance includes nucleic acid based devices that employ technologies such as polymerase chain reaction, reverse-transcriptase polymerase chain reaction, bead-based liquid arrays, microarrays, re-sequencing approaches as well as the measurement of individual targets determined by ≥20 separate assays that are reported out simultaneously through the use of a diagnostic algorithm. This draft guidance is not intended to address devices that utilize detection mechanisms other than nucleic acid based approaches. The document does not apply to devices that are intended to screen donors of blood and blood components, and donors of human cells, tissues, and cellular and tissue-based products for communicable diseases.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on highly multiplexed microbiological/medical countermeasure in vitro nucleic acid based diagnostic devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1803 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: October 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27340 Filed 11–8–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anesthetic and Analgesic Drug Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

DATES: *Date and Time:* The meeting will be held on December 7, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20992–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Philip A. Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *AADPAC@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the risks and benefits of new drug application (NDA) 202880, by Zogenix Inc., for hydrocodone bitartrate extended-release capsules (proposed tradename ZOHYDRO ER), an opioid analgesic medication for the management of moderate to severe chronic pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. This formulation of hydrocodone bitartrate extended-release capsules represents the first single-entity (i.e., containing no other active pharmaceutical ingredients, such as acetaminophen or ibuprofen) hydrocodone-containing drug product. It will be formulated in dose strengths up to 50 milligrams, and administered twice daily (i.e., every 12 hours). The committee will be asked to determine whether the benefit-risk assessment of this product favors its approval for marketing.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 23, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 14, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 15, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Philip Bautista at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 5, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–27368 Filed 11–8–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Ethical Dilemmas in Surgery and Utilization of Hospital Ethics Consultation Service: A Survey

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Clinical Center Department of Bioethics, the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 28, 2011 on page 72955–72956 [FR DOC # 2011–30548] and allowed 60-days for public comment. Two comments were received by the NIH Department of Bioethics. The comments we received included one request from a survey firm that was interested in possibly administering the survey, and one

request from the American Association of Medical Colleges (AAMC) that was interested in knowing what items were in the survey instrument. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Ethical Dilemmas in Surgery and Utilization of Hospital Ethics Consultation Service: A Survey. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This survey is intended to collect information about the ethical dilemmas that surgeons have faced in their practices over the past year, and assess their experiences, if any, with their hospital consultation services. Specifically, the information gathered in this study will be valuable in understanding the ethical dilemmas that surgeons face, the utility of institution ethics consultations services for surgeons, and to identify what barriers, if any, discourage surgeons from utilizing these services. The results of this study can be used by medical professionals, hospitals, and bioethicists in several important ways. First, they will provide a better understanding the ethical dilemmas that surgeons face in their practices. Second, they will provide understanding of factors that determine the current utilization of hospital consultation services by surgeons. Third, information collected on the barriers to surgeons' use of ethics consultation services will provide better insight into the perspective and culture of surgery as it relates to ethical dilemmas in their practices and how ethics consultation services could better support surgeons when faced with these dilemmas. *Frequency of Response:* Once. *Affected Public:* Individuals; Businesses or other for-profit. *Type of Respondents:* Individuals.

The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hours)	Estimated total annual burden hours requested
Surgeons	598	1	15/60	150
Total	598			150

There are no capital, operating, or maintenance costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) 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) 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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Marion Danis, MD, Department of Clinical Bioethics, National Institutes of Health, Building 10, Room 1C118, Bethesda, MD 20892–1156; Telephone: 301–435–8727; Facsimile: 301–496–0760; Email: *mdanis@cc.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: August 28, 2012.

Laura Lee,

Project Clearance Liason, CC, National Institutes of Health.

[FR Doc. 2012–27445 Filed 11–8–12; 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, Public Health Service, 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. 207 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.

Cell Lines Expressing Nuclear and/or Mitochondrial RNase H1

Description of Technology: RNase H1 has been shown to remove RNA/DNA hybrids and either too much or too little enzyme can lead to undesirable effects such as deletions of DNA. The gene encoding RNase H1 in mammalian cells produces two forms of the protein. One is targeted to the nucleus of the cell and the other to the mitochondrial organelle. To study the effects of expression as well as to understand the regulation of the frequency with which each form is made, NIH investigators constructed cells derived from HEK293 cells where expression of each or both forms is/are expressed only after addition of doxycycline as a small molecule inducer compound. The set of cell lines could be important in the process of analysis of RNA/DNA hybrids as each

cell line expresses different amounts of each form.

Potential Commercial Applications: Research materials to study RNA/DNA hybrids

Competitive Advantages: Not available elsewhere

Development Stage:

- Prototype
- Pre-clinical
- In vitro data available

Inventors: Robert J. Crouch and Yutaka Suzuki (NICHD).

Publication: Suzuki Y, et al. An upstream open reading frame and the context of the two AUG codons affect the abundance of mitochondrial and nuclear RNase H1. Mol Cell Biol. 2010 Nov;30(21):5123–34. [PMID 20823270]

Intellectual Property: HHS Reference No. E–273–2012/0—Research Material. Patent protection is not being pursued for this technology.

Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov.*

Collaborative Research Opportunity: The Program in Genomics of Differentiation, NICHD, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize small molecule inhibitors of RNase H1, genome instability, or transcription and translation. For collaboration opportunities, please contact Joseph Conrad III, Ph.D. at *jmconrad@mail.nih.gov.*

Improved Transposase Compositions for Whole Genome Sequencing

Description of Technology: The invention provides improved transposase enzymes engineered to exhibit reduced sequence biases, and to operate more efficiently than wildtype transposases.

Scientists at NIDDK and John Hopkins University jointly developed mutant transposases that are superior to wildtype transposases in whole genome sequencing applications. Transposases facilitate the cleavage of certain DNA segments, called transposons, at specific sites within a genome and their subsequent insertions at random sites. Addition of transposases and labeled transposons to whole genome preparations allow for one-pot, simultaneous fragmentation and identification of targeted DNA sequences.

Mutations introduced by the inventors facilitate formation of dimeric enzyme complexes with enhanced activity and stability. These modifications result in more efficient fragmentation and tagging of genomic DNA.

Potential Commercial Applications: Kits for whole genome sequencing.

Competitive Advantages:

- Can easily be expressed in the bacterium, *E. coli,* and purified in large quantities.
- Are soluble, stable and exist as smaller active complexes compared to native enzymes.
- Are fully active at room temperature (23–30°C).
- Have a higher transposition activity and show minimal insertional sequence bias in-vitro compared to the wild type.

Development Stage:

- Prototype
- Pilot
- In vitro data available

Inventors: Fred Dyda (NIDDK), Alison Hickman (NIDDK), Nancy Craig (Johns Hopkins School of Medicine), Sunil Gangadharan (Johns Hopkins School of Medicine).

Intellectual Property: HHS Reference No. E–194–2012/0—U.S. Provisional Application No. 61/652,560 filed 29 May 2012.

Licensing Contact: Lauren Nguyen-Antczak, Ph.D., J.D.; 301–435–4074; *nguyenantczakla@mail.nih.gov.*

Improved Monoclonal Antibodies Against Neuregulin 2

Description of Technology: The invention provides highly selective monoclonal antibodies against the extracellular domain (ECD) or intracellular domain (ICD) of neuregulin-2, a ligand for the ErbB receptors in adult human brain. Neuregulins regulate a diverse array of neurological process in the central nervous system and are implicated in schizophrenia and other psychiatric disorders. However, an understanding of the specific role of neuregulin 2 has been hindered by a lack of specific antibodies useful in immunoblotting and immunohistology studies. Commercially available antibodies do not perform as well in these applications when compared to the invention antibodies. A mouse monoclonal antibody directed to the ECD is available for licensing (clone 8D11, HHS Ref. No. E–192–2012), and rabbit antibodies directed to the ICD are also available (clone 11–11, HHS Ref. No. E–193–2012; clone 15–10, HHS Ref. No. E–189–2012; and clone 9–2, HHS Ref. No. E–188–2012). Antibodies from clones 8D11 and 11–11 have been validated for immunohistology and antibodies from clones 15–10 and 9–2 have been validated for Western blotting using brain tissue from wild-type and neuregulin 2 deficient mice.

Potential Commercial Applications: Superior monoclonal antibody for Western blotting or immunohistology analysis of tissue sections

Competitive Advantages:

- Superior binding specificity in comparison to commercially available antibodies
- Developed antibodies bind specific, characterized regions on neuregulin 2

Development Stage:

- Prototype
- In vitro data available

Inventors: Detlef Vullhorst, Andres Buonanno, Irina Karavanov (all of NICHD).

Intellectual Property: HHS Reference Nos. E–188–2012/0, E–189–2012/0, E–190–2012/0, E–191–2012/0, E–192–2012/0, E–193–2012/0. This is a Research Tool—patent protection is not being pursued for this technology.

Licensing Contact: Lauren Nguyen-Antczak, Ph.D., J.D.; 301–435–4074; *nguyenantczakla@mail.nih.gov.*

Collaborative Research Opportunity: The NICHD is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize neuregulin-2 monoclonal antibodies. For collaboration opportunities, please contact Charlotte McGuinness at *mcguinnc@mail.nih.gov.*

Glucocerebrosidase Activators for the Treatment of Gaucher Disease, Parkinson's Disease, and Other Proteinopathies

Description of Technology: Gaucher disease is a rare lysosomal storage disease that is characterized by a loss of function of the glucocerebrosidase (GCase) enzyme, which results in a decreased ability to degrade its lipid substrate, glucocerebroside. The intracellular build up of this lipid causes a broad range of clinical manifestations, ranging from enlarged spleen/liver and anemia to neurodegeneration. In Gaucher disease, the loss of GCase function has been attributed to low levels of the protein in the lysosomal compartment, resulting from improper GCase folding and transport. Also, mutations in the GCase gene have been linked to some forms of Parkinson's disease, and may also be involved in other proteinopathies.

This technology describes a collection of salicylic acid-derived small molecules that act as chaperones to activate proper GCase folding and subsequent transport from the endoplasmic reticulum into the lysosome. Unlike many other small molecule chaperones, these salicylic acid derivatives do not inhibit the activity of the GCase enzyme. These

small molecules have been tested for the ability to activate GCase *in vitro* and show chaperone activity in a patient-derived fibroblast translocation assay.

Potential Commercial Applications:

- Treatment of Gaucher disease
- Treatment of Parkinson's disease
- Treatment of other lysosomal storage diseases

Competitive Advantages: The compounds are novel small molecules that enhance proper GCase folding and transport without inhibiting enzyme activity in the lysosome.

Development Stage:

- Early-stage
- In vitro data available

Inventors: Juan Marugan (NCATS), Wei Zheng (NCATS), Samarjit Patnaik (NCATS), Noel Southall (NCATS), Ellen Sidransky (NHGRI), Ehud Goldin (NHGRI), Wendy Westbroek (NHGRI).

Publication: Related publication is currently in preparation.

Intellectual Property:

- HHS Reference No. E–144–2012/0—U.S. Provisional Application No. 61/616,758 filed 28 Mar 2012
- HHS Reference No. E–144–2012/1—U.S Provisional Application No. 61/616,773 filed 28 Mar 2012

Licensing Contact: Tara Kirby, Ph.D.; 301–402–0220; *tarak@mail.nih.gov.*

Collaborative Research Opportunity: The National Center for Advancing Translational Sciences is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Dr. Juan Marugan at *maruganj@mail.nih.gov.*

Cyclodextrins as Therapeutics for Lysosomal Storage Disorders

Description of Technology: Cyclodextrins (CD), alone or in combination with other agents (e.g., vitamin E), as therapeutics for the treatment of lysosomal storage disorders (LSDs) caused by the accumulation of non-cholesterol lipids.

CDs are sugar molecules in a ring form. The alpha-CD (6 sugars), beta-CD (7 sugars) and gamma-CD (8 sugars) are commonly used cyclodextrins. The hydroxypropyl-beta cyclodextrin (HPbCD) has been approved for pharmaceutical use. Recent reports show that beta-cyclodextrin including HPbCD and beta-methyl-cyclodextrin reduced cholesterol accumulation and neuronal cell loss in the mouse model of NPC1 disease.

NCATS investigators found that CD (alpha-, beta- and gamma-CDs) increased intracellular Ca2+ and lysosomal exocytosis in both wild type cells and cells with Wolman disease, and reduced the size of enlarged lysosomes in six patient cell lines with LSDs. Further, CD in combination with tocopherol synergistically/additively reduced cholesterol accumulation in cells of NPC and Wolman diseases. Based on these results, they propose treatment of LSDs with cyclodextrins (such as alpha and gamma forms) alone or in combination with Vitamin E and its analogues for better efficacy and less side effects.

Potential Commercial Applications:

- Treatment of lysosomal storage diseases
- Treatment of disorders caused by accumulation of non-cholesterol lipids

Competitive Advantages:

- Use of cyclodextrins in combination with vitamin-E (e.g., delta-tocopherol) provides additive therapeutic effect
- Less side effects than cyclodextrin only or vitamin E only for LSDs because of reduced doses for both compounds in combination

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available

Inventors: John McKew, Wei Zheng, Miao Xu, Manju Swaroop, Juan Marugan (all of NCATS).

Intellectual Property: HHS Reference No. E–050–2012/0—US Provisional Application No. 61/679,668 filed 12 Aug 2012.

Related Technology: HHS Reference No. E–294–2009/0—PCT Patent Application No. PCT/US2011/044590 filed 19 Jul 2011, entitled'' ''Use of Delta Tocopherol for the Treatment of Lysosomal Storage Disorders'' (Wei Zheng et al., NCATS).

Licensing Contact: Suryanarayana Vepa, Ph.D., J.D.; 301–435–5020; *vepas@mail.nih.gov.*

Collaborative Research Opportunity: The National Center for Advancing Translational Sciences is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Dr. Juan Marugan at *maruganj@mail.nih.gov.*

Selective Treatment of Cancer, HIV, Other RNA Viruses and Genetically Related Diseases Using Therapeutic RNA Switches

Description of Technology: Targeted therapy in cancer or viral infections is a challenge because the disease state manifests itself mainly through differences in the cell interior, for example in the form of the presence of a certain RNAs or proteins in the cytoplasm.

The technology consists of designed RNA switches that activate the RNA interference pathway only in the presence of a trigger RNA or DNA to which they bind, in order to knock down a chosen gene that is not necessarily related to the initial trigger.

This new approach can lead to a new type of drug that has the unique feature of selectively causing a biochemical effect (such as apoptosis) in cells that are infected by RNA viruses (such as HIV), as well as cancer cells. The RNA switch concept can be expanded to selectively treat other genetically related diseases.

Potential Commercial Applications:

- Targeted therapeutic for viral infections, cancer stem cells, and genetically related diseases
- Research tool to study cancer or viral infection

Competitive Advantages:

- Fewer side effects because the therapeutic RNA-interference pathway is only activated by the RNA switch when it is intact and in its active conformation
- Selectively kills cells infected by RNA viruses
- Contains a minimal number of single stranded nucleotides, thus minimizing the effects of nucleases

Development Stage: In vitro data available

Inventors: Bruce A. Shapiro (NCI), Eckart Bindewald (SAIC-Frederick, Inc.), Kirill Afonin (NCI), Arti Santhanam (NCI).

Publications:

1. Afonin KA, et al. Co-transcriptional Assembly of Chemically Modified RNA Nanoparticles Functionalized with siRNAs. Nano Lett. 2012 Oct 10;12(10):5192–5. [PMID 23016824]

2. Grabow WW, et al. ''RNA Nanotechnology in Nanomedicine,'' in Nanomedicine and Drug Delivery (Recent Advances in Nanoscience and Nanotechnology), ed. M Sebastian, et al. (New Jersey: Apple Academic Press, 2012), 208–220. [Book Chapter]

3. Shukla GC, et al. A boost for the emerging field of RNA nanotechnology. ACS Nano. 2011 May 24;5(5):3405–18. [PMID 21604810]

4. Afonin KA, et al. Design and self-assembly of siRNA-functionalized RNA nanoparticles for use in automated nanomedicine. Nat Protoc. 2011 Dec 1;6(12):2022–34. [PMID 22134126]

5. Bindewald E, et al. Multistrand RNA secondary structure prediction and nanostructure design including pseudoknots. ACS Nano. 2011 Dec 27;5(12):9542–51. [PMID 22067111]

6. Grabow WW, et al. Self-assembling RNA nanorings based on RNAI/II inverse kissing complexes. Nano Lett.

2011 Feb9;11(2):878–87. [PMID 21229999]

7. Kasprzak W, et al. Use of RNA structure flexibility data in nanostructure modeling. Methods. 2011 Jun;54:239–50. [PMID 21163354]

8. Afonin KA, et al. In vitro assembly of cubic RNA-based scaffolds designed in silico. Nat Nanotechnol. 2010 Sep;5:676–82. [PMID 20802494]

9. Severcan I, et al. ''Computational and Experimental RNA Nanoparticle Design,'' in Automation in Genomics and Proteomics: An Engineering Case-Based Approach, ed. G Alterovitz, et al. (Hoboken: Wiley Publishing, 2009), 193–220. [Book Chapter]

10. Shapiro B, et al. ''Protocols for the In silico Design of RNA Nanostructures,'' in Nanostructure Design Methods and Protocols, ed. E Gazit, R Nussinov. (Totowa, NJ: Humana Press, 2008), 93–115. [Book Chapter]

11. Bindewald E, et al. Computational strategies for the automated design of RNA nanoscale structures from building blocks using NanoTiler. J Mol Graph Model. 2008 Oct;27(3):299–308. [PMID 18838281]

12. Yingling YG, Shapiro BA. Computational design of an RNA hexagonal nanoring and an RNA nanotube. Nano Lett. 2007 Aug;7(8): 2328–34. [PMID 17616164]

Intellectual Property:

- HHS Reference No. E–038–2012/0 — U.S. Provisional Application No. 61/561,247 filed 17 Nov 2011
- HHS Reference No. E–038–2012/1 — U.S. Provisional Application No. 61/678,434 filed 01 Aug 2012

Related Technology: HHS Reference No. E–039–2012/0—U.S. Provisional Application No. 61/561,257 filed 17 Nov 2011.

Licensing Contact: John Stansberry, Ph.D.; 301–435–5236; *stansbej@mail.nih.gov.*

Collaborative Research Opportunity: The NCI Center for Cancer Research Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize therapeutic RNA switches. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov.*

Activation of Therapeutic Functionalities With Chimeric RNA/DNA Nanoparticles for Treatment of Cancer, Viruses and Other Diseases

Description of Technology: A new strategy based on RNA/DNA hybrid nanoparticles, which can be generally used for triggering multiple functionalities inside diseased cells is presented. Individually, each of the hybrids is functionally inactive and functional representation can only be activated by the re-association of at least two cognate hybrids simultaneously present in the same cell. Overall, this novel approach allows (i) The triggered release of therapeutic siRNAs or miRNAs inside the diseased cells, (ii) activation of other split functionalities (e.g. FRET, different aptamers, rybozymes, split proteins) intracellularly, (iii) higher control over targeting specificity (e.g. if two hybrids are decorated with two different tissue specific recognition moieties), (iv) biosensing and tracking of the delivery and re-association of these hybrids in real-time inside cells, (v) increasing the number of functionalities by introducing a branched hybrid structure, (vi) introduction of additional functionalities without direct interference of siRNA processivity, (vii) increasing the retention time in biological fluids by fine-tuning chemical stability through substituting the DNA strands with chemical analogs (e.g. LNA, PNA, etc.), (viii) conditional release of all functionalities.

Potential Commercial Applications:

- Therapeutic siRNA for cancer, viruses and other diseases
- Therapeutic for delivery of multiple functionalities
- Diagnostic to visualize cancer cells, virus infected cells, or diseased cells, or track the delivery and effectiveness of siRNA treatment or other treatments associated with the particle
- Research tool to study cancer, viral infections or other diseases

Competitive Advantages:

- Novel way for multiple functionality delivery and activation
- Enhanced chemical stability and pharmacokinetics due to the average size of nanoparticles exceeding 10nm
- Increased specificity for selecting cells of interest using more than one target gene

Development Stage:

- In vitro data available
- In vivo data available (animal)

Inventors: Bruce A. Shapiro (NCI), Kirill Afonin (NCI), Arti Santhanam (NCI), Mathias Viard (SAIC-Frederick, Inc.), Eckart Bindewald (SAIC-Frederick, Inc.), Luc Jaeger (U of Cal. Santa Barbara).

Publications:

1. Afonin KA, et al. Co-transcriptional Assembly of Chemically Modified RNA Nanoparticles Functionalized with siRNAs. Nano Lett. 2012 Oct 10;12(10):5192–5. [PMID 23016824]

2. Grabow WW, et al. ''RNA Nanotechnology in Nanomedicine,'' in Nanomedicine and Drug Delivery (Recent Advances in Nanoscience and Nanotechnology), ed. M Sebastian, et al. (New Jersey: Apple Academic Press, 2012), 208–220. [Book Chapter]

3. Shukla GC, et al. A boost for the emerging field of RNA nanotechnology. ACS Nano. 2011 May 24;5(5):3405–18. [PMID 21604810]

4. Afonin KA, et al. Design and self-assembly of siRNA-functionalized RNA nanoparticles for use in automated nanomedicine. Nat Protoc. 2011 Dec 1;6(12):2022–34. [PMID 22134126]

5. Bindewald E, et al. Multistrand RNA secondary structure prediction and nanostructure design including pseudoknots. ACS Nano. 2011 Dec 27;5(12):9542–51. [PMID 22067111]

6. Grabow WW, et al. Self-assembling RNA nanorings based on RNAI/II inverse kissing complexes. Nano Lett. 2011 Feb9;11(2):878–87. [PMID 21229999]

7. Kasprzak W, et al. Use of RNA structure flexibility data in nanostructure modeling. Methods. 2011 Jun;54:239–50. [PMID 21163354]

8. Afonin KA, et al. In vitro assembly of cubic RNA-based scaffolds designed in silico. Nat Nanotechnol. 2010 Sep;5:676–82. [PMID 20802494]

9. Severcan I, et al. ''Computational and Experimental RNA Nanoparticle Design,'' in Automation in Genomics and Proteomics: An Engineering Case-Based Approach, ed. G Alterovitz, et al. (Hoboken: Wiley Publishing, 2009), 193–220. [Book Chapter]

10. Shapiro B, et al. ''Protocols for the In silico Design of RNA Nanostructures,'' in Nanostructure Design Methods and Protocols, ed. E Gazit, R Nussinov. (Totowa, NJ: Humana Press, 2008), 93–115. [Book Chapter]

11. Bindewald E, et al. Computational strategies for the automated design of RNA nanoscale structures from building blocks using NanoTiler. J Mol Graph Model. 2008 Oct;27(3):299–308. [PMID 18838281]

12. Yingling YG, Shapiro BA. Computational design of an RNA hexagonal nanoring and an RNA nanotube. Nano Lett. 2007 Aug;7(8): 2328–34. [PMID 17616164]

Intellectual Property: HHS Reference No. E–039–2012/0—U.S. Provisional Application No. 61/561,257 filed 17 Nov 2011

Related Technology:

- HHS Reference No. E–038–2012/0—U.S. Provisional Application No. 61/561,247 filed 17 Nov 2011
- HHS Reference No. E–038–2012/1—U.S. Provisional Application No. 61/678,434 filed 01 Aug 2012

Licensing Contact: John Stansberry, Ph.D.; 301–435–5236; *stansbej@mail.nih.gov.*

Collaborative Research Opportunity: The NCI Center for Cancer Research

Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize therapeutic RNA/DNA nanoparticles. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov.*

Dated: November 5, 2012.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2012–27426 Filed 11–8–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Human Genome Research Institute Special Emphasis Panel, October 29, 2012, 8:00 a.m. to October 30, 2012, 5:00 p.m., Residence Inn Bethesda Downtown, 7335 Wisconsin Avenue, Montgomery I & II, Bethesda, MD 20814 which was published in the **Federal Register** on October 4, 2012, 77 FR 60706.

Due to Hurricane Sandy, this meeting has been moved from October 29–30, 2012 to January 7, 2013. The meeting is closed to the public.

Dated: November 5, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–27429 Filed 11–8–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Neuronal Plasticity and Regeneration.

Date: November 28–29, 2012.

Time: 9:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Laurent Taupenot, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4811, MSC 7850, Bethesda, MD 20892, 301–435–1203, *taupenol@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Molecular Mechanism of Neurodegeneration.

Date: December 6–7, 2012.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213–9887, *hamelinc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflicts: Asthma, Allergy, and Environmental Exposure Applications.

Date: December 10, 2012.

Time: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Everett E. Sinnett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301–435–1016, *sinnett@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 5, 2012.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–27430 Filed 11–8–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 General Medical Sciences Special Emphasis Panel Review of K99 Grant Applications.

Date: December 5, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room A, Bethesda, MD 20892.

Contact Person: John J. Laffan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An18J, Bethesda, MD 20892, 301–594–2773, *laffanjo@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: November 5, 2012.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–27427 Filed 11–8–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, 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 NIAID Peer Review Meeting.

Date: December 5, 2012.

Time: 9:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Andrea L. Wurster, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, Room 2217, 6700B Rockledge Drive, MSC–7616, Bethesda, MD 20892–761, 301–496–2550, *wurstera@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 5, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–27428 Filed 11–8–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5600–FA–02]

Announcement of Funding Awards; Indian Community Development Block Grant Program; Fiscal Year 2012

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with Section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in a competition for funding under the Fiscal Year 2012 (FY 2012) Notice of Funding Availability (NOFA) for the Indian Community Development Block Grant (ICDBG) Program. This announcement contains the consolidated names and addresses of this year's award recipients under the ICDBG.

FOR FURTHER INFORMATION CONTACT: For questions concerning the ICDBG Program awards, contact the Area Office of Native American Programs (ONAP) serving your area or Glenda Green, Director, Office of Native Programs, 451 7th Street SW., Washington, DC 20410, telephone number 202–402–6329. Hearing or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Relay Service at telephone number 800–877–8339.

SUPPLEMENTARY INFORMATION: This program provides grants to Indian tribes and Alaska Native Villages to develop viable Indian and Alaska Native communities, including the creation of decent housing, suitable living environments, and economic opportunities primarily for persons with low and moderate incomes as defined in 24 CFR 1003.4.

The FY 2012 awards announced in this Notice were selected for funding in a competition posted on HUD's Web site on October 4, 2011 and in a technical amendment posted on November 11, 2011. Applications were scored and selected for funding based on the selection criteria in those notices and Area ONAP geographic jurisdictional competitions.

The amount appropriated in FY 2012 to fund the ICDBG was $60,000,000. Of this amount $3,960,000 was retained to fund imminent threat grants in FY 2012. In addition, a total of $400,000 in carryover funds from prior years was also available. The allocations for the Area ONAP geographic jurisdictions, including carryover from prior years, are as follows:

Eastern/Woodlands:	$6,468,576
Southern Plains:	11,918,554
Northern Plains:	8,095,270
Southwest:	20,969,820
Northwest:	2,876,273
Alaska:	6,073,337
Total	56,401,830

In accordance with Section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat.1987, 42 U.S.C. 3545), the Department is publishing the names, addresses, and amounts of the 76 awards made under the various regional competitions in Appendix A to this document.

Dated: October 24, 2012.

Sandra B. Henriquez,

Assistant Secretary for Public and Indian Housing.

APPENDIX A

Name/Address of applicant	Amount funded	Activity funded	Project description
Agdaagux Tribe of King Cove, Dale Gould, President, P.O. Box 249, King Cove, AK 99612, (907) 497–2648.	$28,175	Housing Rehabilitation	Replacement of meter boxes on 60 homes.
All Mission Indian Housing Authority (LaJolla) Dave Shaffer, Executive Director, 27740 Jefferson Ave, Ste 260, Temecula, CA 92590, (951) 760–7390.	364,679	Housing Construction	Construction of 2 homes.
All Mission Indian Housing Authority (Pauma), Dave Shaffer, Executive Director, 27740 Jefferson Ave, Ste 260, Temecula, CA 92590, (951) 760–7390.	547,679	Housing Construction	Construction of 3 homes.
All Mission Indian Housing Authority (Santa Rosa), Dave Shaffer, Executive Director, 27740 Jefferson Ave, Ste 260, Temecula, CA 92590, (951) 760–7390.	547,679	Public Facility—Infrastructure	Infrastructure improvements that will provide access to reservation housing.
All Mission Indian Housing Authority (Torres-Martinez), Dave Shaffer, Executive Director, 27740 Jefferson Ave, Ste 260, Temecula, CA 92590, (951) 760–7390.	550,635	Housing Construction	Construction of 3 homes.
Arctic Village, Raymond Tritt, First Chief, P.O. Box 22069, Arctic Village, AK 99722, (907) 587–5523.	530,000	Housing Construction	Construction of 2 homes.

APPENDIX A—Continued

Name/Address of applicant	Amount funded	Activity funded	Project description
Bear River Band of Rohnerville Rancheria, Honorable Leonard Bowman, Chairman, 27 Bear River Drive, Loleta, CA 95551, (707) 534–3859.	605,000	Housing Construction	Construction of 4 homes.
Big Pine Paiute Tribe of the Owens Valley, Honorable Virgil Moose, Chairperson, P.O. Box 700, Big Pine, CA 93513, (760) 938–2003.	605,000	Housing Rehabilitation	Rehabilitation of 12 homes.
Bois Forte Band of the Minnesota Chippewa Tribe, Sidra Starkovich, P.O. Box 16—1374 Nett, Nett Lake, MN 55772, (218) 757–3261.	600,000	Public Facility—Community Center.	Pow-Wow grounds and softball fields.
Caddo Nation, Honorable Brenda Edwards, Chairman, P.O. Box 487, Binger, OK 73009, (405) 656–2344.	800,000	Public Facility—Community Center.	Social Services Building.
Campo Band of Diegueno Mission Indians, Honorable Monique La Chappa, Chairperson, 36190 Church Road, Suite 1, Campo, CA 91906, (619) 478–9046.	605,000	Housing Construction	Construction of 4 homes.
Chemehuevi Indian Tribe, Honorable Charles Wood, Chairperson, P.O. Box 1976, Havasu Lake, CA 92363, (760) 858–4219.	604,998	Public Facility—Infrastructure	Replacement of antiquated sewer lines.
Chickasaw Nation, Honorable Bill Anoatubby, Governor, P.O. Box 1548, Ada, OK 74821, (580) 436–2603.	800,000	Public Facility—Community Center.	Renovation of old gymnasium.
Chippewa Cree Tribe, Honorable Bruce Sunchild, Tribal Chairman, 31 Agency Square, Box Elder, MT 59521, (406) 395–5705.	900,000	Public Facility—Infrastructure	Smallville Water Improvement Project.
Choctaw Nation, Honorable Gregory E. Pyle, Chief, P.O. Drawer 1210, Durant, OK 74702, (580) 924–8280.	800,000	Public Facility—Infrastructure	Pocola sanitary sewer.
Cocopah Indian Housing and Development, Dr. Michael Reed, Executive Director, 10488 Steamboat Street, Somerton, AZ 85350, (928) 627–8863.	605,000	Housing Rehabilitation	Rehabilitation of 10 homes.
Coeur D'Alene Tribal Housing Authority, Rosanna Allen, P.O. Box 267, Plummer, ID 83851, (208) 686–1927.	455,200	Public Facility—Infrastructure	Construction of a sewage lagoon.
Cook Inlet Tribal Council, Honorable Gloria O'Neill, President, 3600 San Jeronimo, Anchorage, AK 99508, (907) 793–3088.	600,000	Public Facility—Special Needs.	Construction of a group home for Alaska youth.
Crow Creek Housing Authority, Joseph Sazue, Jr. Executive Director, P.O. Box 19, Fort Thompson, SD 57339, (605) 245–2250.	900,000	Housing Rehabilitation	Rehabilitation of 17 rental and 17 owner-occupied housing units.
Dry Creek Rancheria Band of Pomo Indians, Honorable Harvey Hopkins, Chairperson, P.O. Box 607, Geyserville, CA 95448, (707) 522–4290.	605,000	Homebuyer Assistance	Homeowner Assistance Program.
Eastern Band of Cherokee Indians of NC, Kim Deas, P.O. Box 455, Cherokee, NC 28719, (828) 497–2771.	468,576	Public Facility—Community Center.	Construction of a children's home.
Eastern Shawnee Tribe of Oklahoma, Honorable Glenna J. Wallace, Chief, P.O. Box 350, Seneca, OK 64865, (918) 666–2435.	800,000	Public Facility—Community Center.	Elder Community Center.
Ekwok Village, Honorable Luki Akelkok, President, P.O. Box 70, Ekwok, AK 99580, (907) 464–3336.	600,000	Housing Construction	Construction of 6 new homes.
Ely Shoshone Tribe, Honorable Alvin Marques, Chairperson, 16 Shoshone Circle, Ely, Nevada 89301, (775) 289–3013.	605,000	Housing Construction	Rehabilitation of 13 homes.
Enterprise Rancheria, Honorable Glenda Nelson, Chairperson, 2133 Monte Vista, Oroville, CA 95966, (530) 532–9214.	595,000	Land for Housing	Purchase of 4 existing homes.
Fort McDermitt Paiute-Shoshone Tribe, Honorable Billy Bell, Chairperson, P.O. Box 457, Fort McDermitt, NV, (775) 532–8913.	605,000	Economic Development	Construction of Travel Plaza.
Gila River Health Corporation, Heather Chavez, Executive Director, P.O. Box 38, Sacaton, AZ 85147, (602) 528–1456.	2,750,000	Public Facility—Infrastructure	Renovation/expansion of the Primary Care Department and constructing a Dental Addition.
Grand Ronde Tribe, Cheryle Kennedy, 9615 Grand Ronde Road, Grand Ronde, OR 97347, (503) 879–5211.	500,000	Public Facility—Community Center.	Construction of a Food Bank facility.
Hannahville Indian Community, Jill Beaudo, N14911 Hannahville B1 Road, Wilson, MI 49896, (906) 466–2342.	600,000	Housing Construction	Transitional Housing Facility.
Ho-Chunk Community Development Corporation, Frank Schersing, Executive Director, 509 Ho-Chunk Plaza North, Winnebago, NE 68071, (402) 878–2192.	695,270	Housing Rehabilitation	Rehabilitation of 15 single family homes.
Ho-Chunk Nation of Wisconsin, Paul Tysse, W9814 Airport Rd, Black River Falls, WI 54615, (715) 284–9343.	600,000	Housing Rehabilitation	Installation of solar panels on LMI housing.
Hualapai Indian Tribe, Honorable Wilfred Whatoname, Sr., Chairperson, P.O. Box 179, Peach Springs, AZ 86434, (928) 769–2216.	825,000	Public Facility—Special Needs.	Accessibility improvements to existing public buildings and improvements to the Youth Camp.
Kalispel Tribe, Glen Nenema, P.O. Box 3, Usk, WA 99180, (509) 445–1705.	421,073	Public Facility—Infrastructure	Construction of an Elder Center.

APPENDIX A—Continued

Name/Address of applicant	Amount funded	Activity funded	Project description
Karuk Tribe of California, Honorable Russell Attebery, Chairperson, P.O. Box 1016, Happy Camp, CA 96039, (530) 493–5305.	605,000	Public Facility—Community Center.	Wellness Center to provide recreation and other activities.
Kaw Nation, Honorable Guy Munroe, Chairman, Drawer 50, Kaw City, OK 74641, (580) 269–2552.	800,000	Economic Development	Expansion of a travel plaza.
Klamath Indian Tribe, Gary Frost, P.O. Box 436, Chiloquin, OR 97624, (541) 783–2210.	500,000	Public Facility—Community Center.	Construction of a preschool center.
Lac du Flambeau Band of Lake Superior Chippewa Indians, Patricia O'Neil, P.O. Box 67, Lac du Flambeau, WI 54538, (715) 588–3303.	600,000	Public Facility—Community Center.	Art and Cultural Center.
Lower Brule Sioux Tribe, Honorable Michael Jandreau, Tribal Chairman, 187 Oyate Circle, Lower Brule, SD 57548, (605) 473–5561.	900,000	Housing Rehabilitation	Rehabilitation of 58 rental homes on Lower Brule Reservation.
Lummi Tribal Housing Authority, Diana Phair, 2828 Kwina Road, Bellingham, WA 98226, (541) 783–2210.	500,000	Public Facility—Infrastructure	Construction of roads and utilities for 66 new units.
Mentasta Traditional Council, C. Nora David, First Chief, P.O. Box 601, Mentasta, AK 99780, (907) 291–2319.	600,000	Public Facility—Community Center.	Construction of a Health Facility.
Muscogee Creek Nation, Honorable George Tiger, Principal Chief, P.O. Box 580, Okmulgee, OK 74447, (918) 756–8700.	800,000	Public Facility—Community Center.	Student Auxiliary Services Center.
Native Village of Buckland, Honorable Floyd Ticket, President, P.O. Box 67, Buckland, AK 99727, (907) 494–2171.	600,000	Housing Construction	Construction of 5 homes.
Native Village of Chitina, Honorable Ronald Mahle, President, P.O. Box 31, Chitina, AK 99566, (907) 823–2215.	600,000	Housing Construction	Construction of 3 homes.
Native Village of Kiana, Honorable Larry Westlake, Sr., President, P.O. Box 69, Kiana, AK 99749, (907) 475–2109.	600,000	Housing Rehabilitation	Rehabilitation of 25 homes.
Navajo Nation, Honorable Ben Shelly, President, P.O. Box 7440, Window Rock, AZ 86515, (928) 871–6352.	5,500,000	Public Facility—Infrastructure	Provide Power Lines & Water Treatment Facilities within the Navajo Nation.
North Fork Rancheria of Mono Indians, Honorable Judy Fink, Chairperson, P.O. Box 929, North Fork, CA 93643, (559) 877–2461.	605,000	Public Facility—Community Center.	Center for vocational training and job placement and transportation services for low income residents.
Northern Cheyenne Tribal Housing Authority, Lafe Haugen, Executive Director, P.O. Box 327, Lame Deer, MT 59043, (406) 477–6419.	900,000	Housing Rehabilitation	Rehabilitation of 27 owner-occupied housing units.
Northern Pueblos Housing Authority, Mr. Terry Hudson, Executive Director, 5 West Gutierrez, Santa Fe, NM 87506, (888) 347–6360.	599,150	Housing Construction	Construction of 10 homes.
Oneida Tribe of Indians of Wisconsin, Dale Wheelock, P.O. Box 365, Oneida, WI 54155, (920) 869–2227.	600,000	Public Facility—Infrastructure	Water and sewer lines for 40 housing units.
Organized Village of Kasaan, Honorable Richard Peterson, President, P.O. Box 26, Ketchikan, AK 99950, (907) 542–2230.	599,457	Public Facility—Community Center.	Renovation of an existing structure for a community facility.
Ottawa Tribe of Oklahoma, Honorable Ethel E. Cook, Chief, P.O. Box 110, Miami, OK 74355, (918) 540–1536.	800,000	Economic Development	Construction of a travel plaza.
Paiute Indian Tribe of Utah, Honorable Gayle Rollo, Tribal Chairperson 440 North Paiute Drive, Cedar City, UT 84721, (435) 586–1112.	900,000	Economic Development	Development of an RV park and, Campground.
Pauloff Harbor Village, Honorable Gayle Rollo, Tribal Chairperson, P.O. Box 19, Sand Point, AK 99661, (907) 383–6075.	356,218	Housing Construction	Construction of 1 home.
Pawnee Nation, Honorable Marshall Gover, President, P.O. Box 470, Pawnee, OK 74058, (918) 762–3621.	800,000	Public Facility—Community Center.	Design and construction of Pawnee Tribal Elder Center.
Pokagon Band of Potawatomi Indians, Kevin Daugherty, P.O. Box 180, Dowagiac, MI 49047, (269) 782–8998.	600,000	Public Facility—Infrastructure	Waterline extension project.
Pueblo of Acoma Housing Authority, Floyd Tortalita, Executive Director, P.O. Box 309, Acoma Pueblo, NM 87034, (505) 552–5174.	825,000	Housing Rehabilitation	Rehabilitation of 20 homes.
Qawalangin Tribe of Unalaska, Honorable Denise Rankin, President, P.O. Box 33, Unalaska, AK 99685, (907) 581–2920.	419,487	Housing Construction	Construction of 1 home.
Quapaw Tribe of Oklahoma, Honorable John Berrey, Chairman, P.O. Box 765, Quapaw, OK 74363, (918) 542–1853.	800,000	Public Facility—Community Center.	Construction of a wellness center and community safe room.
Resighini Rancheria, Honorable Donald McCovey, Chairperson, P.O. Box 529, Klamath, CA 95548, (707) 482–2431.	605,000	Economic Development	Rehabilitation and improvement to the Chere-ere Bridge RV Park.
Sac & Fox Tribe of the Mississippi in Iowa, Larry Lasley, Route 2, Box 56C, Tama, IA 52339, (641) 484–4678.	600,000	Economic Development	Construct a Travel Center.

APPENDIX A—Continued

Name/Address of applicant	Amount funded	Activity funded	Project description
Salish & Kootenai Housing Authority, Jason Adams, Executive Director, P.O. Box 38, Pablo, MT 59855, (406) 675–4491.	1,100,000	Housing Rehabilitation	Rehabilitation of 14 owner-occupied/3 rental units and homebuyer assistance.
Sault Ste. Marie Tribe of Chippewa Indians of MI, Joanne Umbrasas, 523 Ashmun Street, Sault Ste. Marie, MI 49783, (906) 635–6050.	600,000	Public Facility Infrastructure	Waterline extension project.
Seminole Nation, Honorable Leonard Harjo, Principal Chief, P.O. Box 1498, Weoka, OK 74884, (405) 257–6287.	800,000	Public Facility—Community Center.	Construction of a multi-purpose community health and wellness center.
Seneca Cayuga Tribe of Oklahoma, Honorable Leroy Howard, Chief, 23701 S. 655 Road, Grove, OK 74344, (918) 787–5452.	800,000	Public Facility—Community Center.	Construction of a Family Services Center.
Shawnee Tribe, Honorable Ron Sparkman, Chairman, P.O. Box 189, Miami, OK 74355, (918) 542–2441.	739,275	Public Facility—Community Center.	Rehabilitation of Social Services Resource Center.
Spirit Lake Housing Corporation, Douglas Yankton, Executive Director, P.O. Box 187, Fort Totten, ND 58335, (701) 766–4131.	900,000	Housing Rehabilitation	Rehabilitation of 21 rental units in an elderly housing complex.
St. Croix Chippewa Indians of Wisconsin, Stuart Bearheart, 24663 Angeline Ave, Webster, WI 54893, (715) 349–2195.	600,000	Housing Rehabilitation	Rehabilitation of 22 units.
Tunica-Biloxi Tribe of Louisiana, Honorable Earl J. Barbry Sr., Chairman, P.O. Box 1589, Markville, LA 71351, (318) 253–9767.	779,279	Public Facility—Community Center.	Construction of a social services building.
United Keetoowah Band of Cherokee Indians of Oklahoma, Honorable George Wickliffe, Chief, P.O. Box 746, Tahlequah, OK 74465, (918) 456–5126.	800,000	Public Facility—Community Center.	Expansion of a Museum/Cultural Center.
Ute Indian TDHE, Emmett Duncan, Executive Director, P.O. Box 250, Fort Duchesne, UT 84026, (435) 722–4656.	900,000	Housing Rehabilitation	Rehabilitation of 23 single family homes.
Village of Venetie, Joshua Roberts, First Chief, P.O. Box 81119, Venetie, AK 99781, (907) 849–8212.	540,000	Housing Construction	Construction of 2 homes.
Wells Indian Colony Band of Te-Moak Tribe of Western Shoshone, Honorable Paula Salazar, Chairperson, P.O. Box 809, Wells, NV 89835, (775) 752–3045.	605,000	Economic Development	Design and construction of a Small Business Development Incubator.
White Earth Band of the Minnesota Chippewa Tribe, Michael Triplett, P.O. Box 418, White Earth, MN 56591, (218) 983–3285.	600,000	Public Facility—Community Center.	Health facility addition.
Wyandotte Nation, Honorable Billy Friend, Chief, 64700 E Highway 60, Wyandotte, OK 74370, (918) 678–2297.	800,000	Public Facility—Community Center.	Housing services center.
Yakama Nation Housing Authority, James Berg, P.O. Box 156, Wapato, WA 98951, (509) 877–6171.	500,000	Public Facility—Infrastructure	Construction of a new hydro well with pump station.
Yurok Tribe, Honorable Thomas O'Rourke Sr., Chairperson, P.O. Box 1027, Klamath, CA 95548, (707) 482–1350.	605,000	Public Facility—Community Center.	Purchase of the Yurok Tribe Early Education and Family Resource Center.

[FR Doc. 2012–27471 Filed 11–8–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5601–N–44]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7262, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: November 1, 2012.

Ann Marie Oliva,

Deputy Assistant Secretary for Special Needs (Acting).

[FR Doc. 2012–27089 Filed 11–8–12; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R9–IA–2011–0087; 96300–1671–0000 FY12 R4]

Conference of the Parties to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES); Sixteenth Regular Meeting; Provisional Agenda; Announcement of Public Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The United States, as a Party to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), will attend the sixteenth regular meeting of the Conference of the Parties to CITES (CoP16) in Bangkok, Thailand, during March 3 to15, 2013. Currently, the United States is developing its negotiating positions on proposed resolutions, decisions, and amendments to the CITES Appendices (species proposals), as well as other agenda items that have been submitted by other Party countries, the permanent CITES committees, and the CITES Secretariat for consideration at CoP16. With this notice we announce the provisional agenda for CoP16, solicit your comments on the items on the provisional agenda, and announce a public meeting to discuss the items on the provisional agenda.

DATES: *Public meeting:* The public meeting will be held on December 5, 2012, at 1:30 p.m. *Comment submission:* In developing the U.S. negotiating positions on proposed resolutions, decisions, and species proposals, and other agenda items submitted by other Party countries, the permanent CITES committees, and the CITES Secretariat for consideration at CoP16, we will consider written information and comments you submit if we receive them by January 8, 2013.

ADDRESSES:

Public Meeting

The public meeting will be held in the Sidney Yates Auditorium at the Main Interior Building at 18th and C Streets NW., Washington, DC. Directions to the building can be obtained by contacting the Division of Management Authority (see **FOR FURTHER INFORMATION CONTACT**). For more information about the meeting, see ''Announcement of Public Meeting'' under **SUPPLEMENTARY INFORMATION**.

Comment Submission

Comments should be submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R9–IA–2011–0087.
- *U.S. mail or hand-delivery:* Public Comments Processing, *Attn:* FWS–R9–IA–2011–0087; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We will not consider comments sent by email or fax, or to an address not listed in the **ADDRESSES** section. Comments and materials we receive in response to this notice will be posted for public inspection on *http://www.regulations.gov* and will be available by appointment, between 8:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays, at either the Division of Management Authority or the Division of Scientific Authority.

FOR FURTHER INFORMATION CONTACT: For information pertaining to resolutions, decisions, and agenda items, contact: Robert R. Gabel, Chief, Division of Management Authority; telephone 703–358–2095; facsimile 703–358–2298. For information pertaining to species proposals, contact: Rosemarie Gnam, Chief, Division of Scientific Authority; telephone 703–358–1708; fascsimile 703–358–2276.

SUPPLEMENTARY INFORMATION:

Background

The Convention on International Trade in Endangered Species of Wild Fauna and Flora, hereinafter referred to as CITES or the Convention, is an international treaty designed to control and regulate international trade in certain animal and plant species that are now or potentially may become threatened with extinction. These species are listed in Appendices to CITES, which are available on the CITES Secretariat's Web site at *http://www.cites.org/eng/app/index.php.* Currently, 176 countries, including the United States, are Parties to CITES. The Convention calls for regular biennial meetings of the Conference of the Parties, unless the Conference of the Parties decides otherwise. At these meetings, the Parties review the implementation of CITES, make provisions enabling the CITES Secretariat in Switzerland to carry out its functions, consider amendments to the lists of species in Appendices I and II, consider reports presented by the Secretariat and the permanent CITES committees (Standing, Animals, and Plants Committees), and make recommendations for the improved effectiveness of CITES. Any country that is a Party to CITES may propose amendments to Appendices I and II, resolutions, decisions, and agenda items for consideration by all the Parties at the meetings.

This is our fifth in a series of **Federal Register** notices that, together with an announced public meeting, provide you with an opportunity to participate in the development of the U.S. negotiating positions for the sixteenth regular meeting of the Conference of the Parties to CITES (CoP16). We published our first CoP16-related **Federal Register** notice on June 14, 2011 (76 FR 34746), in which we requested information and recommendations on species proposals for the United States to consider submitting for consideration at CoP16, and described our approach in determining which species proposals to consider submitting. We published our second such **Federal Register** notice on November 7, 2011 (76 FR 68778), in which we requested information and recommendations on proposed resolutions, decisions, and agenda items for the United States to consider submitting for consideration at CoP16, described our approach in determining which proposed resolutions, decisions, and agenda items to consider submitting, and provided preliminary information on how to request approved observer status for non-governmental organizations that wish to attend the meeting. In our third CoP16-related **Federal Register** notice, published on April 11, 2012 (77 FR 21798), we requested public comments and information on species proposals that the United States was considering submitting for consideration at CoP16; and in our fourth such notice, published on June 21, 2012 (77 FR 37433), we requested public comments and information on proposed resolutions, decisions, and agenda items that the United States was considering submitting for consideration at CoP16, and provided more information on how to request approved observer status for non-governmental organizations that wish to attend the meeting. A link to the complete list of those **Federal Register** notices, along with information on U.S. preparations for CoP16, can be found at *http://www.fws.gov/international/cites/cop16/.* You may obtain additional information on those **Federal Register** notices from the following sources: For information on proposed resolutions, decisions, and agenda items, contact the Division of Management Authority, U.S. Fish and Wildlife Service, 4401 N.

Fairfax Drive, Room 212, Arlington, VA 22203; and for information on species proposals, contact the Division of Scientific Authority, U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Room 110, Arlington, VA 22203. Our regulations governing this public process are found in 50 CFR 23.87.

On October 4, 2012, the United States submitted to the CITES Secretariat, for consideration at CoP16, its species proposals, proposed resolutions, proposed decisions, and other agenda items. These documents are available on our Web site at *http://www.fws.gov/international/cites/cop16/.*

Announcement of Provisional Agenda for CoP16

The provisional agenda for CoP16 is currently available on the CITES Secretariat's Web site at *http://www.cites.org/eng/cop/16/doc/index.php.* The working documents associated with the items on the provisional agenda, including proposed resolutions, proposed decisions, and discussion documents, are also available on the Secretariat's Web site. To view the working document associated with a particular agenda item, access the provisional agenda at the above Web site, locate the particular agenda item, and click on the document link for that agenda item in the column entitled ''Document.'' Finally, the species proposals that will be considered at CoP16 are available on the Secretariat's Web site. Proposals for amendment of Appendices I and II can be accessed at the web address given above. We look forward to receiving your comments on the items on the provisional agenda.

Announcement of Public Meeting

We will hold a public meeting to discuss with you the items on the provisional agenda for CoP16. The public meeting will be held on the date specified in the **DATES** section and at the address specified in the **ADDRESSES** section. You can obtain directions to the building by contacting the Division of Management Authority (see the **FOR FURTHER INFORMATION CONTACT** section above). Please note that the Sidney Yates Auditorium is accessible to the handicapped and all persons planning to attend the meeting will be required to present photo identification when entering the building. Persons who plan to attend the meeting and who require interpretation for the hearing impaired must notify the Division of Management Authority by November 21, 2012. For those who cannot attend the public meeting but are interested in watching via live stream please go to our Web site *http://www.fws.gov/international/cites/cop16/,* and look for the link to the live feed.

Future Actions

Through an additional notice and Web site posting in advance of CoP16, we will inform you about tentative U.S. negotiating positions on species proposals, proposed resolutions, proposed decisions, and agenda items that were submitted by other Party countries, the permanent CITES committees, and the CITES Secretariat for consideration at CoP16.

Author: The primary author of this notice is Mark Bellis, Division of Management Authority; under the authority of the U.S. Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: October 24, 2012.

Rowan W. Gould,

Director.

[FR Doc. 2012–27385 Filed 11–8–12; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLES956000.L19100000.BK0000. LRCMM0E04175]

Eastern States: Filing of Plats of Survey; Mississippi

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) will file the plats of survey of the lands described below in the BLM-Eastern States office in Springfield, Virginia, 30 calendar days from the date of publication in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management-Eastern States, 7450 Boston Boulevard, Springfield, Virginia 22153. Attn: Dominica Van Koten. 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: These surveys were requested by the Bureau of Indian Affairs, Eastern Regions.

The lands surveyed are:

Choctaw Meridian, Mississippi

T. 11 N., R. 11 E.

The dependent resurvey of a portion of the West Boundary, a portion of the subdivisional lines, and the subdivision of Sections 18 and 19, in Township 11 North, Range 11 East, of the Choctaw Meridian, in the State Mississippi, and was accepted September 20, 2012.

We will place copies of the plats we described in the open files. They will be available to the public as a matter of information.

If BLM receives a protest against a survey, as shown on the plat, prior to the date of the official filing, we will stay the filing pending our consideration of the protest.

We will not officially file the plats until the day after we have accepted or dismissed all protests and they have become final, including decisions on appeals.

Dated: November 2, 2012.

Dominica Van Koten,

Chief Cadastral Surveyor.

[FR Doc. 2012–27347 Filed 11–8–12; 8:45 am]

BILLING CODE 4310–GJ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVW01000 L12200000.EA0000 241A; MO# 4500033780; 12–08807; TAS: 14X1106]

Notice of Proposed Supplementary Rules on Public Land in Water Canyon, Humboldt County, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Proposed supplementary rules.

SUMMARY: The Bureau of Land Management (BLM) is proposing supplementary rules relating to camping, the discharge of firearms, and the use of motor vehicles, to protect public safety and resources on public land within the Water Canyon Recreation Area. These proposed supplementary rules would include limitations and restrictions included within the decisions of the Water Canyon Recreation Area Management Plan, Environmental Assessment (EA), Decision Record, and Cooperative Management Agreement approved August 15, 1997, and the Water Canyon Implementation Plan Amendment EA signed August 2005.

DATES: Comments on the proposed supplementary rules must be received or postmarked by January 8, 2013 to be assured consideration.

ADDRESSES: Please mail comments to Michael Truden, Winnemucca District, Humboldt River Field Office, 5100 E Winnemucca Boulevard, Winnemucca,

Nevada 89445; or email comments to *wfoweb@nv.blm.gov,* Attn: ''Water Canyon.''

FOR FURTHER INFORMATION CONTACT: Joey Carmosino, Winnemucca District, Humboldt River Field Office at 775–623–1771 or email: *vcarmosi@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:

I. Public Comment Procedures
II. Background
III. Discussion of the Proposed Supplementary Rules
IV. Procedural Matters
V. Proposed Supplementary Rules

I. Public Comment Procedures

Written comments on the proposed supplementary rules should be specific, be confined to issues pertinent to the proposed supplementary rules, and explain the reason for any recommended change. Where possible, comments should reference the specific section or paragraph of the proposal which the comment is addressing. The BLM is not obligated to consider or include in the Administrative Record for the final supplementary rules comments either postmarked or electronically dated after the deadline or delivered to an address other than the address listed above (See **ADDRESSES**). Comments (including names, street addresses, and other contact information of respondents) will be available for public review at the Winnemucca District Office, 5100 E. Winnemucca Boulevard, Winnemucca, Nevada. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

The Water Canyon Recreation Area is 4 miles southeast of Winnemucca, Nevada. Water Canyon is managed by the BLM Winnemucca District, Humboldt River Field Office with Recreation Management Zones. Zone 1, which is approximately 131 acres, is managed under moderate development actions organized around the lowland and riparian areas of the Water Canyon Recreation Area, allowing for more developed recreation in the form of established campgrounds, facilities, and trails. The Zone 2 upland area of approximately 2,579 acres is managed under an emphasis for more dispersed and undeveloped recreational opportunities. The BLM has completed two site-specific land use plans for the Water Canyon Recreation Area:

- The Water Canyon Management Plan, Cooperative Management Agreement, Environmental Assessment, and Decision Record (August 15, 1997); and
- The Water Canyon Implementation Plan Amendment, Environmental Assessment, and Decision Record (November 16, 2005).

These supplementary rules would affect public lands identified as Zone 1 of the Water Canyon Recreational Area. Zone 1, which is identified in the Water Canyon Management Plan and EA, and the Cooperative Management Agreement, is the portion of the Canyon that receives the most recreational use. Zone 1 is a fenced corridor of public land within Township 35 North, Range 38 East, Mount Diablo Meridian, through portions of sections 2, 11, and 12, in Humboldt County, Nevada. The Zone 1 fenced corridor is of variable width perpendicular to the centerline of Water Canyon Road with an overall width average of approximately 600 feet and runs approximately 1.8 miles in length along Water Canyon Road, in Township 36 North Range 38 East, parts of sections 2, 11 and 12.

A map of the area is available at the Winnemucca District, Humboldt River Field Office at the address shown in the **ADDRESSES** section, above.

The proposed supplementary rules are necessary to help the BLM achieve management objectives and implement decisions in the Management Plan, associated EA, and Decision Record, Cooperative Management Agreement approved August 15, 1997, and the Implementation Plan signed August 2005 and to increase public safety.

The Cooperative Management Agreement for Water Canyon was a collaborative effort undertaken among the BLM, the Nevada Department of Wildlife, Humboldt County, the City of Winnemucca, and the public to elicit concerns, define issues, and develop a set of desired future conditions for the planning area. The outcome of this process was the development of a set of objectives intended to guide subsequent management actions within the canyon. These objectives, which can be found in the 2005 Implementation Plan, include: Protecting surface and subsurface water quality within the watershed; providing recreational opportunities; preserving broad-leafed trees, high quality riparian areas, and grassy meadows; and providing for a diversity of wildlife habitats.

To achieve these objectives, the BLM evaluated a series of alternative proposals that prescribed different allowable uses of the planning area and defined other management actions to reach these desired outcomes. The evaluation process led to a series of management decisions that emphasized a combination of moderate and low development actions organized around the division of the planning area into lowland (Zone 1) and upland (Zone 2) areas.

III. Discussion of the Proposed Supplementary Rules

In the preparation of the two EAs, the BLM sought public review of three alternatives in the Management Plan and two alternatives in the Implementation Plan. These EAs discuss specific management actions that restrict certain activities and define allowable uses. The proposed supplementary rules would implement these management actions within Zone 1 of the Water Canyon Recreation Area.

The proposed supplementary rules would:

1. Limit camping within Zone 1 of the Water Canyon Recreation Area to no more than 3 consecutive nights in a 30-day period. Water Canyon is a popular recreational spot for the local community of Winnemucca. Limiting the length of camping would increase the opportunities for multiple community residents to enjoy the campground and enhance the experience of day users.

2. Prohibit the discharge of any firearm in Zone I. This rule is proposed as a safety measure. The City of Winnemucca, population 7,400, and Grass Valley, population 1,160, are in close proximity to Zone 1, which receives more than 50,000 visitors annually.

3. All motor vehicles must not exceed the posted speed limit of 20 miles per hour on the main access/canyon road in Zone I. This speed limit is proposed because there have been numerous accidents along the main access/canyon road in Zone 1. These accidents have primarily been a result of excess speed due to no posted or enforceable speed limit.

4. All motor vehicles are restricted to travel only on the main access/canyon

road in Zone 1. This restriction is proposed to further protect the wetland and riparian areas that are in close proximity to the main access/canyon road in Zone 1.

IV. Procedural Matters

Regulatory Planning and Review (Executive Orders 12866 and 13563)

The proposed supplementary rules would not constitute a significant regulatory action and are not subject to review by the Office of Management and Budget under Executive Order 12866. The proposed supplementary rules would not have an annual effect of $100 million or more on the economy. They would not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health, or safety, or State, local, or tribal governments or communities. The proposed supplementary rules would not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. The proposed supplementary rules would not materially alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients; nor would they raise novel legal or policy issues. The proposed supplementary rules merely would be rules of conduct for public use of a limited area of public lands.

Clarity of the Regulations

Executive Order 12866 requires each agency to write regulations that are simple and easy to understand. The BLM invites your comments on how to make the proposed supplementary rules easier to understand, including answers to questions such as the following:

1. Are the requirements in the proposed supplementary rules clearly stated?

2. Do the proposed supplementary rules contain technical language or jargon that interferes with their clarity?

3. Does the format of the proposed supplementary rules (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce clarity?

4. Is the description of the proposed supplementary rules in the **SUPPLEMENTARY INFORMATION** section of this preamble helpful in understanding the supplementary rules? How could this description be more helpful in making the proposed supplementary rules easier to understand?

Please send any comments you have on the clarity of the rule to the address specified in the **ADDRESSES** section.

National Environmental Policy Act

These proposed supplementary rules provide for enforcement of decisions made in:

- The Water Canyon Management Plan, Cooperative Management Agreement, EA, and Decision Record; and
- The Water Canyon Implementation Plan Amendment, Environmental Assessment, and Decision Record (November 16, 2005).

During the National Environmental Policy Act process for each plan, many proposed actions were fully analyzed, including these proposed supplementary rules. The pertinent analysis and rationale can be found in the Management Plan, inclusive of the EA, Decision Record, and Cooperative Management Agreement approved August 15, 1997, and the Implementation Plan EA signed in 2005. The EAs mentioned above are available for review in the BLM administrative record at the address specified in the **ADDRESSES** section.

The BLM reviewed the EAs and found that the proposed supplementary rules would not constitute a major Federal action significantly affecting the quality of the human environment under the National Environmental Policy Act (NEPA) Section 102(2)(C), 42 U.S.C. 4332(2)(C).

Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act (RFA) of 1980, as amended (5 U.S.C. 601–612) to ensure that government regulations do not unnecessarily or disproportionately burden small entities. The RFA requires a regulatory flexibility analysis if a rule would have a significant economic impact, either detrimental or beneficial, on a substantial number of small entities. The proposed supplementary rules would merely establish rules of conduct for public use of a limited area of public lands. Therefore, the BLM has determined under the RFA that the proposed supplementary rules would not have a significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act

The proposed supplementary rules are not a ''major rule'' as defined under 5 U.S.C. 804(2). The proposed supplementary rules would merely establish rules of conduct for public use of a limited area of public lands and would not affect commercial or business activities of any kind.

Unfunded Mandates Reform Act

The proposed supplementary rules would not impose an unfunded mandate on State, local, or tribal governments in the aggregate, or on the private sector of more than $100 million per year; nor would they have a significant or unique effect on small governments. The proposed supplementary rules would have no effect on governmental or tribal entities and would impose no requirements on any of these entities. The proposed supplementary rules would merely establish rules of conduct for public use of a limited area of public lands and would not affect tribal, commercial, or business activities of any kind. Therefore, the BLM is not required to prepare a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*).

Executive Order 12630, Governmental Actions and Interference With Constitutionally Protected Property Rights (Takings)

The proposed supplementary rules would not have significant takings implications, nor would they be capable of interfering with Constitutionally protected property rights. The proposed supplementary rules would merely establish rules of conduct for public use of a limited area of public lands and would not affect anyone's property rights. Therefore, the BLM has determined that these rules would not cause a taking of private property or require preparation of a takings assessment under this Executive Order.

Executive Order 13132, Federalism

These proposed supplementary rules would not have a substantial direct effect on the states, the relationship between the national government and the states, nor the distribution of power and responsibilities among the various levels of government. These proposed supplementary rules would not come into conflict with any State law or regulation. Therefore, under Executive Order 13132, the BLM has determined that these proposed supplementary rules would not have sufficient Federalism implications to warrant preparation of a Federalism Assessment.

Executive Order 12988, Civil Justice Reform

Under Executive Order 12988, the BLM has determined that these proposed supplementary rules would not unduly burden the judicial system and that they would meet the requirements of Sections 3(a) and 3(b)(2) of the Order.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, the BLM has determined that these proposed supplementary rules would not include policies that have tribal implications. There are no tribal implications associated with the proposed rule. The proposed rule applies only to the narrow Zone 1 area, which is within the larger area of Water Canyon. There are no tribal lands in the vicinity.

Paperwork Reduction Act

These proposed supplementary rules would not directly provide for any information collection that the Office of Management and Budget must approve under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Any information collection that may result from Federal criminal investigations or prosecution conducted under these proposed supplementary rules is exempt from the provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. 3518(c)(1).

Author

The principal author of these proposed supplementary rules is Joey Carmosino, Humboldt River Field Office Recreation Planner, Winnemucca District, 5100 E. Winnemucca Boulevard, Winnemucca, Nevada 89445.

V. Proposed Supplementary Rules

For the reasons stated in the preamble and under the authorities for supplementary rules found at 43 U.S.C. 1740 and 43 CFR 8365.1–6, the BLM Nevada State Director proposes supplementary rules for public lands managed by the BLM in Nevada, to read as follows:

Proposed Supplementary Rules for Zone 1 of the Water Canyon Recreation Area

Definitions

Firearm means any weapon or any implement designed to or that may be converted to expel a projectile; including, but not limited to, by the action of an explosive, a compressed gas or spring powered pistol or rifle, bow and arrow, crossbow, blowgun, spear gun, spear, sling shot, or irritant gas device.

Motor vehicle includes, but is not limited to, automobiles, motorcycles, all-terrain vehicles, and off-highway vehicles.

Supplementary Rules

1. These supplementary rules apply, except as specifically exempted, to activities within Zone 1 of the Water Canyon Recreation Area, which is comprised of public lands administered by the BLM near Winnemucca, Nevada.

2. These supplementary rules are in effect on a year-round basis.

3. Camping in Zone I is limited to no more than 3 consecutive nights in a 30-day period.

4. The discharge of any firearm in Zone I is prohibited.

5. All motor vehicles must not exceed the posted speed limit of 20 miles per hour on the main access/canyon road in Zone I.

6. All motor vehicles are restricted to travel only on the main access/canyon road in Zone 1.

Exemptions

The following persons are exempt from these supplementary rules: Any Federal, State, local or military persons acting within the scope of their duties; and members of an organized rescue or firefighting force in performance of an official duty.

Penalties

Under Section 303(a) of the Federal Land Policy and Management Act (43 U.S.C. 1733(a)) and 43 CFR 8360.0–7, any person who violates any of these supplementary rules may be tried before a United States Magistrate and fined no more than $1,000 or imprisoned for no more than 12 months, or both. Such violations may also be subject to the enhanced fines provided for by 18 U.S.C. 3571. In accordance with 43 CFR 8365.1–7, State or local officials may also impose penalties for violations of Nevada law.

Amy Lueders,

Bureau of Land Management, State Director, Nevada.

[FR Doc. 2012–27402 Filed 11–8–12; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

Gulf of Mexico (GOM), Outer Continental Shelf (OCS), Western Planning Area (WPA) Lease Sale 233 and Central Planning Area (CPA) Lease Sale 231, Oil and Gas Lease Sales

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of Availability (NOA) of the Draft Supplemental Environmental Impact Statement (EIS) and Public Meetings.

Authority: This NOA is published pursuant to the regulations (40 CFR 1503) implementing the provisions of the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 et seq.).

SUMMARY: BOEM has prepared a Draft Supplemental EIS for oil and gas lease sales tentatively scheduled in 2013 and 2014 in the WPA and CPA offshore the States of Texas, Louisiana, Mississippi, and Alabama. This Draft Supplemental EIS updates the environmental and socioeconomic analyses for proposed WPA Lease Sale 233 and proposed CPA Lease Sale 231, which was completed in July 2012, as part of the 2012–2017 Multisale EIS. The 2012–2017 Multisale EIS covers planning areas in the Gulf of Mexico OCS Oil and Gas Lease Sales: Western Planning Area Lease Sales 229, 233, 238, 246, and 248; and Central Planning Area Lease Sales 227, 231, 235, 241, and 247.

SUPPLEMENTARY INFORMATION: BOEM developed this Draft Supplemental EIS for proposed WPA Lease Sale 233 and proposed CPA Lease Sale 231 to consider new information made available since completion of the 2012–2017 Multisale EIS and to consider, among other things, new information in light of the *Deepwater Horizon* event. This Draft Supplemental EIS provides updates on the baseline conditions and potential environmental effects of oil and natural gas leasing, exploration, development, and production in the WPA and CPA. BOEM conducted an extensive search for new information in consideration of the *Deepwater Horizon* event, reviewing scientific journals, available scientific data, and information from academic institutions and Federal, State, and local agencies. BOEM also interviewed personnel from academic institutions and Federal, State, and local agencies. BOEM has examined the potential impacts of routine activities and accidental events, and the proposed lease sales' incremental contribution to the cumulative impacts on environmental and socioeconomic resources.

Draft Supplemental EIS Availability: BOEM has printed and will distribute a limited number of paper copies of the Draft Supplemental EIS. In keeping with the Department of the Interior's mission of protecting natural resources, and to limit costs while ensuring availability of the document to the public, BOEM will primarily distribute digital copies of this Draft Supplemental EIS on compact discs. If you require a paper copy and copies are still available, BOEM will provide one upon request.

You may request a copy of the Draft Supplemental EIS from the Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, Public Information

Office (GM 250G), 1201 Elmwood Park Boulevard, Room 250, New Orleans, Louisiana 70123–2394 (1–800–200–GULF).

You may download or view the Draft Supplemental EIS on BOEM's Internet Web site at *http://www.boem.gov/Environmental-Stewardship/Environmental-Assessment/NEPA/nepaprocess.aspx.*

Several libraries along the Gulf Coast have been sent copies of the Draft Supplemental EIS. To find out which libraries have copies of the Draft Supplemental EIS for review, you may contact BOEM's Public Information Office (phone number and address above) or visit BOEM's Internet Web site at *http://www.boem.gov/Environmental-Stewardship/Environmental-Assessment/NEPA/nepaprocess.aspx.*

Comments: Federal, state, and local government agencies and other interested parties are requested to send their written comments on the Draft Supplemental EIS in one of the following two ways:

1. In an envelope labeled ''Comments on the Draft Supplemental EIS'' and mailed (or hand carried) to Mr. Gary D. Goeke, Chief, Regional Assessment Section, Office of Environment (GM 623E), Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394.

2. To the following BOEM email address: *LS_233–231SEIS@boem.gov.* Comments should be submitted no later than December 24, 2012.

Public Meetings: BOEM also will hold public meetings to obtain comments regarding the Draft Supplemental EIS. These meetings are scheduled as follows:

- *Houston, Texas:* December 03, 2012, Houston Airport Marriott at George Bush Intercontinental, 18700 John F. Kennedy Boulevard, Houston, Texas 77032, beginning at 1:00 p.m. CST;
- *New Orleans, Louisiana:* December 04, 2012, Bureau of Ocean Energy Management, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123, beginning at 1:00 p.m. CST;
- *Gulfport, Mississippi:* December 05, 2012, Courtyard by Marriott Gulfport Beachfront MS Hotel, 1600 East Beach Boulevard, Gulfport, Mississippi 39501, beginning at 1:00 CST;
- *Mobile, Alabama:* December 06, 2012, Five Rivers—Alabama's Delta Resource Center, 30945 Five Rivers Boulevard, Spanish Fort, Alabama 36527, beginning at 1:00 p.m. CST.

FOR FURTHER INFORMATION CONTACT: For more information on the Draft Supplemental EIS, you may contact Mr. Gary D. Goeke, Bureau of Ocean Energy Management, Gulf of Mexico OCS Region, Office of Environment (GM623E), 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394 or by email at *LS_233–231SEIS@boem.gov.* You may also contact Mr. Goeke by telephone at (504) 736–3233.

Public Disclosure of Names and Addresses

Before including your address, phone number, email address, or other personal identifying information in your comment, please be advised 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 from public review your personal identifying information, we cannot guarantee that we will be able to do so.

Dated: November 6, 2012.

Tommy P. Beaudreau,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2012–27519 Filed 11–8–12; 8:45 am]

BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–350 and 731–TA–616 and 618 (Third Review)]

Corrosion-Resistant Carbon Steel Flat Products From Germany and Korea; Revised Schedule for the Subject Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: *Effective Date:* November 2, 2012.

FOR FURTHER INFORMATION CONTACT: Mary Messer (202–205–3193), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: Effective May 21, 2012, the Commission established a schedule for the conduct of these five-year reviews (77 FR 31877, May 30, 2012). As noted in the Commission's original scheduling notice, ''The Commission has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).'' The hearing in connection with these reviews, originally scheduled for November 1, 2012, was subsequently cancelled by the Chairman due to the severity and duration of Hurricane Sandy. The Commission, therefore, is rescheduling the hearing and revising the remainder of its schedule in the five-year reviews. Prehearing briefs have already been filed in these reviews and there is no need to refile or to supplement those briefs.

The Commission's hearing on the subject reviews will be held at the U.S. International Trade Commission Building at 9:30 a.m. on January 9, 2013. Any revisions to previously submitted hearing appearance requests, which were originally due on or before October 25, 2012, should be filed in writing with the Secretary to the Commission on or before January 2, 2013. Witness hearing testimony must be filed no later than January 4, 2013. The deadline for filing posthearing briefs is January 18, 2013. In addition, any person who has not entered an appearance as a party to the reviews may submit a written statement of information pertinent to the subject of the reviews on or before January 18, 2013. On February 6, 2013, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before February 8, 2013, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules.

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

Issued: November 5, 2012.

By order of the Commission.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2012–27371 Filed 11–8–12; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–12–031]

Government In The Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: November 15, 2012 at 9:30 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: none
2. Minutes
3. Ratification List
4. Vote in Inv. Nos. 701–TA–487 and 731–TA–1197 (Final) (Steel Wire Garment Hangers from Taiwan). The Commission is currently scheduled to transmit its determinations and Commissioners' opinions to the Secretary of Commerce on or before November 29, 2012.
5. Outstanding action jackets: none

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: November 7, 2012.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2012–27484 Filed 11–7–12; 11:15 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC Se–12–030]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: November 14, 2012 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: none
2. Minutes
3. Ratification List
4. Vote in Inv. Nos. 701–TA–482–484 and 731–TA–1191–1194 (Final)(Circular Welded Carbon-Quality Steel Pipe from India, Oman, the United Arab Emirates, and Vietnam). The Commission is currently scheduled to transmit its determinations and Commissioners' opinions to the Secretary of Commerce on or before November 28, 2012.
5. Outstanding action jackets: none

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: November 7, 2012.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2012–27483 Filed 11–7–12; 11:15 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under The Comprehensive Environmental Response, Compensation, and Liability Act

On November 5, 2012, the Department of Justice lodged a proposed consent decree with the United States District Court for the Western District of Washington in the lawsuit entitled *United States* v. *Index Sportsmen, Inc. (aka Index Sportsmen Club),* Civil Action No. 12–1949.

The United States filed this CERCLA lawsuit on behalf of the United States Forest Service. The complaint requests recovery of costs that the United States incurred responding to releases of hazardous substances at the Index Shooting Range Site in the Mt. Baker-Snoqualmie National Forest near Index, Washington. Index Sportsmen, Inc., operated a trap shooting range at the site for more than 60 years and the site is contaminated with lead and arsenic from discarded shot. The proposed consent decree requires total payments of about $687,000, which includes $600,000 to be paid by American States Insurance Company. In return, the United States agrees not to sue the defendant under sections 106 and 107(a) of CERCLA.

The publication of this notice opens a period for public comment on the consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Index Sportsmen, Inc.,* D.J. Ref. No. 90–11–3–10090. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By e-mail	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General U.S. DOJ—ENRD P.O. Box 7611 Washington, D.C. 20044–7611.

During the public comment period, the consent decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $5.75 (25 cents per page reproduction cost) payable to the United States Treasury.

Robert E. Maher, Jr.,

Acting Deputy Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2012–27436 Filed 11–8–12; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application, Fisher Clinical Services, Inc.

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on August 20, 2012, Fisher Clinical Services, Inc., 7554 Schantz Road,

Allentown, Pennsylvania 18106, made application to the Drug Enforcement Administration (DEA) for registration as an importer of Tapentadol (9780), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance to conduct clinical trials.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance listed in schedule II, which falls under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR § 1301.43 and in such form as prescribed by 21 CFR § 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than December 10, 2012.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR § 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic class of any controlled substances in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR § 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: November 1, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2012–27437 Filed 11–8–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer Of Controlled Substances; Notice of Registration; Boehringer Ingelheim Chemicals, Inc.

By Notice dated July 17, 2012, and published in the **Federal Register** on July 26, 2012, 77 FR 43861, Boehringer Ingelheim Chemicals, Inc., 2820 N. Normandy Drive, Petersburg, Virginia 23805, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Phenylacetone (8501), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance to bulk manufacture amphetamine.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a), and determined that the registration of Boehringer Ingelheim Chemicals, Inc., 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.

DEA has investigated Boehringer Ingelheim, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of 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 class of controlled substance listed.

Dated: November 1, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2012–27440 Filed 11–8–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application; Noramco, Inc.

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on July 9, 2012, Noramco, Inc., 1440 Olympic Drive, Athens, Georgia 30601, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Gamma Hydroxybutyric Acid (2010).	I
Codeine-N-oxide (9053)	I
Dihydromorphine (9145)	I
Morphine-N-oxide (9307)	I
Amphetamine (1100)	II
Methylphenidate (1724)	II
Codeine (9050) II Dihydrocodeine (9120).	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Carfentanil (9743)	II
Tapentadol (9780)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than January 8, 2013.

Dated: November 1, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2012–27394 Filed 11–8–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application; Johnson Matthey, Inc.

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on September 10, 2012, Johnson Matthey, Inc., Pharmaceuticals Materials, 900 River Road, Conshohocken, Pennsylvania 19428, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Gamma Hydroxybutyric Acid (2010).	I
Amphetamine (1100)	II
Methylphenidate (1724)	II
Codeine (9050)	II
Oxycodone (9143)	II

Drug	Schedule
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 also be used to manufacture other controlled substances for sale in bulk to its customers.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, **Federal Register** Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than January 8, 2013.

Dated: November 1, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2012–27398 Filed 11–8–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application, Cody Laboratories, Inc.

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on May 30, 2012, Cody Laboratories, Inc., ATTN: Richard Asherman, 601 Yellowstone Avenue, Cody, Wyoming 82414, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	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 on manufacturing the listed controlled substances in bulk for sale to its customers.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than January 8, 2013.

Dated: November 1, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2012–27401 Filed 11–8–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances Notice of Application; National Center For Natural Products Research (NIDA MPROJECT)

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on July 17, 2012, National Center for Natural Products Research—NIDA MProject, University of Mississippi, 135 Coy Waller Complex, University, Mississippi 38677, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Drug	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I

The company plans to cultivate marihuana for the National Institute on Drug Abuse for research approved by the Department of Health and Human Services.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than January 8, 2013.

Dated: November 1, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2012–27441 Filed 11–8–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application; INB Hauser Pharmaceutical Services, Inc.

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on September 20, 2012, InB Hauser Pharmaceutical Services, Inc., 6880 N. Broadway, Suite H, Denver, Colorado 80221, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of 4-Anilino-N-phenethyl-4-piperidine (8333), a basic class of controlled substance listed in schedule II.

The company plans to manufacture the listed controlled substance in bulk for distribution and sale to its customers.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substance, may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections should be addressed, in

quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than January 8, 2013.

Dated: November 1, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2012–27400 Filed 11–8–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,393]

Trim Systems Operating Corp., a Subsidiary of Commercial Vehicle Group, Inc., Including On-Site Leased Workers From Staffmark, Including On-Site Leased Workers From Staffmark Whose Wages Are Paid Under CBS Personnel, Inc., Statesville, NC; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on April 6, 2012, applicable to workers and former workers of Trim Systems Operating Corp., a subsidiary of Commercial Vehicle Group, Inc., Statesville, North Carolina. The workers' firm is engaged in activities related to production of interior headliners, backwall and sidewall panels, flooring, curtains, and bunks for commercial vehicles. The worker group also includes on-site leased workers from Staffmark.

At the request of a company official, the Department reviewed the certification for workers of the subject firm. New information provided by company officials show that some workers of Staffmark had wages paid under the name CBS Personnel, Inc.

The intent of the Department's certification is to include all workers of the subject firm, including on-site leased worker, who were adversely affected by a shift in production to a foreign country.

The amended notice applicable to TA–W–81,393 is hereby issued as follows:

All workers of Trim Systems Operating Corp., a subsidiary of Commercial Vehicle Group, Inc., including on-site leased workers of Staffmark and including on-site leased workers of Staffmark whose wages are paid under CBS Personnel, Inc., Statesville, North Carolina, who became totally or partially separated from employment on or after March 1, 2011 through April 6, 2014, and all workers in the group threatened with total or partial separation from employment on April 6, 2012 through April 6, 2014, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

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

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–27413 Filed 11–8–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,576]

State Street Corporation, Putnam Cash Reconciliations Team, Including On-Site Leased Workers From APC Workforce Solutions II, LLC, D/B/A ZeroChaos, Quincy, MA; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. § 2273, the Department of Labor (Department) issued a Certification of Eligibility To Apply for Worker Adjustment Assistance on June 16, 2012, applicable to workers and former workers of State Street Corporation, Putnam Cash Reconciliation Team, Quincy, Massachusetts. The workers were engaged in activities related to the supply of cash reconciliation services.

New information obtained by the Department revealed that workers leased from APC Workforce Solutions II, LLC, doing business as (D/B/A) ZeroChaos, were employed on-site at State Street Corporation, Putnam Cash Reconciliation Team, Quincy, Massachusetts. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include on-site workers leased from APC Workforce Solutions II, LLC, D/B/A ZeroChaos, and has terminated the investigation of the petition that was filed on behalf of workers of APC Workforce Solutions II, LLC, D/B/A ZeroChaos, who worked on-site at State Street Corporation, Putnam Cash Reconciliation Team, Quincy, Massachusetts (TA–W–81,998).

The amended notice applicable to TA–W–81,576 is hereby issued as follows:

All workers of State Street Corporation, Putnam Cash Reconciliations Team, including on-site leased workers from APC Workforce Solutions II, LLC, D/B/A ZeroChaos, Quincy, Massachusetts, who became totally or partially separated from employment on or after April 26, 2011 through June 18, 2012, and all workers in the group threatened with total or partial separation from employment on June 18, 2012 through June 18, 2014, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 24th day of October, 2012.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–27414 Filed 11–8–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,739; TA–W–81,739A]

Hewlett-Packard Company, Design Delivery Organization (DDO), Including On-Site Leased Workers From Manpower, Synova Inc., and Pinnacle Technical Resources, Corvallis, OR; Hewlett-Packard Company, Ink Jet & Web Services, World Wide Design Group, Vancouver, WA; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on September 18, 2012, applicable to workers of Hewlett-Packard Company, Design Delivery Organization (DDO), Corvallis, Oregon. The Department's notice of determination was published in the **Federal Register** on October 5, 2012 (77 FR 194). Workers are engaged in activities related to the supply of new product introduction, development, and support.

New information obtained by the subject firm revealed that workers at Hewlett-Packard Company, Ink Jet & Web Services, World Wide Design Group, Vancouver, Washington

operated in conjunction with Hewlett-Packard Company, DDO, Corvallis, Oregon.

The intent of the Department's certification is to include all workers at Hewlett-Packard Company, DDO, Corvallis, Oregon and Hewlett-Packard Company, Ink Jet & Web Services, World Wide Design Group, Vancouver, Washington who were adversely affected by a shift of services abroad.

The amended notice applicable to TA–W–81,739 is hereby issued as follows:

All workers of Hewlett-Packard Company, Design Delivery Organization (DDO), including on-site leased workers from Manpower, Synova, Inc., and Pinnacle Technical Resources, Corvallis, Oregon (TA–W–81,739), and all workers of Hewlett-Packard Company, Ink Jet & Web Services, World Wide Design Group, Vancouver, Washington (TA–W- 81,739A), who became totally or partially separated from employment on or after June 20, 2011 through September 18, 2012, and all workers in the groups threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1074, as amended.

Signed at Washington, DC this 31st day of October, 2012.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–27415 Filed 11–8–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,879]

RG Steel Wheeling, LLC, a Division of RG Steel, LLC, Doing Business as Wheeling Corrugating Company, Including Workers Whose Wages Were Reported Through Severstal Wheeling, Beech Bottom, WV; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on September 25, 2012, applicable to workers of RG Steel Wheeling, LLC, a division of RG Steel, LLC, doing business as Wheeling Corrugating Company, Beech Bottom, West Virginia. The Department's notice of determination was published in the **Federal Register** on October 12, 2012 (77 FR 62262).

At the request of a state workforce office, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to the production of roof and floor decks.

New information shows that some workers separated from employment at RG Steel Wheeling, LLC had their wages reported through a separate unemployment insurance (UI) tax account under the name Severstal Wheeling, a former owner of the workers' firm.

The intent of the Department's certification is to include all workers of the subject firm who meet the worker group certification criteria under Section 222(b) of the Act, 19 U.S.C. 2272(b).

Accordingly, the Department is amending this certification to properly reflect this matter.

The amended notice applicable to TA–W–81,879 is hereby issued as follows:

All workers of RG Steel Wheeling, LLC, a division of RG Steel, LLC, doing business as Wheeling Corrugating Company, Beech Bottom, West Virginia, including workers whose unemployment insurance (UI) wages are reported through Severstal Wheeling who became totally or partially separated from who became totally or partially separated from employment on or after August 7, 2011, through September 25, 2014, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC this 1st day of November, 2012.

Elliott S. Kushner,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–27416 Filed 11–8–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers by (TA–W) number issued during the period of October 15, 2012 through October 19, 2012.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Under Section 222(a)(2)(A), the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The sales or production, or both, of such firm have decreased absolutely; and

(3) One of the following must be satisfied:

(A) Imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) Imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) Imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased;

(D) Imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) The increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) There has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive with those produced/supplied by the workers' firm;

(B) There has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) The shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in public agencies and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) A significant number or proportion of the workers in the public agency have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The public agency has acquired from a foreign country services like or directly competitive with services which are supplied by such agency; and

(3) The acquisition of services contributed importantly to such workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(c) of the Act must be met.

(1) A significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm is a Supplier or Downstream Producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(f) of the Act must be met.

(1) The workers' firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) An affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) An affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) An affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) The petition is filed during the 1-year period beginning on the date on which—

(A) A summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the **Federal Register** under section 202(f)(3); or

(B) Notice of an affirmative determination described in subparagraph (1) is published in the **Federal Register**; and

(3) The workers have become totally or partially separated from the workers' firm within—

(A) The 1-year period described in paragraph (2); or

(B) Notwithstanding section 223(b)(1), the 1-year period preceding the 1-year period described in paragraph (2).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
81,717	Sanmina-SCI, MSD Division, Manpower	Turtle Lake, WI	June 7, 2011.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production or services) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
81,918	Avnet, Inc., Logistics Div., Collectron and Sonitronics, Remote Workers in Nogales, AZ.	Richardson, TX	August 23, 2011.
81,921	Schneider Electric, Global Supply Chain, NA, leased workers from Volt Workforce Solutions.	Cedar Rapids, IA	August 24, 2011.
81,961	American Express Travel Related Services Company, Inc., World Service Global New Accounts, Kelly Services.	Salt Lake City, UT	September 6, 2011.
81,966	AT&T Services, Inc., Information Technology Operations, Global Systems Hosting, etc.	Bothell, WA	August 5, 2012.
81,966A	Leased Workers from Collabera, Inc., Data Domain LLC, Data Vista, Inc., Decision One, EMC Corporation, Etech, Evergreen Power Systems, etc.	Bothell, WA	September 12, 2011.
81,973	Sun Life Financial (U.S.) Services Company, Inc., Sun Life Financial, Inc., Adecco.	Greenfield, MA	September 17, 2011.
81,987	Cincinnati Bell Telephone Company, LLC, Cincinnati Bell, Inc., Call Center Operations Division.	Norwood, OH	September 19, 2011.
81,987A	Cincinnati Bell Telephone Company, LLC, Cincinnati Bell, Inc., Call Center Operations Division.	Lebanon, OH	September 19, 2011.
81,992	Cox Media Group Ohio, Inc., Graphic Design Group, Cox Enterprises, Inc.	Dayton, OH	September 20, 2011.

TA–W No.	Subject firm	Location	Impact date
81,994	Ahlstrom West Carrollton LLC	West Carrollton, OH	September 20, 2011.
82,002	E! Entertainment Television, LLC, G4 Media, NBC Universal, Cable Networks, Randstad Sourceright, etc..	Los Angeles, CA	September 24, 2011.
82,006	Tellabs Inc., Supply Chain Test Engineering Division	Naperville, IL	September 25, 2011.
82,007	Maysteel LLC, a subsidiary of Everett Smith Group LTD, leased from Randstad Engineering, Aerotek Commercial Staffing.	Creedmoor, NC	September 25, 2011.
82,007A	Maysteel LLC, a subsidiary of Everett LTD	Allenton, WI	September 25, 2011.
82,008	BRP US, Inc., Sport Boat Division, Select Remedy	Benton, IL	September 25, 2011.
82,009	ITT Cannon, LLC, a subsidiary of ITT Corporation, on-site leased Innovative, First Choice, Prosearch, First, Peopleware, etc.	Santa Ana, CA	September 25, 2011.
82,012	Oxford Collections, Customer Service Department, LF USA	Gaffney, SC	March 13, 2012.
82,039	Wellpoint, Inc., Wellpoint Companies, West Host Claims & Adjustment, Kelly Services, Aerotek.	Denver, CO	October 2, 2011.
82,046	Wire Company Holdings, Inc. DBA New York Wire, Wire Mesh Holdings, Inc., Manpower.	Hanover, PA	October 2, 2011.
82,046A	Wire Company Holdings, Inc. DBA New York Wire, E. Market Street Facility, Wire Mesh Holdings, Manpower and Temp Star.	York, PA	October 2, 2011.
82,046B	Wire Company Holdings, Inc. DBA New York Wire, Loucks Mill Road, Wire Mesh Holdings, Temp Star Staffing.	York, PA	October 2, 2011.
82,048	Hartford Financial Services Group, Inc., Operations/Wealth Management/Document Control Services.	Windsor, CT	October 3, 2011.
82,049	Hartford Financial Services Group, Inc., Corporate/Finance/Controllers/Accounting Operations.	Simsbury, CT	October 3, 2011.
82,049A	Hartford Financial Services Group, Inc., Corporate/Finance/Controllers/Accounting Operations.	Hartford, CT	October 3, 2011.
82,050	Hartford Financial Services Group, Inc., IT/Project Management	Simsbury, CT	October 3, 2011.
82,050A	Hartford Financial Services Group, Inc., IT/Project Management	Hartford, CT	October 3, 2011.
82,050B	Hartford Financial Services Group, Inc., IT/Project Management	Windsor, CT	October 3, 2011.
82,051	Hartford Financial Services Group, Inc., Operations/Commercial/Premium Audit/Reviewers.	San Antonio, TX	October 3, 2011.
82,051A	Hartford Financial Services Group, Inc., Operations/Commercial/Premium Audit/Reviewers.	Clinton, NY	October 3, 2011.
82,055	Hartford Financial Services Group, Inc., Operations/Commercial Markets/Group Benefits/STAT BRC.	Windsor, CT	October 4, 2011.
82,056	Hartford Financial Services Group, Inc., Operations/Commercial Markets/Group Benefits/STAT BRC.	Overland Park, KS	October 4, 2011.

The following certifications have been issued. The requirements of Section 222(c) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
81,859	PBS Coals, Inc., David Stanley Consultants and Strata Mine Services, UI Wages through Roxcoal.	Friedens, PA	August 6, 2011.

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

The investigation revealed that the criteria under paragraphs (a)(2)(A)(i) (decline in sales or production, or both) and (a)(2)(B) (shift in production or services to a foreign country) of section 222 have not been met.

TA–W No.	Subject firm	Location	Impact date
81,929	Joy Global, Inc., Joy Technologies, All Seasons Temporaries and Manpower.	Franklin, PA.	

The investigation revealed that the criteria under paragraphs(a)(2)(A) (increased imports) and (a)(2)(B) (shift in production or services to a foreign country) of section 222 have not been met.

TA–W No.	Subject firm	Location	Impact date
81,744	Kyowa America Corporation, Pennsylvania Division, Kyowa Electric & Chemical Japan, Spherion Staffing.	Waynesburg, PA.	
81,804	Earthgrains Baking Companies, Inc., Earthgrains Baking Group, dba Bimbo Bakeries, USA, Randstand.	Knoxville, TN.	
81,964	Hewlett Packard Company, Switchboard Division	Plano, TX.	

TA–W No.	Subject firm	Location	Impact date
82,022	RG Steel	Allenport, PA.	

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and on the Department's Web site, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioner has requested that the petition be withdrawn.

TA–W number	Subject firm	Location	Impact date
81,934	Zenda Leather	Connelly Springs, NC.	
82,042	Covidien	Seneca, SC.	

The following determinations terminating investigations were issued because the petitioning groups of workers are covered by active certifications. Consequently, further investigation in these cases would serve no purpose since the petitioning group of workers cannot be covered by more than one certification at a time.

TA–W No.	Subject firm	Location	Impact date
81,998	APC Workforce Solutions II, LLC, dba Zerochaos, State Street Corporation.	Quincy, MA.	
82,054	Hartford Financial Services Group, Inc., IT/Project Management	Windsor, CT.	

The following determinations terminating investigations were issued because the petitions are the subject of ongoing investigations under petitions filed earlier covering the same petitioners.

TA–W No.	Subject firm	Location	Impact date
82,017	PotashCorp-Aurora	Aurora, NC.	

I hereby certify that the aforementioned determinations were issued during the period of October 15, 2012 through October 19, 2012. These determinations are available on the Department's Web site *tradeact/taa/taa search firm.cfm* under the searchable listing of determinations or by calling the Office of Trade Adjustment Assistance toll free at 888–365–6822.

Dated: October 31, 2012.

Elliott S. Kushner,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–27418 Filed 11–8–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers by (TA–W) number issued during the period of October 22, 2012 through October 26, 2012.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Under Section 222(a)(2)(A), the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The sales or production, or both, of such firm have decreased absolutely; and

(3) One of the following must be satisfied:

(A) Imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) Imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) Imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased;

(D) Imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) The increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) There has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive

with those produced/supplied by the workers' firm;

(B) There has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) The shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in public agencies and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) A significant number or proportion of the workers in the public agency have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The public agency has acquired from a foreign country services like or directly competitive with services which are supplied by such agency; and

(3) The acquisition of services contributed importantly to such workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(c) of the Act must be met.

(1) A significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm is a Supplier or Downstream Producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(f) of the Act must be met.

(1) The workers' firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) An affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) An affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) An affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) The petition is filed during the 1-year period beginning on the date on which—

(A) A summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the **Federal Register** under section 202(f)(3); or

(B) Notice of an affirmative determination described in subparagraph (1) is published in the **Federal Register**; and

(3) The workers have become totally or partially separated from the workers' firm within—

(A) The 1-year period described in paragraph (2); or

(B) Notwithstanding section 223(b)(1), the 1-year period preceding the 1-year period described in paragraph (2).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
81,747	Logan Industries	Spokane, WA	January 26, 2012.
81,747A	Aerotek Commercial, Inc., Working On-Site at Logan Industries	Spokane, WA	June 14, 2011.
81,861	Marlatex Corporation	Belmont, NC	August 3, 2011.
82,052	Envelope Product Group, LLC, Cenveo Corporation	Kenosha, WI	October 2, 2011.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production or services) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
81,857	Cordia IP Corporation, Cordia Communications Corporation	Winter Garden, FL	August 4, 2011.
81,904	American Showa, Inc., Blanchester Plant, Adecco	Blanchester, OH	August 16, 2011.
81,945	Pfizer Therapeutic Research, Pfizer Worldwide R&D, Warner Lambert, Charles River, etc.	Groton, CT	September 5, 2011.
81,949	SDL Enterprise Technologies, Inc., Help Desk	Chicago, IL	September 6, 2011.
81,951	AGI—Shorewood	Weaverville, NC	September 6, 2011.
81,960	Verizon Business Networks Services, Inc., Verizon Services Organization, Senior Coordinator—Customer Service.	Highlands, CO	September 7, 2011.
81,962	Verizon Business Networks Services, Inc., Lead Specialist—Technical Service and Manager—Technical Service.	Richardson, TX	September 10, 2011.
81,962A	Verizon Business Networks Services, Inc., Lead Specialist—Technical Service and Manager—Technical Service.	Rancho Cordova, CA	September 10, 2011.

TA–W No.	Subject firm	Location	Impact date
81,962B	Verizon Business Networks Services, Inc., Lead Specialist—Technical Service and Manager—Technical Service.	Patchogue, NY	September 10, 2011.
81,962C	Verizon Business Networks Services, Inc., Lead Specialist—Technical Service and Manager—Technical Service.	Rye Brook, NY	September 10, 2011.
81,962D	Verizon Business Networks Services, Inc., Lead Specialist—Technical Service and Manager—Technical Service.	San Antonio, TX	September 10, 2011.
81,962E	Verizon Business Networks Services, Inc., Lead Specialist—Technical Service and Manager—Technical Service.	Ashburn, VA	September 10, 2011.
81,969	Schawk Minneapolis	Minneapolis, MN	October 17, 2011.
81,986	Genzyme Corporation, Sanofi S.A., Enterprise IT Network Operations Center, Pro-Unlimited.	Framingham, MA	September 20, 2011.
81,991	Delphi Electronics and Safety, Delphi Corporation	Kokomo, IN	March 25, 2012.
81,991A	Leased Workers from ACRO Service Corporation, Advantage, Technical Resources, Aerotek, Delphi Electronics, Delphi Corp.	Kokomo, IN	September 20, 2011.
81,991B	Delphi Electronics and Safety, Delphi Corporation, Alliance Group Technologies, Bartech Group, etc.	Auburn Hills, MI	September 20, 2011.
81,993	Experian Marketing Solutions, Data Marketing Service Division, Tapfin Manpower Group Solutions.	Schaumburg, IL	September 20, 2011.
81,995	Bank of America, Internal Recon Control (IRC), Corp. Infrastructure Finance Division.	Seattle, WA	September 19, 2011.
82,001	Royal Appliance Manufacturing Company, dba TTI Flooring Care N.A., Hoover, Inc.	Canton, OH	September 25, 2011.
82,001A	Royal Appliance Manufacturing Company, dba TTI Flooring Care N.A., Hoover, Inc.	North Canton, OH	September 25, 2011.
82,010	Dell Marketing L.P., Public Sales in Major Public Accounts, Select Public Accounts, etc.	Round Rock, TX	September 26, 2011.
82,020	Asheboro Wire Plant-Hyosung USA, On-site Leased Workers from Defender Staffing, Starr Electric Company, etc.	Asheboro, NC	September 28, 2011.
82,063	Fashion Tech, Inc., A Division of Hunter Douglas	Portland, OR	October 8, 2011.
82,070	The Great Atlantic & Pacific Tea Company, Inc., Accounting Clerks.	Montvale, NJ	October 10, 2011.
82,072	The Denver Post, Circulation Call Center, Ultimate Staffing Service.	Denver, CO	October 11, 2011.
82,073	Sartorius Stedim SUS, Inc., Sartorius Group North America, Aerotek.	Concord, CA	October 12, 2011.

The following certifications have been issued. The requirements of Section 222(c) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
81,974	Maryland Pig Services L.P	Sparrows Point, MD	September 17, 2011.

The following certifications have been issued. The requirements of Section 222(c) (downstream producer for a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
81,955	Pocahontas Machine Works, Inc., A.I.D. Temporary Services, Inc	Pocahontas, AR	September 6, 2011.

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

The investigation revealed that the criterion under paragraph (a)(1), or (b)(1), or (c)(1)(employment decline or threat of separation) of section 222 has not been met.

TA–W No.	Subject firm	Location	Impact date
81,977	Flavor House Products, Inc., Ralcorp Holdings, Inc., Ralcorp Snacks, Sauces and Spreads Division.	Dothan, AL.	

The investigation revealed that the criteria under paragraphs(a)(2)(A) (increased imports) and (a)(2)(B) (shift in production or services to a foreign country) of section 222 have not been met.

TA–W No.	Subject firm	Location	Impact date
81,926	Hewlett Packard, Enterprise Services Division, Applications Best Shore (CAGD).	Pontiac, MI.	
81,926A	Hewlett Packard, Enterprise Services Division, Applications Best Shore (CAGD).	Cincinnati, OH.	

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and on the Department's Web site, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioner has requested that the petition be withdrawn.

TA–W No.	Subject firm	Location	Impact date
81,980	Bank of America	Addison, TX.	

The following determinations terminating investigations were issued in cases where these petitions were not filed in accordance with the requirements of 29 CFR 90.11. Every petition filed by workers must be signed by at least three individuals of the petitioning worker group. Petitioners separated more than one year prior to the date of the petition cannot be covered under a certification of a petition under Section 223(b), and therefore, may not be part of a petitioning worker group. For one or more of these reasons, these petitions were deemed invalid.

TA–W No.	Subject firm	Location	Impact date
81,978	Peabody Energy	Evansville, IN.	

The following determinations terminating investigations were issued because the petitioning groups of workers are covered by active certifications. Consequently, further investigation in these cases would serve no purpose since the petitioning group of workers cannot be covered by more than one certification at a time.

TA–W No.	Subject firm	Location	Impact date
81,997	Tyco Electronics, Telecom Networks (Business Unit) Division	Shakopee, MN.	
82,019	Delphi Electronics and Safety, Delphi Corporation	Auburn Hills, MI.	

I hereby certify that the aforementioned determinations were issued during the period of October 22, 2012 through October 26, 2012. These determinations are available on the Department's Web site tradeact/taa/taa search firm.cfm under the searchable listing of determinations or by calling the Office of Trade Adjustment Assistance toll free at 888–365–6822.

Dated: November 1, 2012.

Elliott S. Kushner,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2012–27419 Filed 11–8–12; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221 (a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than November 19, 2012.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than November 19, 2012.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC this 24th day of October 2012.

Elliott S. Kushner,

Certifying Officer, Office of Trade Adjustment Assistance.

APPENDIX

[22 TAA petitions instituted between 10/15/12 and 10/19/12]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
82074	Komax Solar, Inc. (Workers)	York, PA	10/15/12	10/12/12
82075	Ingersoll Rand/Trane (Union)	Tyler, TX	10/15/12	10/12/12
82076	Manitowoc Foodservice, Lincoln Foodservice Division (Union).	Fort Wayne, IN	10/15/12	10/12/12
82077	Consolidated Pine Inc. (Workers)	Prineville, OR	10/15/12	10/12/12
82078	ASF Keystone, Inc. (Union)	Granite City, IL	10/15/12	10/12/12
82079	WellPoint Inc. (Anthem Blue Cross Blue Shield) (Workers)	Richmond & Roanoke, VA	10/15/12	10/12/12
82080	International Business Machines Corporation (IBM) (State/One-Stop).	Richmond, VA	10/15/12	10/11/12
82081	Teters Floral Products (Workers)	Bolivar, MO	10/15/12	10/12/12
82082	The Evercare Company dba OneCare (State/One-Stop)	Waynesboro, GA	10/16/12	10/15/12
82083	Net Cracker (State/One-Stop)	Cincinnati, OH	10/16/12	10/15/12
82084	Greene Brothers Furniture (Workers)	North Wilkesboro, NC	10/17/12	09/20/12
82085	Spherion Staffing (State/One-Stop)	Ft. Collins, CO	10/17/12	10/16/12
82086	Ball Metal Container Corporation (Union)	Columbus, OH	10/17/12	10/16/12
82087	Medtronic Advanced Energy (Formerly Known as PEAK Surgical., Inc) (Company).	Palo Alto, CA	10/17/12	10/16/12
82088	Deloitte Tax LLP (State/One-Stop)	Los Angeles, CA	10/17/12	10/16/12
82089	The Billings Gazette (Workers)	Billings, MT	10/17/12	10/15/12
82090	Oce Reprographic Technologies (State/One-Stop)	Phoenix, AZ	10/17/12	10/16/12
82091	T-Shirt International Inc. (Company)	Culloden, WV	10/18/12	10/16/12
82092	General Mills (State/One-Stop)	Minneapolis, MN	10/18/12	10/18/12
82093	Korean Air (Workers)	Los Angeles, CA	10/18/12	10/17/12
82094	Anthem Insurance Companies/Wellpoint, Inc. (State/One-Stop).	Cape Girardeau, MO	10/18/12	10/17/12
82095	Verizon Services Corporation (Workers)	Clarksburg, WV	10/18/12	08/07/12

[FR Doc. 2012–27417 Filed 11–8–12; 8:45 am]

BILLING CODE 4510–FN–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of Permit Applications Received under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at Title 45 Part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by December 10, 2012. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Polly A. Penhale at the above address or (703) 292–7420.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

The applications received are as follows:

1. Applicant

Permit Application: 2013–024.

Diane M. McKnight, INSTARR, 1560 30th Street, Boulder, CO 80309.

Activity for Which Permit Is Requested

Enter Antarctic Specially Protected Areas. The applicant plans to enter access the recently designated Antarctic Specially Protected Area (ASPA) 172-Blood Falls, Santa Fe Stream and the lower Taylor Glacier in order to conduct ongoing research at Blood Falls and nearby streams and the glacier mass balance measurement sites located on the lower Taylor Glacier. Activities include collecting samples of water and ice, measuring stream discharge, and traveling through the area on foot to access monitoring sites on the glacier surface.

Location

ASPA 172- Blood Falls, Santa Fe Stream and the lower Taylor Glacier, Taylor Valley, McMurdo Dry Valleys.

Dates

December 1, 2012 to February 28, 2017.

Nadene G. Kennedy,

Permit Officer, Office of Polar Programs.

[FR Doc. 2012–27383 Filed 11–8–12; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permits issued under the Antarctic Conservation of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy, Permit Office, Office of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

SUPPLEMENTARY INFORMATION: On October 3, 2012, the National Science Foundation published a notice in the **Federal Register** of a permit application received. A permit was issued on November 5, 2012 to:

Diana Wall Permit No. 2013–023

Nadene G. Kennedy,

Permit Officer.

[FR Doc. 2012–27359 Filed 11–8–12; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permits issued under the Antarctic Conservation of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy, Permit Office, Office of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

SUPPLEMENTARY INFORMATION: On October 3, 2012, the National Science Foundation published a notice in the **Federal Register** of a permit application received. A permit was issued on November 6, 2012 to: Mahlon C. Kennicutt, II; Permit No. 2013–022.

Nadene G. Kennedy,

Permit Officer.

[FR Doc. 2012–27377 Filed 11–8–12; 8:45 am]

BILLING CODE 7555–01–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 host the SEC Government-Business Forum on Small Business Capital Formation on Thursday, November 15, 2012, beginning at 9:00 a.m. in the auditorium of the Commission's headquarters at 100 F Street NE., Washington, DC. Doors will open at 8:30 a.m. Visitors will be subject to security checks.

This Sunshine Act notice is being issued because a majority of the Commission may attend the meeting.

The forum will include remarks by SEC Commissioners and panel discussions that Commissioners may attend. Panel topics will include JOBS Act implementation and small business capital formation issues not addressed by the JOBS Act. Members of the public may attend the forum without charge. The Commissioner remarks and panel discussions will be webcast from the SEC's Web site.

For further information, please contact the Office of the Secretary at (202) 551–5400.

Dated: November 7, 2012.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2012–27528 Filed 11–7–12; 4:15 pm]

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 Friday, November 9, 2012 at 9:00 a.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(5), (7), 9(B) and (10) and 17 CFR 200.402(a)(5), (7), 9(ii) and (10), permit consideration of the scheduled matters at the Closed Meeting.

Commissioner Aguilar, as duty officer, voted to consider the items listed for the Closed Meeting in a closed session and determined that no earlier notice thereof was possible.

The subject matter of the Closed Meeting scheduled for Thursday, November 8, 2012 will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative 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: November 7, 2012.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2012–27529 Filed 11–7–12; 4:15 pm]

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, November 15, 2012 at 10:00 a.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(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 matters at the Closed Meeting.

Commissioner Aguilar, as duty officer, voted to consider the items listed for the Closed Meeting in a closed session.

The subject matter of the Closed Meeting scheduled for Thursday, November 8, 2012 will be:

Institution and settlement of injunctive actions; institution and settlement of administrative proceedings; and a litigation matter.

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: November 7, 2012.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2012–27530 Filed 11–7–12; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68153; File No. SR–NASDAQ–2012–124]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To Amend Several NASDAQ Rules To Reflect Changes to Rules of the Financial Industry Regulatory Authority (''FINRA'')

November 5, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 22, 2012, The NASDAQ Stock Market LLC (''Exchange''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. On October 26, 2012, the Exchange submitted Amendment No. 1 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1 thereto, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend several NASDAQ rules to reflect changes to rules of the Financial Industry Regulatory Authority (''FINRA''). NASDAQ will implement the proposed rule change thirty days after the date of the filing. The text of the proposed rule change is available at *http://nasdaq.cchwallstreet.com,* at NASDAQ's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Many of NASDAQ's rules governing member conduct are based on rules of FINRA (formerly the National Association of Securities Dealers (''NASD'')). During 2008, FINRA embarked on an extended process of moving rules formerly designated as ''NASD Rules'' into a consolidated FINRA rulebook. In most cases, FINRA has renumbered these rules, and in some cases has substantively amended them. Accordingly, NASDAQ has also been undertaking a process of modifying its rulebook to ensure that NASDAQ rules corresponding to FINRA/NASD rules continue to mirror them as closely as practicable. To the extent possible, NASDAQ will designate a NASDAQ rule that is intended to parallel a FINRA rule with the suffix ''A''. For example, the NASDAQ rule paralleling FINRA Rule 5320 will be designated as Rule 5320A. This filing makes the following changes:

(1) NASDAQ is redesignating IM–2110–2 (Trading Ahead of Customer Limit Order) and Rule 2111 (Trading Ahead of Customer Market Orders) as NASDAQ Rule 5320A, which incorporates FINRA Rule 5320 (Prohibition Against Trading Ahead of Customer Orders) by reference.[4] FINRA Rule 5320.02(b) and the reference to Rule 6420 contained therein, which relate to over-the-counter equity securities, will not be reflected in NASDAQ's rule since NASDAQ, unlike FINRA, does not regulate the over-the-counter market.

(2) NASDAQ is redesignating Rules 6950, 6951, 6952, 6953, 6954, 6955, and 6956 as Rules 7400A (Order Audit Trail System), 7410A (Definitions), 7420A (Applicability), 7430A (Synchronization of Member Business Clocks), 7440A (Recording of Order Information), 7450A (Order Data Transmission Requirements), and 7460A (Violation of Order Audit Trail System Rules). NASDAQ is also deleting Rule 6957 (Effective Date), redesignating Rule 6958 as Rule 7470A, and amending that rule to reinstate its effectiveness until July 10, 2015 and make [sic] conforming changes to rule cross-references. By its terms, the effectiveness of the rule had lapsed on July 10, 2011. NASDAQ is reinstating the rule in order to ensure that NASDAQ has the same exemptive authority as FINRA with regard to the application of OATS rules, to ensure that its respective members are not subject to disparate requirements.[5] NASDAQ is also making changes to rule text to conform to changes to corresponding FINRA rules.[6]

(3) NASDAQ is redesignating Rule 2110 as Rule 2010A (Standards of Commercial Honor and Principles of Trade) and deleting IM–2110–1 (Reserved).[7]

NASDAQ notes that in some instances, the amended rules reference rules that are being adopted by contemporaneous NASDAQ rule filings that have been filed on an immediately effective basis.[8]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[9] in general, and with Section 6(b)(5) of the Act,[10] in particular, in that the proposal is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The proposed changes will conform various NASDAQ Rules to changes made to corresponding FINRA rules, thus promoting application of consistent regulatory standards with respect to rules that FINRA enforces pursuant to its regulatory services agreement with NASDAQ.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the Exchange amended Exhibit 1 to: (1) Explain the lapse of effectiveness of Nasdaq Rule 6958; (2) redesignate Rule 6958 as Rule 7470A; and (3) reinstate that Rule's effectiveness to grant Nasdaq exemptive authority with regard to the application of OATS rules. In addition, the Exchange made technical amendments to Exhibit 5 to reflect that prior Rule 6958 is being redesignated as Rule 7470A.

[4] *See* Securities Exchange Act Release No. 63895 (February 11, 2011), 76 FR 9386 (February 17, 2011) (SR–FINRA–2009–090).

[5] The Commission notes that no retroactive coverage is granted to Nasdaq for any actions taken under this Rule during its lapsed period.

[6] *See* Securities Exchange Act Release No. 58643 (September 25, 2008), 73 FR 57174 (October 1, 2008) (SR–FINRA–2008–021, –022, –026, –028, –029).

[7] *Id.*

[8] *See* SR–NASDAQ–2012–122 (October 22, 2012); SR–NASDAQ–2012–123 (October 22, 2012).

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(5).

any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change is effective upon filing pursuant to Section 19(b)(3)(A) of the Act [11] and paragraph (f)(6) of Rule 19b–4 thereunder,[12] in that the proposed rule change: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest; provided the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

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, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2012–124 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2012–124. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2012–124, and should be submitted on or before November 30, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27356 Filed 11–8–12; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68159; File No. SR–NSCC–2012–08]

Self-Regulatory Organizations; The National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Rule 52 (Mutual Fund Services) and Addendum A (NSCC's Fee Structure)

November 5, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on October 22, 2012, the National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I and II below, which Items have been prepared primarily by NSCC. NSCC filed the proposal pursuant to Section 19(b)(3)(A)(iii) [2] of the Act, Rule 19b-4(f)(2),[3] and Rule 19b-4(f)(4)(i) [4] thereunder so that the proposal was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change modifies Rule 52 (Mutual Fund Services) and Addendum A (NSCC's Fee Structure) of NSCC's Rules.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NSCC 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. NSCC has prepared summaries, set forth in Sections (A), (B), and (C) below, of the most significant aspects of these statements.[5]

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78s(b)(3)(A)(iii).

[3] 17 CFR 240.19b–4(f)(2).

[4] 17 CFR 240.19b–4(f)(4)(i).

[5] The Commission has modified the text of the summaries prepared by NSCC.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Pursuant to the rule change proposal, NSCC will (i) rename the ''Mutual Fund Commission Settlement'' service under Rule 52 (the ''Service'') as the ''DTCC Payment aXis'' service in order to better align the name of the Service with the various commission and other fee data transmission and payment settlement functionalities available through the Service (*i.e.,* not solely commission settlement), (ii) make clear that the Service permits for the transmission of commission and other fee related data, and the settlement of such payments, among users of the Service without regard to whether the flow of funds is from the fund company (''Fund'') to the retail broker-dealer (''Distributor''), from the Distributor to the Fund, from a Distributor to another Distributor, or otherwise, (iii) specify that commission and other fee data transmission, and the settlement of such payments, with regard to investor accounts held on an omnibus account basis at the Fund (''Omnibus'') may be made through the Service, (iv) specify the process for the payment of 12b–1 fees [6] with regard to investor accounts held in Omnibus, and (v) establish the fees that NSCC will charge users of the Service with regard to investor accounts held in Omnibus.

Background. The Service was initially approved by the Commission on December 9, 1992 (''1992 Rule Filing'').[7] In the 1992 Rule Filing, NSCC described that the new service would provide for the automation of payments of commissions owed in respect of mutual fund transactions, explaining that under the new service, Funds would be able to transmit commission debit data to NSCC on a daily basis. NSCC's role in this new commission service would be to transmit data between the Funds (*i.e.,* the payers of commission payments) and the Distributors (*i.e.,* the receivers of commission payments). In 2005 (''2005 Rule Filing''),[8] NSCC expanded the scope of the Service to permit Distributors to submit fee data through NSCC to other Distributors and to settle the fee payments in respect thereof through NSCC, expanding the Service to allow for more than the exchange of commission-related information from the Funds to Distributors.

The Proposed Rule Changes. There has been a growing trend in the mutual fund industry toward omnibus processing, a practice pursuant to which Distributors maintain a single account at a Fund, which account represents multiple investor positions of that Distributor in that Fund's securities. Where multiple investor positions are held in Omnibus, the Distributor maintains the individual investor account records on the Distributor's books and records. The trend toward omnibus processing is anticipated to continue growing into the foreseeable future; however, invoicing for the fees related to these investor accounts is not standardized. The current state of fee invoicing with regard to such investor accounts is manually intensive, involving the exchange of reports and spreadsheets via fax, email, and regular mail, and the settlement of payments thereof generally occurs by check or wire. Due to the lack of standardization and automation, the industry has sought NSCC's assistance to create a standardized file for omnibus invoicing. As a result, NSCC has enhanced the Service's functionality to permit for fee data transmission and settlement of payments with regard to investor accounts held in Omnibus. By this proposed rule change, NSCC seeks to do the following:

a. *Rename Service:* The Service will be renamed ''DTCC Payment aXis'' to better represent the broadened functionality of fee data exchange and settlement capabilities offered by the Service today, as opposed to its capabilities at initial implementation in 1992.

b. *Clarify Scope of Commission and other Fee Data Transmission and Flow of Funds:* Although the Service, as described in Rule 52, does not specify from whom and to whom the transmission of commission and fee related data, and settlement of such payments, may be made, the previous rule filing descriptions do identify a specific flow. In the 1992 Rule Filing, the type of fee payment and the flow of data and payments were specified to be commission data and settlements by the Fund to the Distributors. The 2005 Rule Filing expanded the scope to permit the transmission of other fee payment data and settlement thereof by one Distributor to another Distributor. In the current rule filing, NSCC seeks to make clear that the Service permits for the transmission of commission and other fee related data, and the settlement of such payments, among users of the Service without regard to whether the flow of funds is from the Fund to the Distributor, from the Distributor to the Fund, from a Distributor to another Distributor, or otherwise.

c. *Specify Omnibus Invoicing within the Service:* NSCC proposes to specify in Rule 52 that the transmission of commission and other fee data with regard to investor accounts held in Omnibus, and the settlement of payments thereof, shall be included within the suite of functionalities offered by the Service. In all events, the Fund or Distributor being debited will either be the initiator of the commission or other fee payment transaction, or will otherwise confirm the debit that will be charged against its account.

d. *Specify 12b–1 Fee Payment Process with regard to Omnibus Invoicing:* NSCC will specify in Rule 52 the process for 12b–1 fee payments with regard to investor accounts held in Omnibus. Unlike the process applicable to all other commission and other fee payments within the Service, 12b–1 fee payment instructions with regard to investor accounts held in Omnibus in all events must be initiated by the Distributor. When NSCC receives the 12b–1 fee payment instruction with regard to these accounts, NSCC will transmit such instruction to the contra-side Fund. The contra-side Fund will then either (i) confirm or reject the payment instruction, or (ii) release settlement (either with or without a confirmation). If NSCC receives a confirmation or rejection instruction, NSCC will transmit such confirmation or rejection to the initiating Distributor.

e. *Establish Fees to be charged by NSCC:* NSCC proposes to update Addendum A of its Rules and Procedures to incorporate the fees associated with omnibus invoicing. The NSCC fees for omnibus invoicing will be as follows:

a. From 1 to 500,000 records $0.10 per 1 record.

b. From 500,001 to 1,000,000 records $0.08 per 1 record.

c. More than 1,000,000 records $0.06 per 1 record.

d. Monthly Fee $500.

As with all of NSCC's Mutual Fund Services, the Service is a non-guaranteed service of NSCC and shall remain so after the effectiveness of this proposed rule change.

The proposed rule change is consistent with the requirements of the Act and the rules and regulations issued thereunder applicable to NSCC because it will promote processing efficiencies between Funds and Distributors, thereby facilitating the prompt and accurate processing of commission and other fee related payment data

[6] This is a category of fees paid out by the Fund out of Fund assets to cover distribution expenses and sometimes shareholder service expenses.

[7] Securities Exchange Act Release No. 34–31579 (December 9, 1992), 57 FR 60018 (December 17, 1992).

[8] Securities Exchange Act Release No. 34–52458 (September 16, 2005), 70 FR 56200 (September 26, 2005).

transmissions and settlement with respect to such payments.

(B) Self-Regulatory Organization's Statement on Burden on Competition

NSCC does not believe that the proposed rule change will have any impact or impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to the proposed rule change have not been solicited or received. NSCC will notify the Commission of any written comments received by NSCC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective upon filing pursuant to Section 19(b)(3)(A)(iii) [9] of the Act, Rule 19b–4(f)(2),[10] and Rule 19b–4(f)(4)(i) [11] thereunder because it effects changes in an existing service of NSCC that do not adversely affect the safeguarding of securities or funds in the custody or control of NSCC or for which NSCC is responsible and do not significantly affect the respective rights or obligations of NSCC or persons using the service. NSCC's Mutual Fund Services are non-guaranteed services, and therefore, the funds in NSCC's control are not adversely affected by the proposed rule change. Further, the proposed rule change does not provide any greater or lesser rights to or obligations on either NSCC or the users of the Service in comparison to the current rights and obligations of the respective parties with regard to the Service as it is currently offered. In addition, the proposed rule change establishes fees charged by NSCC applicable only to members. The implementation date for the proposals in this proposed rule change filing other than the change in the Service's name will be December 1, 2012.

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.

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(2).

[11] 17 CFR 240.19b–4(f)(4)(i).

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–NSCC–2012–08 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NSCC–2012–08. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings also will be available for inspection and copying at the principal office of NSCC and on NSCC's Web site at *http://www.dtcc.com/downloads/legal/rule_filings/2012/nscc/SR-NSCC-2012-08.pdf.*

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–NSCC–2012–08 and should be submitted on or before November 30, 2012.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[12]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27357 Filed 11–8–12; 8:45 am]

BILLING CODE 8011–01–P

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68158; File No. SR–NYSEArca–2012–101]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Granting Approval of Proposed Rule Change To List and Trade Shares of the PowerShares S&P 500 Downside Hedged Portfolio Under NYSE Arca Equities Rule 8.600

November 5, 2012.

I. Introduction

On September 6, 2012, 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'' or ''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares (''Shares'') of the PowerShares S&P 500 Downside Hedged Portfolio (''Fund'') under NYSE Arca Equities Rule 8.600. The proposed rule change was published for comment in the **Federal Register** on September 24, 2012.[3] The Commission received no comments on the proposed rule change. This order grants approval of the proposed rule change.

II. Description of the Proposed Rule Change

The Exchange proposes to list and trade Shares of the Fund pursuant to NYSE Arca Equities Rule 8.600, which governs the listing and trading of Managed Fund Shares on the Exchange. The Shares will be offered by PowerShares Actively Managed Exchange-Traded Fund Trust (''Trust''),[4] a statutory trust organized under the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 67881 (September 18, 2012), 77 FR 58889 (''Notice'').

[4] The Trust is registered under the Investment Company Act of 1940 (''1940 Act''). On August 14, 2012, the Trust filed with the Commission a post-effective amendment to Form N–1A under the Securities Act of 1933 (''Securities Act'') and under the 1940 Act relating to the Fund (File Nos. 333–147622 and 811–22148) (''Registration Statement''). In addition, the Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act. *See* Investment Company Act Release No. 28171 (February 27, 2008) (File No. 812–13386).

laws of the State of Delaware and registered with the Commission as an open-end management investment company. The investment adviser to the Fund is Invesco PowerShares Capital Management LLC (''Adviser''). The Bank of New York Mellon Corporation is the administrator, custodian, and transfer agent for the Fund, and Invesco Distributors, Inc. is the distributor for the Fund Shares. The Exchange states that the Adviser is affiliated with a broker-dealer and has implemented a fire wall with respect to its broker-dealer affiliate regarding access to information concerning the composition and/or changes to the Fund's portfolio.[5]

The Fund will be an actively managed exchange-traded fund that will seek to achieve positive total returns in rising or falling markets that are not directly correlated to broad equity or fixed income market returns. The Fund will seek to achieve its investment objective by using a quantitative, rules-based strategy designed to provide returns that correspond to the performance of the S&P 500 Dynamic VEQTOR Index (''Benchmark''). The Fund's Benchmark allocates between equity securities and CBOE Volatility Index futures. The Fund seeks to gain exposure to equity securities contained in the S&P 500 Index, CBOE Volatility Index (''VIX Index'') related instruments (as described in more detail below, ''VIX Index Related Instruments''), money market instruments, cash, cash equivalents, and futures contracts that track the S&P 500 Index (''E-mini S&P 500 Futures'').

The Benchmark, the VIX Index, and the S&P 500 VIX Short Term Futures Index

The Benchmark is comprised of three types of components at any given time: An equity component, represented by the S&P 500 Index; a volatility component, represented by the S&P 500 VIX Short Term Futures Index (''VIX Futures Index''); and cash, represented by the overnight London Interbank Offered Rate.[6] The VIX Futures Index utilizes the prices of the first and second month futures contracts based on the VIX Index, replicating a position that rolls the nearest month VIX futures contracts to the next month VIX futures contracts on a daily basis in equal fractional amounts.

Following the proprietary formula of Standard & Poor's (''S&P'' or ''Index Provider''), under normal circumstances (*i.e.,* times other than when the Benchmark's stop-loss process is triggered, as described below), the allocation to the VIX Futures Index constitutes between 2.5% and 40% of the Benchmark, with equity securities contained in the S&P 500 Index composing the remainder. The allocation to the VIX Futures Index generally increases when realized volatility and implied volatility are higher, and decreases when realized volatility and implied volatility are lower. With respect to the stop-loss process, in the event losses on the Benchmark over the previous five business days are greater than 2%, the Benchmark moves its entire allocation to cash. Unless the stop-loss is in place, the Benchmark is entirely allocated to a combination of the S&P 500 Index and the VIX Futures Index. While allocations are reviewed daily, these allocations may change on a less frequent basis.

The Benchmark's allocation to the VIX Futures Index serves as an implied volatility hedge as volatility historically tends to correlate negatively to the performance of the U.S. equity markets (*i.e.,* rapid declines in the performance of the U.S. equity markets generally are associated with particularly high volatility in such markets). ''Implied volatility'' is a measure of the expected volatility of the S&P 500 Index that is reflected by the value of the VIX Index.

The U.S. Index Committee of the Index Provider maintains the Benchmark.[7] That Committee meets monthly. At each meeting, the Committee reviews pending corporate actions that may affect Benchmark constituents, statistics comparing the composition of the Benchmark to the market, companies that are being considered as candidates for addition to the Benchmark, and any significant market events. In addition, the Committee may revise the Benchmark's policy covering rules for selecting companies, treatment of dividends, share counts, or other matters.

The VIX Index is a theoretical calculation and cannot be traded. It is a benchmark index designed to measure the market price of volatility in large cap U.S. stocks over 30 days in the future, and is calculated based on the prices of certain put and call options on the S&P 500 Index. The VIX Index measures the premium paid by investors for certain options linked to the S&P 500 Index. During periods of market instability, the implied level of volatility of the S&P 500 Index typically increases and, consequently, the prices of options linked to the S&P 500 Index typically increase (assuming all other relevant factors remain constant or have negligible changes). This, in turn, causes the level of the VIX Index to increase. The VIX Index historically has had negative correlations to the S&P 500 Index.

Investments

The Fund, in accordance with strategy allocation rules provided by the Index Provider, will invest in a combination of equity securities contained in the S&P 500 Index and that are listed on a U.S. securities exchange; VIX Index Related Instruments; money market instruments; cash; cash equivalents; and E-mini S&P 500 Futures that are listed on the Chicago Mercantile Exchange (''CME'').[8]

The allocation among the Fund's investments will approximate the allocation among the components of the Benchmark. Accordingly, during periods of low volatility, a greater portion of the Fund's assets will be invested in equity securities, and during periods of increased volatility, a greater portion of the Fund's assets will be invested in VIX Index Related Instruments. However, the Fund will be actively managed, and, although the Fund will seek performance comparable to the Benchmark, the Fund may have a higher or lower exposure to any component within the Benchmark at any time.

VIX Index Related Instruments that the Fund will invest in include listed VIX futures contracts contained in the VIX Futures Index or exchange-traded funds (''ETFs'')[9] and exchange-traded notes (''ETNs'')[10] that are listed on a U.S. securities exchange and provide exposure to the VIX Index. All of the

[5] *See* NYSE Arca Equities Rule 8.600, Commentary .06. In the event (a) the Adviser becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser becomes affiliated with a broker-dealer, it will implement a fire wall with respect to such broker-dealer 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.

[6] As of June 30, 2012, the Benchmark allocation was as follows: 97.5% to the equity component, represented by the S&P 500 Index; 2.5% to the VIX Futures Index; and 0% allocated to cash.

[7] The Index Provider is not a broker-dealer and has implemented procedures designed to prevent the use and dissemination of material, non-public information regarding the Index.

[8] The Fund will be ''non-diversified'' under the 1940 Act and may invest more of its assets in fewer issuers than ''diversified'' funds. The diversification standard is set forth in Section 5(b)(1) of the 1940 Act.

[9] For purposes of this proposed rule change, ETFs are securities registered under the 1940 Act such as those listed and traded on the Exchange under NYSE Arca Equities Rules 5.2(j)(3), 8.100, and 8.600.

[10] For purposes of this proposed rule change, ETNs are securities registered under the Securities Act such as those listed and traded on the Exchange under NYSE Arca Equities Rule 5.2(j)(6).

VIX Index Related Instruments will be listed on a U.S. exchange.

Futures contracts on the VIX Index have expirations ranging from the near month consecutively out to the tenth month. Futures on the VIX Index provide investors the ability to invest in forward market volatility based on their view of the future direction or movement of the VIX Index. Because the VIX Index is not a tangible item that can be purchased and sold directly, a futures contract on the VIX Index provides for the payment and receipt of cash based on the level of the VIX Index at settlement or liquidation of the contract.

The Fund may invest a portion of its assets in high-quality money market instruments, cash, and cash equivalents to provide liquidity, to collateralize its futures contracts investments, or to track the Benchmark during times when the Benchmark moves its entire allocation to cash. The instruments in which the Fund may invest include: (i) Short-term obligations issued by the U.S. Government; [11] (ii) short-term negotiable obligations of commercial banks, fixed time deposits, and bankers' acceptances of U.S. and foreign banks and similar institutions; (iii) commercial paper rated at the date of purchase ''Prime-1'' by Moody's Investors Service, Inc., or ''A–1+'' or ''A–1'' by S&P, or has a similar rating from a comparable rating agency, or, if unrated, of comparable quality as determined by the Adviser; and (iv) money market mutual funds.

The Fund also may invest in E-mini S&P 500 Futures that are listed on the CME. E-mini S&P 500 Futures are futures contracts that track the S&P 500 Index. They are substantially similar to traditional futures contracts on the S&P 500 Index, except that the notional value of E-mini S&P 500 Futures are one-fifth the size of their larger counterpart futures contracts.

The Subsidiary

The Fund may gain exposure to the VIX Index futures markets through investments in a subsidiary organized in the Cayman Islands (''Subsidiary''). Should the Fund invest in the Subsidiary, that investment may not exceed 25% of the Fund's total assets at the end of each tax year quarter. The Subsidiary would be wholly-owned and controlled by the Fund, and its investments would be consolidated into the Fund's financial statements. The Fund's and Subsidiary's investments would be disclosed on the Fund's Web site on a daily basis. Should the Fund invest in the Subsidiary, it would be expected to provide the Fund with exposure to investment returns from VIX Index futures contracts within the limits of the federal tax requirements applicable to investment companies, such as the Fund.

The Subsidiary would be able to invest in VIX Index futures, as well as other investments that would serve as margin or collateral or otherwise support the Subsidiary's VIX Index futures positions. The Subsidiary would be subject to the same general investment policies and restrictions as the Fund, except that, unlike the Fund (which is subject to Rule 4.5 of the Commodity Exchange Act (''CEA'')), the Subsidiary would be able to invest without limitation in VIX Index futures and may use leveraged investment techniques. Otherwise, references to the investment strategies of the Fund for non-equity investments include the investment strategies of the Subsidiary.

The Fund may utilize the Subsidiary, but is not required to do so. If it is utilized, the Subsidiary will not be registered under the 1940 Act. The Fund, as the sole shareholder of the Subsidiary, will not have the protections offered to investors in registered investment companies. However, because the Fund wholly owns and controls the Subsidiary, and the Fund and the Subsidiary will be managed by the Adviser, it is unlikely that the Subsidiary will take action contrary to the interests of the Fund or the Fund's shareholders. The Board of Trustees of the Trust (''Board'') will have oversight responsibility for the investment activities of the Fund, including its investment in the Subsidiary, and the Fund's role as the sole shareholder of the Subsidiary. Also, in managing the Subsidiary's portfolio, the Adviser will be subject to the same investment restrictions and operational guidelines that apply to the management of the Fund.

Other Investments

In addition to the VIX Index futures contracts and E-mini S&P 500 Futures that are part of its primary investments, the Fund may enter into other U.S.-listed futures contracts on the S&P 500 Index. The Fund will not use futures for speculative purposes. The Fund will only enter into futures contracts that are traded on U.S. exchanges.

The Fund may invest in stock index contracts, in addition to the E-mini S&P 500 Futures. Stock index contracts are futures based on indices that reflect the market value of common stock of the firms included in the indices. The Fund may enter into U.S.-listed futures contracts to purchase security indices when the Adviser anticipates purchasing the underlying securities and believes prices will rise before the purchase will be made.

To the extent the Fund uses futures it will do so only in accordance with Rule 4.5 of the CEA.[12] Under recently adopted amendments to Rule 4.5, an investment adviser of a registered investment company may claim exclusion from registration as a commodity pool operator (''CPO'') only if the registered investment company it advises uses futures contracts solely for ''bona fide hedging purposes'' or limits its use of futures contracts for non-bona fide hedging purposes in specified ways. Because the Fund does not expect to use futures contracts solely for ''bona fide hedging purposes,'' effective December 31, 2012, the Fund will be subject to rules that will require it to limit its use of positions in futures contracts in accordance with the requirements of amended Rule 4.5, unless it otherwise complies with CPO regulation.

The Fund may enter into repurchase agreements, which are agreements pursuant to which securities are acquired by the Fund from a third party with the understanding that they will be repurchased by the seller at a fixed price on an agreed date. These agreements may be made with respect to any of the portfolio securities in which the Fund is authorized to invest. Repurchase agreements may be characterized as loans secured by the underlying securities. The Fund may enter into repurchase agreements with: (i) Member banks of the Federal Reserve System having total assets in excess of $500 million; and (ii) securities dealers (''Qualified Institutions''). The Adviser will monitor the continued creditworthiness of Qualified Institutions.

The Fund may enter into reverse repurchase agreements, which involve the sale of securities with an agreement to repurchase the securities at an agreed-upon price, date, and interest payment and have the characteristics of borrowing. The securities purchased with the funds obtained from the agreement and securities collateralizing

[11] The Fund may invest in short-term obligations issued or guaranteed by the U.S. Government, its agencies and instrumentalities, including bills, notes, and bonds issued by the U.S. Treasury, as well as ''stripped'' or ''zero coupon'' U.S. Treasury obligations representing future interest or principal payments on U.S. Treasury notes or bonds.

[12] The Trust, on behalf of the Fund, has filed a notice of eligibility for exclusion from the definition of the term ''commodity pool operator'' in accordance with Rule 4.5 of the CEA so that the Fund is not subject to registration or regulation as a CPO under the CEA.

the agreement will have maturity dates no later than the repayment date.

In addition to the ETFs and ETNs that are listed on U.S. exchanges and provide exposure to the VIX Index, the Fund may invest in the securities of other investment companies (including money market funds) to the extent permitted under the 1940 Act. The Fund also may purchase warrants.

The Fund does not expect to invest in options or enter into swap agreements, including credit default swaps, but may do so if such investments are in the best interests of the Fund's shareholders.

Investment Limitations

The Fund's investments will be consistent with the Fund's investment objective and will not be used to enhance leverage. The Fund will not invest in equities that are traded over-the-counter (''OTC'') or equities listed on a non-U.S. exchange, or enter into futures that are not traded on a U.S. exchange.

The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid securities (calculated at the time of investment), including 144A Securities. The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid securities and other illiquid assets.

The Fund may not concentrate its investments (*i.e.,* invest more than 25% of the value of its total assets in securities of issuers in any one industry or group of industries). This restriction does not apply to obligations issued or guaranteed by the U.S. Government, its agencies, or instrumentalities. The Fund intends to qualify for and to elect to be treated as a separate regulated investment company under Subchapter M of the Internal Revenue Code.[13]

Additional information regarding the Trust, the Fund, and the Shares, including investment strategies, risks, creation and redemption procedures, net asset value (''NAV''), fees, portfolio holdings disclosure policies, distributions, and taxes, among other things, is included in the Notice and Registration Statement, as applicable.[14]

[13] *See* 26 U.S.C. 851.

[14] *See* Notice and Registration Statement, *supra* notes 3 and 4, respectively.

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 [15] and the rules and regulations thereunder applicable to a national securities exchange.[16] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[17] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission notes that the Fund and the Shares must comply with the requirements of NYSE Arca Equities Rule 8.600 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,[18] 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. Quotation and last-sale information for the Shares will be available via the Consolidated Tape Association (''CTA'') high-speed line. In addition, the Portfolio Indicative Value, as defined in NYSE Arca Equities Rule 8.600(c)(3), will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Core Trading Session.[19] On each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Fund will disclose on its Web site the Disclosed Portfolio, as defined in NYSE Arca Equities Rule 8.600(c)(2), held by the Fund and the Subsidiary that will form the basis for the Fund's calculation of NAV at the end of the business day.[20] The NAV of the Fund will be determined at the close of regular trading (ordinarily 4:00 p.m. Eastern Time) every day the New York Stock Exchange is open. 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 intra-day, closing and settlement prices of the portfolio investments (*e.g.,* futures contracts, equity securities, ETFs, and ETNs) are also readily available from the national securities exchanges trading such securities, automated quotation systems, published or other public sources, or on-line information services such as Bloomberg or Reuters. The Fund's Web site will include a form of the prospectus for the Fund 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 will be made available to all market participants at the same time.[21] 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 the 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 comprising the Disclosed Portfolio of the Fund, or if other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly

[15] 15 U.S.C. 78f.

[16] 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).

[17] 15 U.S.C. 78f(b)(5).

[18] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[19] According to the Exchange, several major market data vendors widely disseminate Portfolio Indicative Values taken from CTA or other data feeds.

[20] On a daily basis, the Adviser will disclose for each portfolio security and other financial instrument of the Fund and the Subsidiary, if applicable, the following information on the Fund's Web site: Ticker symbol (if applicable); name of security and financial instrument; number of shares or dollar value of each security and financial instrument held in the portfolio; and percentage weighting of the security and financial instrument in the portfolio. The Web site information will be publicly available at no charge.

[21] *See* NYSE Arca Equities Rule 8.600(d)(1)(B).

market are present.[22] Further, the Commission notes that the Reporting Authority that provides the Disclosed Portfolio must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the actual components of the portfolio.[23] All equity securities, ETFs, and ETNs in which the Fund invests will be listed on a U.S. securities exchange. The Exchange may obtain information via the Intermarket Surveillance Group (''ISG'') from other exchanges that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange could obtain information from the U.S. futures exchanges, all of which are ISG members, on which futures held by the Fund are listed and traded. 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 affiliated with a broker-dealer, and the Adviser has implemented a fire wall with respect to its broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio.[24]

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 representations, including:

(1) The Shares will be subject to NYSE Arca Equities Rule 8.600, which sets forth the initial and continued listing criteria applicable to Managed Fund Shares.

(2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(3) The Exchange's surveillance procedures applicable to derivative products, which include Managed Fund Shares, are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws.

(4) Prior to the commencement of trading, the Exchange will inform its Equity Trading Permit (''ETP'') 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 Units (and that Shares are not individually redeemable); (b) NYSE Arca Equities Rule 9.2(a), which imposes a duty of due diligence on its ETP 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 is disseminated; (e) the requirement that ETP 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 Fund must be in compliance with Rule 10A–3 under the Exchange Act,[25] as provided by NYSE Arca Equities Rule 5.3.

(6) All of the equities and VIX Index Related Instruments will be listed on a U.S. exchange. The Fund will not enter into futures that are not traded on a U.S. exchange. In addition, the Fund does not expect to invest in options or enter into swap agreements, including credit default swaps, but may do so if such investments are in the best interests of the Fund's shareholders. The Fund's investments will be consistent with its investment objective and will not be used to enhance leverage.

(7) The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid securities (calculated at the time of investment), including Rule 144A securities.

(8) Should the Fund invest in the Subsidiary, that investment may not exceed 25% of the Fund's total assets at the end of each tax year quarter.

(9) A minimum of 100,000 Shares of the Fund will be outstanding at the commencement of trading on the Exchange.

This approval order is based on all of the Exchange's representations and description of the Fund, including those set forth above and in the Notice.[26]

For the foregoing reasons, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act[27] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[28] that the proposed rule change (SR–NYSEArca–2012–101) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27364 Filed 11–8–12; 8:45 am]

BILLING CODE 8011–01–P

[22] *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 other relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund. Trading in Shares of the 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.

[23] *See* NYSE Arca Equities Rule 8.600(d)(2)(B)(ii).

[24] *See supra* note 5. The Commission notes that an investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (''Advisers Act''). As a result, the Adviser and its related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

[25] 17 CFR 240.10A–3.

[26] The Commission notes that it does not regulate the market for futures in which the Fund plans to take positions, which is the responsibility of the Commodity Futures Trading Commission (''CFTC''). The CFTC has the authority to set limits on the positions that any person may take in futures. These limits may be directly set by the CFTC or by the markets on which the futures are traded. The Commission has no role in establishing position limits on futures even though such limits could impact an exchange-traded product that is under the jurisdiction of the Commission.

[27] 15 U.S.C. 78f(b)(5).

[28] 15 U.S.C. 78s(b)(2).

[29] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68157; File No. SR–NYSEARCA–2012–119]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the NYSE Arca Options Fee Schedule To Remove Dividend Spreads From the List of Strategy Executions for Which Fee Caps Apply

November 5, 2012.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on October 23, 2012, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Options Fee Schedule (''Fee Schedule'') to remove dividend spreads from the list of strategy executions for which fee caps apply. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule to remove dividend spreads from the list of strategy executions for which fee caps apply. The proposed fee change will be operative on November 1, 2012.

Under the Exchange's current Fee Schedule, there is a $750 cap on transaction fees for strategy executions involving (a) reversals and conversions,[4] (b) dividend spreads,[5] (c) box spreads,[6] (d) short stock interest spreads,[7] (e) merger spreads,[8] and (f) jelly rolls [9] (''Strategy Executions''). The cap applies to each Strategy Execution executed on the same trading day in the same option class. Transaction fees for Strategy Executions are further capped at $25,000 per month per initiating firm. Manual Broker Dealer and Firm Proprietary Strategy trades that do not reach the $750 cap are billed at $0.25 per contract.[10]

The Exchange proposes to remove dividend spreads from the list of Strategy Executions that are subject to the fee caps. The fee caps may provide an incentive to engage in the Strategy Executions. The Exchange has determined that it does not wish to continue to provide an incentive via its Fee Schedule to engage in dividend spread trading because this strategy may encourage high volumes of trading of certain securities near the ex-dividend date and present operational risks to market participants with respect to clearing, exercise, and assignment or other issues that may prevent the market participant from the timely exercise of call options and collecting the dividend owed. As such, the Exchange proposes to remove dividend spreads from the Strategy Executions fee caps.

The Exchange also proposes to specify that, as a result of removing dividend spreads from the list of Strategy Executions that are subject to the fee caps, the type of execution that the Exchange currently considers to be a dividend spread [11] would no longer be excluded from the $75,000 cap per month on Firm Proprietary fees and Broker Dealer fees for transactions cleared in the customer range for manual (open outcry) executions.[12] Currently, all Strategy Executions are excluded from this cap, including dividend spreads. However, because dividend spreads would no longer be considered a Strategy Execution for purposes of billing on the Exchange, the cap would no longer exclude such executions. However, the Exchange does not anticipate that this would result in a significant amount of such executions occurring on the Exchange. In this regard, the Exchange believes that the elimination of the $750 fee cap would eliminate the incentive for market participants to effect such executions on the Exchange.

The proposed change is not otherwise intended to address any other matter, and the Exchange is not aware of any significant problem that the affected market participants would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange

[4] A ''reversal'' is established by combining a short security position with a short put and a long call position that shares the same strike and expiration. A ''conversion'' is established by combining a long position in the underlying security with a long put and a short call position that shares the same strike and expiration.

[5] A ''dividend spread'' is defined as transactions done to achieve a dividend arbitrage involving the purchase, sale and exercise of in-the-money options of the same class, executed prior to the date on which the underlying stock goes ex-dividend.

[6] A ''box spread'' is defined as transactions involving a long call option and a short put option at one strike, combined with a short call option and long put at a different strike, to create synthetic long and synthetic short stock positions, respectively.

[7] A ''short stock interest spread'' is defined as transactions done to achieve a short stock interest arbitrage involving the purchase, sale and exercise of in-the-money options of the same class.

[8] A ''merger spread'' is defined as transactions done to achieve a merger arbitrage involving the purchase, sale and exercise of options of the same class and expiration date, each executed prior to the date on which shareholders of record are required to elect their respective form of consideration, i.e., cash or stock.

[9] A ''jelly roll'' is created by entering into two separate positions simultaneously. One position involves buying a put and selling a call with the same strike price and expiration. The second position involves selling a put and buying a call, with the same strike price, but with a different expiration from the first position.

[10] All Royalty fees associated with Strategy Executions on Index and Exchange Traded Funds are passed through to trading participants on the Strategy Executions on a pro-rata basis. These Royalty fees are not included in the calculation of the $750 per trade cap or the $25,000 per month strategy fee cap. FLEX Option trades also are not eligible for strategy treatment.

[11] *See supra* note 5.

[12] This resulting change would not require a corresponding change in the Fee Schedule and, accordingly, there is not a change proposed in this respect in the Exhibit 5 attached hereto. In this regard, while Strategy Executions are referenced with respect to the $75,000 fee cap, the different types of Strategy Executions are not specifically identified, as is done for the $750 fee cap. Nonetheless, the Exchange believes that describing the resulting treatment will specify the impact regarding the $75,000 fee cap.

Act of 1934 (the ''Act''),[13] in general, and furthers the objectives of Section 6(b)(4) of the Act,[14] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed change is reasonable because the fee caps may provide an incentive to engage in dividend spreads and the Exchange has determined that it no longer wishes to offer any potential incentive via its Fee Schedule in light of the operational risks that dividend spreads may present. The Exchange also believes that the proposed change is equitable and not unfairly discriminatory because it would apply equally to all market participants and because the remaining Strategy Executions that would continue to be subject to the fee caps do not present the same type of potential operational risks.

Furthermore, it is reasonable to specify that the type of execution that the Exchange currently considers to be a dividend spread [15] would no longer be excluded from the $75,000 cap per month on Firm Proprietary fees and Broker Dealer fees for transactions cleared in the customer range for manual (open outcry) executions. Specifically, because dividend spreads would no longer be considered a Strategy Execution for purposes of billing on the Exchange, the $75,000 fee cap would no longer exclude such executions. However, the Exchange does not anticipate that this would result in a significant amount of such executions occurring on the Exchange. In this regard, the Exchange believes that the elimination of the $750 fee cap would eliminate the incentive for market participants to effect such executions on the Exchange. This would also be equitable and not unfairly discriminatory because it would not differentiate between any particular market participants when determining whether the $75,000 fee cap has been reached with respect to the inclusion of the type of execution that the Exchange currently considers to be a dividend spread.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [16] of the Act and subparagraph (f)(2) of Rule 19b–4 [17] thereunder, because it establishes a due, fee, or other charge imposed by NYSE Arca.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEARCA–2012–119 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2012–119. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549–1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2012–119 and should be submitted on or before November 30, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27363 Filed 11–8–12; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4).

[15] *See supra* note 5.

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(2).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68156; File No. SR–NYSEMKT–2012–57]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the NYSE Amex Options Fee Schedule To Remove Dividend Spreads From the List of Strategy Executions for Which Fee Caps Apply

November 5, 2012.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on October 24, 2012, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Amex Options Fee Schedule (''Fee Schedule'') to remove dividend spreads from the list of strategy executions for which fee caps apply. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule to remove dividend spreads from the list of strategy executions for which fee caps apply. The proposed fee change will be operative on November 1, 2012.

Under the Exchange's current Fee Schedule, there is a $750 cap on transaction fees for strategy executions involving (a) reversals and conversions,[4] (b) dividend spreads,[5] (c) box spreads,[6] (d) short stock interest spreads,[7] (e) merger spreads,[8] and (f) jelly rolls[9] (''Strategy Executions''). The cap applies to each Strategy Execution executed on the same trading day in the same option class. Transaction fees for Strategy Executions are further capped at $25,000 per month per initiating firm. Manual Broker Dealer and Firm Proprietary Strategy trades that do not reach the $750 cap are billed at $0.25 per contract.[10]

The Exchange proposes to remove dividend spreads from the list of Strategy Executions that are subject to the fee caps. The fee caps may provide an incentive to engage in the Strategy Executions. The Exchange has determined that it does not wish to continue to provide an incentive via its Fee Schedule to engage in dividend spread trading because this strategy may encourage high volumes of trading of certain securities near the ex-dividend date and present operational risks to market participants with respect to clearing, exercise, and assignment or other issues that may prevent the market participant from the timely exercise of call options and collecting the dividend owed. As such, the Exchange proposes to remove dividend spreads from the Strategy Executions fee caps.

The Exchange also proposes to specify that, as a result of removing dividend spreads from the list of Strategy Executions that are subject to the fee caps, the type of execution that the Exchange currently considers to be a dividend spread [11] would no longer be excluded when determining whether certain other caps and thresholds that exclude Strategy Executions have been satisfied, as described in the Fee Schedule. This would apply to (i) the $350,000 cap and the volume threshold of 3,500,000 contracts described in endnote 5 in the Fee Schedule (ii) the $100,000 fee cap described in endnote 6 of the Fee Schedule, (iii) the 75% volume threshold related to Market Maker ATP fees, (iv) the 120,000 average daily volume (''ADV'') threshold related to Customer Electronic ADV Tiers, and (v) the 120,000 and 200,000 volume thresholds described in endnote 17 of the Fee Schedule as well as the rebate referenced therein.[12] Currently, all Strategy Executions, including dividend spreads, are excluded from these fee caps and volume thresholds. However, because dividend spreads would no longer be considered a Strategy Execution for purposes of billing on the Exchange, the caps and thresholds would no longer exclude such executions. However, the Exchange does not anticipate that this would result in a significant amount of such executions occurring on the Exchange. In this regard, the Exchange believes that the elimination of the $750 fee cap would eliminate the incentive for market participants to effect such executions on the Exchange.

The proposed change is not otherwise intended to address any other matter, and the Exchange is not aware of any significant problem that the affected

[4] A ''reversal'' is established by combining a short security position with a short put and a long call position that shares the same strike and expiration. A ''conversion'' is established by combining a long position in the underlying security with a long put and a short call position that shares the same strike and expiration.

[5] A ''dividend spread'' is defined as transactions done to achieve a dividend arbitrage involving the purchase, sale and exercise of in-the-money options of the same class, executed prior to the date on which the underlying stock goes ex-dividend.

[6] A ''box spread'' is defined as transactions involving a long call option and a short put option at one strike, combined with a short call option and long put at a different strike, to create synthetic long and synthetic short stock positions, respectively.

[7] A ''short stock interest spread'' is defined as transactions done to achieve a short stock interest arbitrage involving the purchase, sale and exercise of in-the–money options of the same class.

[8] A ''merger spread'' is defined as transactions done to achieve a merger arbitrage involving the purchase, sale and exercise of options of the same class and expiration date, each executed prior to the date on which shareholders of record are required to elect their respective form of consideration, i.e., cash or stock.

[9] A ''jelly roll'' is created by entering into two separate positions simultaneously. One position involves buying a put and selling a call with the same strike price and expiration. The second position involves selling a put and buying a call, with the same strike price, but with a different expiration from the first position.

[10] All Royalty fees associated with Strategy Executions on Index and Exchange Traded Funds are passed through to trading participants on the Strategy Executions on a pro-rata basis. These Royalty fees are not included in the calculation of the $750 per trade cap or the $25,000 per month strategy fee cap. FLEX Option trades also are not eligible for strategy treatment. In addition, any qualifying Strategy Execution executed as a Qualified Contingent Cross order is ineligible for the fee caps.

[11] *See supra* note 5.

[12] The Exchange proposes to remove references to dividend spreads from endnotes 5 and 6.

market participants would have in complying with the proposed change.[13]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[14] in general, and furthers the objectives of Section 6(b)(4) of the Act,[15] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed change is reasonable because the fee caps may provide an incentive to engage in dividend spreads and the Exchange has determined that it no longer wishes to offer any potential incentive via its Fee Schedule in light of the operational risks that dividend spreads may present. The Exchange also believes that the proposed change is equitable and not unfairly discriminatory because it would apply equally to all market participants and because the remaining Strategy Executions that would continue to be subject to the fee caps do not present the same type of potential operational risks.

Furthermore, it is reasonable to specify that the type of execution that the Exchange currently considers to be a dividend spread[16] would no longer be excluded from the fee caps and volume thresholds described in the Fee Schedule. Specifically, because dividend spreads would no longer be considered a Strategy Execution for purposes of billing on the Exchange, the fee caps and volume thresholds would no longer exclude such executions. However, the Exchange does not anticipate that this would result in a significant amount of such executions occurring on the Exchange. In this regard, the Exchange believes that the elimination of the $750 fee cap would eliminate the incentive for market participants to effect such executions on the Exchange. This would also be equitable and not unfairly discriminatory because it would not differentiate between any particular market participants when determining whether the fee caps and volume thresholds have been reached with respect to the inclusion of the type of execution that the Exchange currently considers to be a dividend spread.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[17] of the Act and subparagraph (f)(2) of Rule 19b–4[18] thereunder, because it establishes a due, fee, or other charge imposed by the NYSE MKT.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEMKT–2012–57 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2012–57. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549–1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2012–57 and should be submitted on or before November 30, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27362 Filed 11–8–12; 8:45 am]

BILLING CODE 8011–01–P

[13] The Exchange is proposing a minor non-substantive change to the Fee Schedule to correct the grammar of the existing text therein.

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(4).

[16] *See supra* note 5.

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(2).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68155; File No. SR–CBOE–2012–100]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to System Access, Connectivity, and Testing

November 5, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 23, 2012, Chicago Board Options Exchange, Incorporated (the ''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend its rules regarding Hybrid Trading System (the ''System'')[3] access, connectivity, and testing by Trading Permit Holders. 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.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its rules regarding System access, connectivity, and testing by Trading Permit Holders. The Exchange makes available to Trading Permit Holders various application programming interfaces (''APIs''),[4] such as CBOE Market Interface (''CMi'') and Financial Information eXchange (''FIX'') Protocol, for authorized Trading Permit Holders to use to access the System.[5] Trading Permit Holders may select which of these APIs they would like to use to connect to the System when registering with the Exchange for System access. The Exchange believes it is important to provide Trading Permit Holders with this flexibility so that they can determine the API that will be most compatible with their systems and maximize the efficiency of their systems' connection to the System. Connection to the System allows authorized Trading Permit Holders to enter and execute orders, as well as submit certain order and trade data to the Exchange, which data the Exchange uses to conduct surveillances of its markets and Trading Permit Holders.

After a Trading Permit Holder registers with the Exchange to use a specific API, the Exchange may require the Trading Permit Holder to use a specific connectivity protocol that, among other things, may require the input of certain information (e.g. trading acronym, category of Trading Permit Holder) during the connectivity process in accordance with technical specifications established by the Exchange. The Exchange may prescribe a specific connectivity protocol for all Trading Permit Holders, or for certain categories of similarly situated Trading Permit Holders (e.g. Floor Brokers, Designated Primary Market-Makers (''DPMs''), or Market-Makers).

It is imperative for the Exchange to receive during the connectivity process information regarding a Trading Permit Holder's identification so that the Exchange can ensure that the connecting party is a Trading Permit Holder authorized to access the System and that the Exchange is aware of what type of Trading Permit Holder the connecting party is. Requiring a specific connectivity protocol allows the Exchange to receive this information in a uniform manner for all Trading Permit Holders, or categories of similarly situated Trading Permit Holders, as the Exchange deems necessary. This information allows the Exchange to, among other things, perform the necessary surveillances applicable to the Trading Permit Holder and determine whether the Trading Permit Holder is complying with all relevant Exchange Rules. Many of the Exchange's surveillances are conducted by type of Trading Permit Holders, as different types have different responsibilities they must meet under the Exchange rules.[6] The Exchange believes that receiving trade data in an organized and uniform format from all Trading Permit Holders, or types of Trading Permit Holders, allows it to efficiently identify Trading Permit Holders and monitor and conduct surveillances of its markets and Trading Permit Holder, and thus effectively fulfill its regulatory responsibilities. Additionally, the Exchange believes that prescribing connectivity protocols on either all Trading Permit Holders or categories of similarly situated Trading Permit Holders ensures that the Exchange makes these prescriptions in an objective manner.

The Exchange also periodically requires Trading Permit Holders that have been authorized to access the System to conduct or participate in the testing of their computer systems to ascertain the compatibility of these systems with the System. The Exchange believes that it is critical that Trading

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The System is a trading platform that allows automatic executions to occur electronically and open outcry trades to occur on the floor of the Exchange. To operate in this ''hybrid'' environment, the Exchange has a dynamic order handling system that has the capability to route orders to the trade engine for automatic execution and book entry, to Trading Permit Holder and PAR Official workstations located in the trading crowds for manual handling, and/or to other order management terminals generally located in booths on the trading floor for manual handling. Where an order is routed for processing by the Exchange order handling system depends on various parameters configured by the Exchange and the order entry firm itself.

[4] APIs are computer programs that allow Trading Permit Holders to interface with the Exchange.

[5] Only Trading Permit Holders may access the System. The Commission adopted Rule 15c3–5 under the Act, which, among other things, requires broker-dealers providing others with access to an exchange or alternative trading system to establish, document, and maintain a system of risk management controls and supervisory procedures reasonably designed to manage the financial, regulatory, and other risks of providing such access. *See* Securities Exchange Act Release No. 63241 (November 3, 2010), 75 FR 69792 (November 15, 2010). Rule 15c3–5 effectively eliminated ''naked access'' (i.e. ''Sponsored Users'') to the Exchange by non-Trading Permit Holders and effectively requires Trading Permit Holders to filter all non-Trading Permit Holder orders prior to being sent to the Exchange. The Exchange expects to eliminate the concept of Sponsored Users under its Rules in connection with the adoption of Rule 15c3–5 in a separate rule filing.

[6] For example, a DPM must satisfy quoting obligations that are different than those that a Market-Maker must satisfy, and the Exchange reviews their quoting activity to determine whether they have satisfied their respective obligations. *See* Rule 8.85 (obligations of DPMs) and Rule 8.7 (obligations of Market-Makers).

Permit Holders work closely with the Exchange in testing new software releases and other System changes. System testing allows the Exchange to ensure that Trading Permit Holders' systems are continuously compatible with the System in the event of System changes and that the Exchange continues to receive all necessary data from Trading Permit Holders in a timely manner and efficient format. Additionally, System testing allows Trading Permit Holders to make any necessary adjustments to their systems in the event of System changes to ensure that their connections to the System are functioning properly and that they are able to submit order and trade information in compliance with all applicable Exchange Rules.

The Exchange proposes to codify these current Exchange practices and requirements related to System access and connectivity. Proposed Rule 6.23A(c) clarifies in the Rules that only Trading Permit Holders (and their associated persons) may be authorized to access the System to enter and execute orders. This proposed provision also provides that the Exchange will require a Trading Permit Holder to enter into a software user or license agreement with the Exchange in a form or forms prescribed by the Exchange in order to obtain authorized access to the System if the Trading Permit Holder elects to use an API for which the Exchange has determined that this type of an agreement is necessary. In other words, whether the Exchange requires a Trading Permit Holder to enter into a user or license agreement will depend solely on the objective criteria of what type of API the Trading Permit Holder opts to use.[7] The proposed rule change also amends Rule 6.23A(a) to clarify that the term API means application programming interface.

Proposed Rule 6.23A(d) provides that the Exchange may prescribe technical specifications pursuant to which all Trading Permit Holders, or categories of similarly situated Trading Permit Holders (e.g., Floor Brokers, DPMs, Market-Makers), may establish an electronic connection to the System and its facilities. The Exchange will announce to Trading Permit Holders via Regulatory Circular any connectivity protocol prescription.

Proposed Rule 6.23A(e)(i) provides that each Trading Permit Holder that the Exchange designates as required to participate in a system test must conduct or participate in the testing of its computer systems to ascertain the compatibility of such systems with the System in the manner and frequency prescribed by the Exchange. The Exchange will designate Trading Permit Holders as required to participate in a system test based on: (1) The category of the Trading Permit Holder (e.g. Floor Broker, DPM, Market-Maker); (2) the computer system(s) the Trading Permit Holder uses; and (3) the manner in which the Trading Permit Holder connects to the System. The Exchange will give Trading Permit Holders reasonable notice of any mandatory systems test, which notice will specify the nature of the test and Trading Permit Holders' obligations in participation in the test.

In connection with this mandatory system testing, proposed Rule 6.23A(e)(ii) provides that every Trading Permit Holder required by the Exchange to conduct or participate in testing of computer systems must provide to the Exchange any reports relating to the testing as the Exchange may prescribe. Trading Permit Holders must maintain adequate documentation of tests required by this Rule and results of this testing for examination by the Exchange.

Proposed Rule 6.23A(e)(iii) states that a Trading Permit Holder that fails to conduct or participate in mandatory systems tests, fails to file the required reports, or fails to maintain the required documentation, as required by proposed Rule 6.23A(e)(i) and (ii), may be subject to summary suspension or other action taken pursuant to Chapter XVI (Summary Suspension) and/or disciplinary action pursuant to Chapter XVII (Discipline) of the Exchange Rules. Disciplinary action may include fines pursuant to proposed Rule 17.50(g)(19), which provides that Trading Permit Holders that violate proposed Rule 6.23A(e) may be subject to fines under the Exchange's minor rule violation plan.[8] As with all other violations in the Exchange's minor rule violation plan, the Exchange retains the ability to refer a violation of the system testing requirements to its Business Conduct Committee should the circumstances warrant such a referral. The Exchange believes that violations of the proposed mandatory system testing provision are suitable for its minor rule violation plan because they are generally technical in nature. Further, including these violations into the minor rule violation plan will allow the Exchange to carry out its regulatory responsibilities more quickly and efficiently.

The proposed rule change also amends Rule 50.2(a) in the CBOE Stock Exchange, LLC (''CBSX'')[9] Rules to clarify that references to ''Hybrid Trading System,'' ''Hybrid System,'' and ''System'' in Exchange Rules that are applicable to trading on CBSX should be read to mean ''CBSX System.'' Additionally, the proposed rule change amends Appendix A to the CBSX Rules to provide that Rule 6.23A(c) through (e) applies to the trading of equity securities on CBSX. This change clarifies that the Exchange may similarly require CBSX Trading Permit Holders, or categories of CBSX Trading Permit Holders (e.g. Remote Market-Makers), to connect to the Exchange in accordance with a specific connectivity protocol and to participate in system testing as the Exchange deems necessary.

Codification of these requirements gives the Exchange the ability to discipline any Trading Permit Holders that fail to comply with these requirements. While Trading Permit Holders generally comply with these requirements, their inclusion in the Rules (and the resulting potential for discipline for noncompliance) may enhance Trading Permit Holders' overall compliance with them.

Codification of these requirements is also consistent with the Rules of other exchanges. Proposed Rule 6.23A(c) is substantially similar to: BATS Exchange, Inc. (''BATS'') Rule 11.3(a); BOX Options Exchange LLC (''BOX'') Rule 7000(a); EDGA Exchange, Inc. (''EDGA'') Chapter XI, Rule 11.3(a); EDGX Exchange, Inc. (''EDGX'') Chapter XI, Rule 11.3(a); International Securities Exchange, LLC (''ISE'') Rule 706(a); NASDAQ Option Market (''NOM'') Chapter V, Section 1(a); NYSE Arca, Inc. (''NYSE Arca'') Rule 6.2A(a); and NYSE MKT LLC (''NYSE MKT'') Rule 902.1NY(a). Proposed Rule 6.23A(e) is substantially similar to: BATS Rule 18.13; BOX Rule 3180; ISE Rule 419; and NOM Chapter III, Section 13. BOX Rule 12140(d)(7) and ISE Rule 1614(d)(8) also allow those exchanges to fine their members for violations of their respective mandatory system provisions

[7] For example, the Exchange developed CMi and currently requires all Trading Permit Holders that opt to connect to the System using CMi to enter into a software license agreement with the Exchange to use CMi. The Exchange has determined that Trading Permit Holders that opt to connect to the System using FIX do not currently have to enter into any type of software user or license agreement, which is a universally available application for which the developer does not require a user agreement.

[8] These fines are as follows: $250 for the first offense, $500 for the second offense, $1,000 for the third offense, $2,000 for the fourth offense, and referral to the Business Conduct Committee for any subsequent offenses. The fines are based on the number of offenses in one calendar year.

[9] CBSX is a stock trading facility of the Exchange.

pursuant to their respective minor rule violation plans.[10]

Additionally, proposed Rule 6.23A(c) is consistent with Rule 15c3–1 [sic] under the Act.[11]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[12] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, 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 to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest.[13] Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of a national securities exchange be designed to not permit unfair discrimination between customer, issuers, brokers or dealers.[14] The Exchange also believes the proposed rule change is consistent with the Section 6(b)(6)[15] requirement that the rules of an exchange provide that its members and persons associated with its members be appropriately disciplined for violation of the provisions of the Act, the rules and regulations thereunder, or the rules of the exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a member, or any other fitting sanction.

The proposed rule change codifies current Exchange requirements that enhance CBOE's market surveillances and System functionality. Proposed Rule 6.23A(c) is consistent with Rule 15c3–5 under the Act, and the Exchange believes the proposed rule change promotes compliance by Trading Permit Holders with the market access requirements under that rule. The Exchange believes that proposed Rule 6.23A(d) allows the Exchange to receive from Trading Permit Holders, or categories of similarly situated Trading Permit Holders, information in a uniform format, which aids the Exchange's efforts to monitor and regulate CBOE's markets and Trading Permit Holders and helps prevent fraudulent and manipulative practices. This also helps coordinate the ability of Trading Permit Holders to electronically trade on the Exchange with the Exchange's ability to receive the necessary information to regulate those transactions. Proposed Rule 6.23A(e) allows the Exchange to ensure that Trading Permit Holders' connections to the System function correctly, which promotes efficiency and enhances compliance by Trading Permit Holders with Exchange Rules. The proposed changes to the CBSX Rules clarify for CBSX Trading Permit Holders that they are subject to and must comply with the requirements in proposed Rule 6.23A.

In addition, codification of these requirements is consistent with the Act because it gives the Exchange the ability to discipline Trading Permit Holders that fail to comply with these requirements, which may enhance overall Trading Permit Holder compliance with these requirements. This proposed rule change will also promote consistency in the minor rule violation programs of other exchanges and allow the Exchange to carry out its regulatory responsibilities more quickly and efficiently by including violations of the mandatory system testing provision in the Exchange's minor rule violation plan.

The Exchange believes that the proposed rule change is designed to not permit unfair discrimination among Trading Permit Holders, as the proposed rule change provides for the Exchange to impose requirements on Trading Permit Holders in an objective manner. For example, under proposed Rule 6.23A(d), the Exchange may impose connectivity protocol requirements on all Trading Permit Holders, or similarly situated Trading Permit Holders. Additionally, under proposed Rule 6.23A(c), whether the Exchange requires a Trading Permit Holder to enter into a software user or license agreement depends solely on what type of API the Trading Permit Holder opts to use to connect to the System.

Finally, the proposed rule change will help remove impediments to and promote a free and open market and a national market system because it is consistent with rules in place at other exchanges and imposes substantially similar requirements on Trading Permit Holders as those rules do on those exchanges' members.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule 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)[16] of the Act and Rule 19b–4(f)(6)[17] thereunder.

At any time within 60 days of the filing of this proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2012–100 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission,

[10] The proposed fine amounts in proposed Rule 17.50(g)(19) are the same as the fine amounts in the corresponding BOX and ISE rules.

[11] *See supra* note 5.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] *Id.*

[15] 15 U.S.C. 78f(b)(6).

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6).

100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2012–100. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2012–100, and should be submitted on or before November 30, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27361 Filed 11–8–12; 8:45 am]

BILLING CODE 8011–01–P

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68154; File No. SR–C2–2012–036]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to System Access, Connectivity, and Testing

November 5, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 23, 2012, C2 Options Exchange, Incorporated (the ''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend its rules regarding System[3] access, connectivity, and testing by Participants. The text of the proposed rule change is available on the Exchange's Web site (*http://www.c2exchange.com/Legal/*), at the Exchange's Office of the Secretary, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its rules regarding System access, connectivity, and testing by Participants. The Exchange makes available to Participants various application programming interfaces (''APIs''),[4] such as CBOE Market Interface (''CMi'') and Financial Information eXchange (''FIX'') Protocol, for authorized Participants to use to access the System.[5] Participants may select which of these APIs they would like to use to connect to the System when registering with the Exchange for System access. The Exchange believes it is important to provide Participants with this flexibility so that they can determine the API that will be most compatible with their systems and maximize the efficiency of their systems' connection to the System. Connection to the System allows authorized Participants to enter and execute orders, as well as submit certain order and trade data to the Exchange, which data the Exchange uses to conduct surveillances of its markets and Participants.

After a Participant registers with the Exchange to use a specific API, the Exchange may require the Participant to use a specific connectivity protocol that, among other things, may require the input of certain information (e.g. trading acronym, category of Participant) during the connectivity process in accordance with technical specifications established by the Exchange. The Exchange may prescribe a specific connectivity protocol for all Participants, or for certain categories of similarly situated Participants (e.g. Market-Makers, Designated Primary Market-Makers (''DPMs'')).

It is imperative for the Exchange to receive during the connectivity process information regarding a Participant's identification so that the Exchange can ensure that the connecting party is a Participant authorized to access the System and that the Exchange is aware of what type of Participant the connecting party is. Requiring a specific connectivity protocol allows the Exchange to receive this information in a uniform manner for all Participants, or categories of similarly situated Participants, as the Exchange deems necessary. This information allows the Exchange to, among other things, perform the necessary surveillances applicable to the Participant and determine whether the Participant is complying with all relevant Exchange Rules. Many of the Exchange's surveillances are conducted by type of Participants, as different types have

[3] The System means the automated trading system used by the Exchange for the trading of options products.

[4] APIs are computer programs that allow Participants to interface with the Exchange.

[5] Only Participants may access the System. The Commission adopted Rule 15c3–5 under the Act, which, among other things, requires broker-dealers providing others with access to an exchange or alternative trading system to establish, document, and maintain a system of risk management controls and supervisory procedures reasonably designed to manage the financial, regulatory, and other risks of providing such access. *See* Securities Exchange Act Release No. 63241 (November 3, 2010), 75 FR 69792 (November 15, 2010). Rule 15c3–5 effectively eliminated ''naked access'' (i.e. ''Sponsored Users'') to the Exchange by non-Participants and effectively requires Participants to filter all non-Participant orders prior to being sent to the Exchange. The Exchange expects to eliminate the concept of sponsored use under its Rules in connection with the adoption of Rule 15c3–5 in a separate rule filing.

different responsibilities they must meet under the Exchange rules.[6] The Exchange believes that receiving trade data in an organized and uniform format from all Participants, or types of Participants, allows it to efficiently identify Participants and monitor and conduct surveillances of its markets and Participant, and thus effectively fulfill its regulatory responsibilities. Additionally, the Exchange believes that prescribing connectivity protocols on either all Participants or categories of similarly situated Participants ensures that the Exchange makes these prescriptions in an objective manner.

The Exchange also periodically requires Participants that have been authorized to access the System to conduct or participate in the testing of their computer systems to ascertain the compatibility of these systems with the System. The Exchange believes that it is critical that Participants work closely with the Exchange in testing new software releases and other System changes. System testing allows the Exchange to ensure that Participants' systems are continuously compatible with the System in the event of System changes and that the Exchange continues to receive all necessary data from Participants in a timely manner and efficient format. Additionally, System testing allows Participants to make any necessary adjustments to their systems in the event of System changes to ensure that their connections to the System are functioning properly and that they are able to submit order and trade information in compliance with all applicable Exchange Rules.

The Exchange proposes to codify these current Exchange practices and requirements related to System access and connectivity. Proposed Rule 6.34(c) clarifies in the Rules that only Participants (and their associated persons) may be authorized to access the System to enter and execute orders. This proposed provision also provides that the Exchange will require a Participant to enter into a software user or license agreement with the Exchange in a form or forms prescribed by the Exchange in order to obtain authorized access to the System if the Participant elects to use an API for which the Exchange has determined that this type of an agreement is necessary. In other words, whether the Exchange requires a Participant to enter into a user or license agreement will depend solely on the objective criteria of what type of API the Participant opts to use.[7] The proposed rule change also amends Rule 6.34(a) to clarify that the term API means application programming interface.

Proposed Rule 6.34(d) provides that the Exchange may prescribe technical specifications pursuant to which all Participants, or categories of similarly situated Participants (e.g., DPMs, Market-Makers), may establish an electronic connection to the System (and any facilities). The Exchange will announce to Participants via Regulatory Circular any connectivity protocol prescription.

Proposed Rule 6.34(e)(i) provides that each Participant that the Exchange designates as required to participate in a system test must conduct or participate in the testing of its computer systems to ascertain the compatibility of such systems with the System in the manner and frequency prescribed by the Exchange. The Exchange will designate Participants as required to participate in a system test based on: (1) The category of the Participant (e.g. DPM, Market-Maker); (2) the computer system(s) the Participant uses; and (3) the manner in which the Participant connects to the System. The Exchange will give Participants reasonable notice of any mandatory systems test, which notice will specify the nature of the test and Participants' obligations in participation in the test.

In connection with this mandatory system testing, proposed Rule 6.34(e)(ii) provides that every Participant required by the Exchange to conduct or participate in testing of computer systems must provide to the Exchange any reports relating to the testing as the Exchange may prescribe. Participants must maintain adequate documentation of tests required by this Rule and results of this testing for examination by the Exchange.

Proposed Rule 6.34(e)(iii) states that a Participant that fails to conduct or participate in mandatory systems tests, fails to file the required reports, or fails to maintain the required documentation, as required by proposed Rule 6.34(e)(i) and (ii), may be subject to summary suspension or other action taken pursuant to Chapter 16 (Summary Suspension) and/or disciplinary action pursuant to Chapter 17 (Discipline) of the Exchange Rules. Disciplinary action may include fines pursuant to proposed Rule 17.50(g)(19), which provides that Participants that violate proposed Rule 6.34(e) may be subject to fines under the Exchange's minor rule violation plan.[8] As with all other violations in the Exchange's minor rule violation plan, the Exchange retains the ability to refer a violation of the system testing requirements to its Business Conduct Committee should the circumstances warrant such a referral. The Exchange believes that violations of the proposed mandatory system testing provision are suitable for its minor rule violation plan because they are generally technical in nature. Further, including these violations into the minor rule violation plan will allow the Exchange to carry out its regulatory responsibilities more quickly and efficiently.

Codification of these requirements gives the Exchange the ability to discipline any Participants that fail to comply with these requirements. While Participants generally comply with these requirements, their inclusion in the Rules (and the resulting potential for discipline for noncompliance) may enhance Participants' overall compliance with them.

Codification of these requirements is also consistent with the Rules of other exchanges. Proposed Rule 6.34(c) is substantially similar to: BATS Exchange, Inc. (''BATS'') Rule 11.3(a); BOX Options Exchange LLC (''BOX'') Rule 7000(a); EDGA Exchange, Inc. (''EDGA'') Chapter XI, Rule 11.3(a); EDGX Exchange, Inc. (''EDGX'') Chapter XI, Rule 11.3(a); International Securities Exchange, LLC (''ISE'') Rule 706(a); NASDAQ Option Market (''NOM'') Chapter V, Section 1(a); NYSE Arca, Inc. (''NYSE Arca'') Rule 6.2A(a); and NYSE MKT LLC (''NYSE MKT'') Rule 902.1NY(a). Proposed Rule 6.34(e) is substantially similar to: BATS Rule 18.13; BOX Rule 3180; ISE Rule 419; and NOM Chapter III, Section 13. BOX Rule 12140(d)(7) and ISE Rule 1614(d)(8) also allow those exchanges to fine their members for violations of their respective mandatory system provisions pursuant to their respective minor rule violation plans.[9]

[6] For example, a DPM must satisfy quoting obligations that are different than those that a Market-Maker must satisfy, and the Exchange reviews their quoting activity to determine whether they have satisfied their respective obligations. *See* Rule 8.17 (obligations of DPMs) and Rule 8.5 (obligations of Market-Makers).

[7] For example, the Exchange developed CMi and currently requires all Participants that opt to connect to the System using CMi to enter into a software license agreement with the Exchange to use CMi. The Exchange has determined that Participants that opt to connect to the System using FIX do not currently have to enter into any type of software user or license agreement, which is a universally available application for which the developer does not require a user agreement.

[8] These fines are as follows: $250 for the first offense, $500 for the second offense, $1,000 for the third offense, $2,000 for the fourth offense, and referral to the Business Conduct Committee for any subsequent offenses. The fines are based on the number of offenses in one calendar year.

[9] The proposed fine amounts in proposed Rule 17.50(g)(19) are the same as the fine amounts in the corresponding BOX and ISE rules.

Additionally, proposed Rule 6.34(c) is consistent with Rule 15c3–1 [sic] under the Act.[10]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, 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 to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest.[12] Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of a national securities exchange be designed to not permit unfair discrimination between customer, issuers, brokers or dealers.[13] The Exchange also believes the proposed rule change is consistent with the Section 6(b)(6)[14] requirement that the rules of an exchange provide that its members and persons associated with its members be appropriately disciplined for violation of the provisions of the Act, the rules and regulations thereunder, or the rules of the exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a member, or any other fitting sanction.

The proposed rule change codifies current Exchange requirements that enhance C2's market surveillances and System functionality. Proposed Rule 6.34(c) is consistent with Rule 15c3–5 under the Act, and the Exchange believes the proposed rule change promotes compliance by Participants with the market access requirements under that rule. The Exchange believes that proposed Rule 6.34(d) allows the Exchange to receive from Participants, or categories of similarly situated Participants, information in a uniform format, which aids the Exchange's efforts to monitor and regulate C2's markets and Participants and helps prevent fraudulent and manipulative practices. This also helps coordinate the ability of Participants to electronically trade on the Exchange with the Exchange's ability to receive the necessary information to regulate those transactions. Proposed Rule 6.34(e) allows the Exchange to ensure that Participants' connections to the System function correctly, which promotes efficiency and enhances compliance by Participants with Exchange Rules.

In addition, codification of these requirements is consistent with the Act because it gives the Exchange the ability to discipline Participants that fail to comply with these requirements, which may enhance overall Participants compliance with these requirements. This proposed rule change will also promote consistency in the minor rule violation programs of other exchanges and allow the Exchange to carry out its regulatory responsibilities more quickly and efficiently by including violations of the mandatory system testing provision in the Exchange's minor rule violation plan.

The Exchange believes that the proposed rule change is designed to not permit unfair discrimination among Participants, as the proposed rule change provides for the Exchange to impose requirements on Participants in an objective manner. For example, under proposed Rule 6.34(d), the Exchange may impose connectivity protocol requirements on all Participants, or similarly situated Participants. Additionally, under proposed Rule 6.34(c), whether the Exchange requires a Participant to enter into a software user or license agreement depends solely on what type of API the Participant opts to use to connect to the System.

Finally, the proposed rule change will help remove impediments to and promote a free and open market and a national market system because it is consistent with rules in place at other exchanges and imposes substantially similar requirements on Participants as those rules do on those exchanges' members.

B. Self-Regulatory Organization's Statement on Burden on Competition

C2 does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule 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)[15] of the Act and Rule 19b–4(f)(6)[16] thereunder.

At any time within 60 days of the filing of this proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–C2–2012–036 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–C2–2012–036. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/*

[10] *See supra* note 5.

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] 15 U.S.C. 78f(b)(6).

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6).

rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–C2–2012–036, and should be submitted on or before November 30, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27360 Filed 11–8–12; 8:45 am]

BILLING CODE 8011–01–P

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68152; File No. SR–ICEEU–2012–09]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change To Provide for a Customer Clearing Model for CDS Products and To Amend, Clarify and Consolidate Certain Rules and Procedures

November 5, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on October 22, 2012, ICE Clear Europe Limited (''ICE Clear Europe'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I, II and III below, which items have been prepared primarily by ICE Clear Europe. The Commission is publishing this Notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(2).

[2] 17 CFR 240.19b-4.

I. Self-Regulatory Organization's Statement of Terms of Substance of the Proposed Rule Change

ICE Clear Europe proposes rule changes to provide for a clearing model for CDS products whereby customers of ICE Clear Europe have the ability to clear CDS products through ICE Clear Europe (the ''Customer CDS Clearing Model''). Additionally, ICE Clear Europe also seeks to amend, clarify and consolidate the terms of certain rules and procedures, including those that relate to default and membership requirements.

II. Self-Regulatory Organization's Statement of Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe 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. ICE Clear Europe has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.[3]

[3] The Commission has modified the text of the summaries prepared by ICE Clear Europe.

A. Self-Regulatory Organization's Statement of Purpose of, and Statutory Basis for, the Proposed Rule Change

As noted above, the principal purpose of the proposed rule change is to provide for a Customer CDS Clearing Model whereby customers of ICE Clear Europe Clearing Members have the ability to clear CDS products through ICE Clear Europe. In addition, ICE Clear Europe proposes to amend its Rules and CDS Procedures in order to implement certain rule changes that are unrelated to Customer CDS Clearing Model.

Currently, ICE Clear Europe Clearing Members are only able to clear CDS products at ICE Clear Europe through their proprietary accounts and not on behalf of their customers. The Customer CDS Clearing Model will extend ICE Clear Europe's customer clearing models that are currently available for other products to CDS products, with certain modifications appropriate for the nature of the product.

ICE Clear Europe has identified customer clearing of CDS products as a service that has become increasingly important for market participants to manage risk and express views with respect to the credit markets. In addition, the CFTC has proposed, pursuant to the Dodd-Frank Act, that clearing of certain CDS products, including iTraxx index CDS currently cleared by ICE Clear Europe, will become subject to mandatory clearing under Section 2(h) of the Commodity Exchange Act, including for customers. Customers subject to the clearing mandate will therefore need access to clearing in order to comply with their own clearing obligations. Moreover, ICE Clear Europe believes that extending CDS clearing to customers of its Clearing Members will facilitate the prompt and accurate settlement of swaps and contribute to the safeguarding of securities and funds associated with swap transactions.

The Customer CDS Clearing Model builds on the customer clearing framework available for other products at ICE Clear Europe. For US customers, clearing would have to occur through a registered futures commission merchant and/or broker-dealer (depending on whether the product is an index CDS or single-name CDS), consistent with the requirements of the Commodity Exchange Act and Securities Exchange Act of 1934. Non-US customers would be permitted to clear through a non-US clearing member in accordance with applicable local laws or through a registered futures commission merchant and/or broker-dealer.

The terms of the Customer CDS Clearing Model, as well as various related enhancements to the clearing model, are being proposed as amendments to the ICE Clear Europe Rules and CDS Procedures. Proposed changes to Part 1 of the Rules contain various clarifying and conforming amendments to definitions, various new CDS-specific definitions used in new operative provisions, clarifications to customer and proprietary account class definitions that will now be relevant to CDS, and clarifications to general standards of Clearing Member responsibility and liability requested by CDS Clearing Members. Other proposed changes reflect the incorporation into the Rules of provisions that used to be in a separate master agreement entered into between the Clearing Member and ICE Clear Europe. Proposed changes to Part 2 of the Rules provide updates related to anti-money laundering legislation applicable to customers, clarify membership standards for Clearing Members, clarify the obligations of Clearing Members with respect to customer accounts and proprietary accounts and clarify and/or restate certain provisions relating to Clearing Member default and termination of clearing membership.

The proposed changes in Part 3 of the Rules clarify certain payment mechanics for Clearing Members with respect to amounts owed by their customers and include a waiver of set-off by Clearing Members. Part 4 of the Rules contains proposed changes related to the obligations of Clearing Members with respect to formation of contracts, including whether such contract is being entered into for the customer account or proprietary account, particularly in the context of the clearing of CDS on behalf of customers. The proposed changes in Part 5 of the Rules address the delivery of margin from customers to Clearing Members and add provisions dealing with transfer of margin by security interest rather than title transfer. The proposed changes to Part 6 of the Rules, which governs position limits, clarify the procedures for providing notice of such position limits. Some proposed minor technical changes clarify further how position limits apply in instances where contracts arise due to firm trades, voiding or error policies. The proposed changes in Parts 7 and 8 of the Rules clarify that references in those parts of the Rules (covering Settlement and Delivery of Futures (Part 7) and Options (Part 8)), which relate solely to Energy contracts, do not apply to CDS Customer Accounts or Customers in the context of CDS clearing. Part 9 of the Rules contain various proposed changes to consolidate and clarify the respective rights and obligations of ICE Clear Europe and Clearing Members, in the case of a Clearing Member or ICE Clear Europe default and the procedures to be followed in determining a net sum payable to or receivable from a defaulting Clearing Member. Part 10 of the Rules contains proposed clarifying language providing more detail as to how a disciplinary or appeals panel could impose a sanction on a customer and to determine liability or responsibility appropriately in any instance where there is joint misfeasance. Part 11 contains proposed conforming changes related to the operation of the ICE Clear Europe guaranty funds, including proposed changes relating to the introduction of customer clearing. ICE Clear Europe will continue to operate separate guaranty funds for CDS products and for energy products. Part 12 of the Rules on settlement finality contains proposed updates to conform to and be consistent with the new terms and definitions that are part of the Customer CDS Customer Model. Part 15 of the Rules, which governs clearing of CDS generally, contains proposed updates to include various additional provisions dealing with CDS contracts cleared in the customer account (including the representation of customer transactions in relevant books and records and treatment of customer transactions in the case of credit events) and elimination of the separate master agreement previously entered into between CDS Clearing Members and ICE Clear Europe. Part 16 of the Rules contains certain proposed amendments to the ICE Clear Europe FCM customer clearing model that address the addition of CDS clearing and certain other clarifications and enhancements requested by CDS Clearing Members.

In connection with the proposal of the Customer CDS Clearing Model, ICE Clear Europe proposes to establish in Exhibit 1 of the Rules certain standard terms (the Customer-CM CDS Transactions Standard Terms) that will be applicable to Customer-CM CDS Transactions, which are CDS transactions between a Non-FCM/BD Clearing Member and a non-U.S. customer. Under the proposed changes to Rule 1516, all Non-FCM/BD Clearing Members must agree to the applicability of these terms as between them and each of their Customers. The Standard Terms provisions inter alia would ensure that the terms of Customer-CM CDS Transactions mirror the terms of the cleared transaction, enable a clearing member to pass on clearing house performance (or non-performance) to their Customers, facilitate the provision of margin to ICE Clear Europe and amend provisions in underlying agreements relating to events of default and close-out in order to ensure that the porting of contracts and margin under the default rules will be effective. In addition, various consents would be supplied for ICE Clear Europe to update customer records in DTCC and receive other information as required relating to customers. As noted above, US customers would clear through an FCM/BD Clearing Member, and the Customer-CM CDS Transactions Standard Terms would not apply to that relationship.

The adoption of the Customer CDS Clearing Model will also require changes to ICE Clear Europe's CDS Procedures. Part 1 of the CDS Procedures contains various proposed clarifying and conforming amendments to definitions, as well as new definitions used in new operative provisions. Part 2 of the CDS Procedures also contains various proposed clarifying and conforming amendments to membership requirements, largely resulting from implementation of the Dodd-Frank Act. Part 3 of the CDS Procedures also contains certain proposed conforming changes. Proposed changes in Part 4 of the CDS Procedures contain updates concerning information that must be provided with respect to CDS contracts and procedures for submission of CDS contracts for clearing. Proposed changes in Part 5 of the CDS Procedures have been made in furtherance of the Customer CDS Clearing Model to address customer clearing in the context of the CDS Default Committee procedures. Part 6 of the CDS Procedures would be removed as no longer necessary in light of the clearinghouse's use of determinations made by the ISDA Determinations Committees with respect to credit and succession events. Proposed changes in Part 7 address restructuring as a credit event with respect to CDS contracts cleared in the customer account, including the processing for triggering settlement of such contracts. Part 8 of the CDS Procedures contains proposed clarifying changes to the procedures for listing new CDS Contracts, in particular to enable the clearing house to respond in timely fashion to any prohibition on trading in CDS imposed under the EU Short Selling Regulation (Regulation 236/2012 dated 14 March 2012). Part 9 of the CDS Procedures would be updated to include various provisions previously included in the separate master agreement between CDS Clearing Members and ICE Clear Europe as well as certain tax provisions relevant to customer clearing. These updated provisions would apply to all CDS Contracts, both customer positions and proprietary positions of CDS Clearing Members. Part 10 of the CDS Procedures would be revised to update the cross-references and definitions relevant to customer clearing as they relate to index CDS Contracts. Part 11 of the CDS Procedures also would be revised to update the cross-references and definitions relevant to customer clearing as they relate to Single Name CDS Contracts. Similarly, Part 12 of the CDS Procedures would include updates to the cross-references and the definitions relevant to customer clearing with respect to Sovereign Contracts. Finally, Part 13 of the CDS Procedures would add certain general procedures relating to customer clearing of CDS contracts, including as to transfer of customer positions.

ICE Clear Europe believes that the proposed Customer CDS Clearing Model is consistent with the requirements of Section 17A of the Act and the CDS procedures and regulations thereunder applicable to it. Specifically, the Customer CDS Clearing Model would

promote market transparency for derivatives markets, promote the prompt and accurate clearance of securities transactions, and derivative agreements, contracts, and transactions, and protect investors and the public interest. The Customer CDS Clearing Model is designed to permit customers of Clearing Members to clear CDS transactions, thereby permitting the increased use of clearing and the prompt and accurate clearance and settlement of securities transactions in furtherance of the goals of Section 17A of the Act. ICE Clear Europe also believes the proposed changes are specifically designed to protect investors and the public interest. The non-Customer CDS Clearing Model proposed rule changes also achieve such ends by clarifying the rights and obligations of Clearing Members and ICE Clear Europe with respect to key aspects of the clearance and settlement process.

B. Self-Regulatory Organization's Statement on Burden on Competition

ICE Clear Europe does not believe that the proposed rule change will have any impact or impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

ICE Clear Europe has consulted extensively with CDS Clearing Members and others in developing the Customer CDS Clearing Model. ICE Clear Europe has not solicited and does not intend to solicit comments regarding this proposed rule change. ICE Clear Europe has not received any unsolicited written comments from interested parties. ICE Clear Europe will notify the Commission of any written comments received by ICE Clear Europe.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

• Electronic comments may be submitted by using the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*), or send an email to *rule-comments@sec.gov*. Please include File No. SR–ICEEU–2012–09 on the subject line.

• Paper comments should be sent in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICEEU–2012–09. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's Web site at *https://www.theice.com/notices/Notices.shtml?regulatoryFilings*.

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–ICEEU–2012–09 and should be submitted on or before November 30, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[4]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27355 Filed 11–8–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68151; File No. SR–OCC–2012–20]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Clarify the Applicability of OCC's Rules Governing Delivery of Treasury Securities Underlying Treasury Futures Contracts to Futures on Treasury Securities With Maturities of Greater Than 25 Years

November 5, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and

Rule 19b–4 thereunder[2] notice is hereby given that on October 22, 2012, The Options

Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared primarily by OCC. OCC filed the proposed rule change pursuant to Section 19(b)(3)(A)[3] of the Act and Rule 19b–4(f)(4)[4] thereunder so that the proposal was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

OCC proposes to clarify the applicability of OCC's rules governing delivery of Treasury securities underlying Treasury futures contracts to futures on Treasury securities with maturities of greater than 25 years.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC included statements concerning

[4] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(4).

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. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[5]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of this proposed rule change is to clarify the applicability of OCC's Rules governing delivery of Treasury securities underlying Treasury futures contracts to futures on Treasury securities with maturities of greater than 25 years, which are currently traded on ELX Futures, L.P. (''ELX'').

Clearing members that are, or that represent, the seller of a physically-settled Treasury future must make delivery of the underlying Treasury security in accordance with the procedures set forth in Rule 1302B. A clearing member need not deliver Treasury securities of a particular issue to satisfy a delivery obligation.[6] Instead, Interpretation and Policy .02 to Rule 1302B sets forth criteria for specific Treasury securities that may be delivered in settlement of Treasury futures contracts. For example, for a Treasury futures contract with an underlying interest that is a Treasury bond, a clearing member may deliver Treasury bonds, if not callable, with a remaining term of at least fifteen years or, if callable, that are not callable for at least 15 years.

ELX trades futures on Treasury securities of various maturities, including futures on treasury bonds with a maturity of greater than 25 years (''Ultra-Long Treasury Futures''). Under the rules of ELX, delivery obligations on Ultra-Long Treasury Futures may be satisfied by delivering Treasury bonds that, if not callable, have a remaining term of at least 25 years, or if callable, are not callable for at least 25 years. Interpretation and Policy .02 does not specifically address the delivery of Treasury bonds with maturities of 25 years or greater against Ultra-Long Treasury Futures. Accordingly, OCC is proposing to amend Interpretation and Policy .02 to Rule 1302B to provide that the characteristics of Treasury securities that may be delivered in settlement of futures on Treasury securities will be as set forth in the relevant exchange rules and reflected in OCC's procedures. This amendment will clarify the applicability of Rule 1302B to Ultra-Long Treasury Futures, as well as accommodate futures on other Treasury securities that may be introduced by an exchange at a later date that allow for delivery of Treasury securities with different maturity dates than those currently listed in Interpretation and Policy .02.

OCC believes that the proposed rule change is consistent with the purposes and requirements of Section 17A of the Securities Exchange Act of 1934, because they are designed to permit OCC to perform clearing services for products that are subject to the jurisdiction of the Commodity Futures Trading Commission (''CFTC'') without adversely affecting OCC's obligations with respect to the prompt and accurate clearance and settlement of securities transactions or the protection of investors and the public interest. The proposed rule change is not inconsistent with any rules of OCC, including any that are proposed to be amended.

(B) Self-Regulatory Organization's Statement on Burden on Competition

OCC does not believe the proposed rule change would impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments on the proposed rule change were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to Section 19(b)(3)(A)(iii)[7] of the Act and Rule 19b–4(f)(4)(ii)[8] thereunder because it affects a change in an existing service of a registered clearing agency that primarily affects the futures clearing operations of the clearing agency with respect to futures that are not security futures and it does not significantly affect any securities clearing operations of the clearing agency or any related rights or obligations of the clearing agency or persons using such service. OCC will delay the implementation of the rule change until it is deemed certified under CFTC Regulation § 40.6. At any time within 60 days of the filing of such rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–OCC–2012–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–OCC–2012–20. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Section, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of OCC and on OCC's Web site at (*http://www.theocc.com/components/docs/legal/rules_and_bylaws/sr_occ_12_20.pdf*).

All comments received will be posted without change; the Commission does

[5] The Commission has modified the text of the summaries prepared by OCC.

[6] Subject to the condition that all Treasury securities delivered against a single physically-settled Treasury futures contract be of the same issue.

[7] 15 U.S.C. 78s(b)(3)(A)(iii).

[8] 17 CFR 240.19b–4(f)(4)(ii).

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–OCC–2012–20 and should be submitted on or before November 30, 2012.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[9]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27354 Filed 11–8–12; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68150; File No. SR–NYSE–2012–56]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Proposing To Make Changes to Certain Fees and Credits Within the New York Stock Exchange LLC Price List

November 5, 2012.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on October 22, 2012, New York Stock Exchange LLC (the ''Exchange'' or ''NYSE'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to make changes to certain fees and credits within its Price List, which the Exchange proposes to become operative on November 1, 2012. The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make changes to certain fees and credits within its Price List, which the Exchange proposes to become operative on November 1, 2012.

Currently, for transactions in stocks with a per share stock price of $1.00 or more, the Exchange charges a transaction fee of $0.00055 per share for all market at-the-close (''MOC'') and limit at-the-close (''LOC'') orders from any member organizations that execute an average daily trading volume (''ADV'') of MOC and LOC activity on the Exchange in that month of at least 14 million shares. Member organizations that do not execute an ADV of MOC and LOC activity on the Exchange of at least 14 million shares are charged a transaction fee of $0.00095 per share. The Exchange proposes to modify the threshold for the $0.00055 transaction fee for MOC and LOC orders from an ADV of at least 14 million shares to an ADV of at least 0.375% of consolidated average daily volume in NYSE-listed securities during the billing month (''NYSE CADV'').

The Exchange believes that modifying the transaction fee threshold for MOC and LOC orders with a per share stock price of $1.00 or more as proposed would provide a more flexible method by which member organizations may qualify for the lower fee for MOC and LOC orders by changing from a fixed volume to one that will adjust automatically based on higher or lower NYSE CADV. The Exchange believes that the proposed change would continue to allocate a lower fee to member organizations that make significant contributions to market quality by providing higher volumes of liquidity.

Currently, the Exchange provides a credit of $0.0018 per share for transactions in stocks with a per share stock price of $1.00 or more when adding displayed liquidity to the Exchange if either:

(i) The member organization has ADV that adds liquidity to the Exchange during the billing month (''Adding ADV,'' which excludes any liquidity added by a Designated Market Maker (''DMM'')) that is at least 1.5% of NYSE CADV, and executes MOC and LOC orders of at least 0.375% of NYSE CADV; or

(ii) The member organization has Adding ADV that is at least 0.8% of NYSE CADV, executes MOC and LOC orders of at least 0.12% of NYSE CADV, and adds liquidity to the Exchange as a Supplemental Liquidity Provider (''SLP'') for all assigned SLP securities in the aggregate (including shares of both an SLP proprietary trading unit (''SLP-Prop'') and an SLP market maker (''SLMM'') of the same member organization) of more than 0.25% of NYSE CADV.

The Exchange proposes to modify the second method by which member organizations may qualify for the credit and add a third method by which member organizations may qualify for the credit when adding displayed liquidity. More specifically, the Exchange proposes to revise the second method to qualify for the credit such that a member organization would qualify for the credit if the member organization has Adding ADV that is at least 0.8% of NYSE CADV, executes MOC and LOC orders of at least 0.12% of NYSE CADV, and adds liquidity to the Exchange as a SLP for all assigned SLP securities in the aggregate (including shares of both an SLP-Prop and an SLMM of the same member organization) of more than 0.15% of NYSE CADV. Currently, a member organization would have to provide liquidity to the Exchange as an SLP for all assigned SLP securities in the aggregate of more than 0.25% of NYSE CADV, as opposed to the proposed 0.15% of NYSE CADV. The Exchange believes that reducing the threshold to 0.15% of NYSE CADV would allow more member organizations to qualify for the higher credit, and therefore, in turn, attract multiple sources of liquidity to the Exchange.

Finally, the Exchange proposes that a member organization would qualify for the credit of $0.0018 per share if the member organization has ADV that adds liquidity in customer electronic orders to the Exchange (''Customer Electronic Adding ADV,'' which would exclude any liquidity added by a Floor broker,

[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

DMM, or SLP) during the billing month that is at least 0.5% of NYSE CADV, executes MOC and LOC orders of at least 0.12% of NYSE CADV, and has Customer Electronic Adding ADV during the billing month that, taken as a percentage of NYSE CADV, is at least equal to the member organization's Customer Electronic Adding ADV during September 2012 as a percentage of consolidated average daily volume in NYSE-listed securities during September 2012 (''September 2012 NYSE CADV'') plus 15%.[3] For example, if a member organization's Customer Electronic Adding ADV during September 2012 was 0.10% of September 2012 NYSE CADV, then the member organization's Customer Electronic Adding ADV during the billing month must be at least 0.115% of NYSE CADV in order to qualify for the proposed credit.

The Exchange believes that adding this third method by which member organizations may qualify for the $0.0018 per share credit would encourage additional displayed liquidity on the Exchange. In addition, the method would provide discounts that are reasonably related to the value to the Exchange's market quality associated with higher volumes and would encourage multiple sources of liquidity by providing member organizations without a DMM, SLP, or Floor broker unit an alternative method to qualify for the credit when adding displayed liquidity.

The proposed changes are not otherwise intended to address any other problem, and the Exchange is not aware of any significant problem that the affected member organizations would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[4] in general, and furthers the objectives of Section 6(b)(4) of the Act,[5] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers, or dealers.

The Exchange believes that modifying the transaction fee threshold for MOC and LOC orders with a per share stock price of $1.00 or more is reasonable because it provides a more flexible method by which member organizations may qualify for the lower fee for MOC and LOC orders. In addition, the proposed change is reasonable because the threshold would adjust automatically based on higher or lower NYSE CADV. The Exchange believes that the proposed change to MOC and LOC orders is equitable and not unfairly discriminatory because all similarly situated member organizations would be subject to the same fee structure, which automatically adjusts based on prevailing market conditions, and would continue to allocate a lower fee to member organizations that make significant contributions to market quality by providing higher volumes of liquidity.

The Exchange believes that modifying the second method by which member organizations may qualify for the credit of $0.0018 per share for transactions in stocks with a per share stock price of $1.00 or more when adding displayed liquidity is reasonable because lowering the threshold for SLP provide volume to 0.15% of NYSE CADV would allow more member organizations to qualify for the reduced fee, which in turn would attract multiple sources of liquidity to the Exchange. In addition, the proposed change is equitable and not unfairly discriminatory because it would continue to provide a higher credit to member organizations that is reasonably related to the value to the Exchange's market quality associated with higher volumes.

The Exchange believes the new method by which member organizations may qualify for the credit for transactions in stocks with a per share stock price of $1.00 or more when adding displayed liquidity is reasonable because it would encourage additional displayed liquidity on the Exchange. The Exchange believes the new method is equitable and not unfairly discriminatory because it is open to all member organizations on an equal basis and provides discounts that are reasonably related to the value to the Exchange's market quality associated with higher volumes. In addition, the Exchange believes that the proposed change is equitable and not unfairly discriminatory because it would encourage multiple sources of liquidity by providing member organizations without a DMM, SLP, or Floor broker unit an alternative method to qualify for the credit.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[6] of the Act and subparagraph (f)(2) of Rule 19b–4[7] thereunder, because it establishes a due, fee, or other charge imposed by the NYSE.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[3] For purposes of determining whether a firm that becomes a member organization after September 2012 qualifies for this proposed third method by which member organizations may qualify for the $0.0018 per share credit, the new member organization's September 2012 NYSE CADV would be zero, and therefore, the member organization would only need to have Customer Electronic Adding ADV of at least 0.5% of NYSE CADV and execute MOC and LOC orders of at least 0.12% of NYSE CADV to qualify for the credit of $0.0018 per share. Additionally, the September 2012 NYSE CADV of a firm that becomes a member organization during September 2012 would be calculated based on the number of trading days during September 2012, not the number of trading days during September 2012 during which the firm was a member organization.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(4).

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(2).

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2012–56 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2012–56. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2012–56 and should be submitted on or before November 30, 2012.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2012–27353 Filed 11–8–12; 8:45 am]

BILLING CODE 8011–01–P

[8] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Community Advantage Pilot Program

AGENCY: U.S. Small Business Administration.

ACTION: Notice of extension of and changes to Community Advantage Pilot Program and request for comments.

SUMMARY: The Community Advantage (''CA'') Pilot Program is a pilot program to increase SBA-guaranteed loans to small businesses in underserved areas. SBA continues to refine and improve the design of the Community Advantage Pilot Program. To support SBA's commitment to expanding access to capital for small businesses and entrepreneurs in underserved markets, SBA is issuing this Notice to extend the term of the CA Pilot Program, to modify the loan loss reserve requirements for CA loans, and to revise other program requirements, including certain of the regulatory waivers.

DATES: *Effective Date:* The changes to the CA Pilot Program identified in this Notice will be effective November 9, 2012, and the CA Pilot Program will remain in effect until March 15, 2017.

Comment Date: Comments must be received on or before January 8, 2013.

ADDRESSES: You may submit comments, identified by SBA docket number SBA–2012–0016 by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Mail: Community Advantage Pilot Program Comments—Office of Financial Assistance, U.S. Small Business Administration, 409 Third Street SW., Suite 8300, Washington, DC 20416.
- Hand Delivery/Courier: Grady B. Hedgespeth, Director, Office of Financial Assistance, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416.

SBA will post all comments on *www.regulations.gov*. If you wish to submit confidential business information (CBI) as defined in the User Notice at *www.regulations.gov,* please submit the information to Grady B. Hedgespeth, Director, Office of Financial Assistance, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416, or send an email to *communityadvantage@sba.gov*. Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review the information and make the final determination whether it will publish the information.

FOR FURTHER INFORMATION CONTACT: Grady B. Hedgespeth, Director, Office of Financial Assistance, U.S. Small Business Administration, 409 Third Street SW., Washington DC 20416; (202) 205–7562; *grady.hedgespeth@sba.gov*. For information regarding revisions to the loan loss reserve requirements, contact Brent Ciurlino, Director, Office of Credit Risk Management, U.S. Small Business Administration, 409 Third Street SW., Washington DC 20416; (202) 205–6538; *brent.ciurlino@sba.gov*.

SUPPLEMENTARY INFORMATION:

1. Background

On February 18, 2011, SBA issued a notice and request for comments introducing the CA Pilot Program (76 FR 9626). The CA Pilot Program was introduced to increase the number of SBA-guaranteed loans made to small businesses in underserved markets. The February 18, 2011 notice provided an overview of the CA Pilot Program requirements and, pursuant to the authority provided to SBA under 13 CFR 120.3 to suspend, modify or waive certain regulations in establishing and testing pilot loan initiatives, SBA modified or waived as appropriate certain regulations which otherwise apply to 7(a) loans for the CA Pilot Program. On September 12, 2011, SBA issued a second notice modifying certain of those regulatory waivers in order to permit Community Advantage Lenders (''CA Lenders'') to pledge loans made under the CA Pilot Program (''CA loans'') as collateral for certain lender financings approved by SBA. (76 FR 56262).

SBA continues to refine and improve the design of the CA Pilot Program and, on February 8, 2012, SBA issued a third notice revising certain program requirements in order to, among other things, change the maximum allowable interest rate for CA loans and permit CA Lenders to contract with Lender Service Providers. (77 FR 6619). To further support SBA's commitment to expanding access to capital for small businesses and entrepreneurs in underserved markets, SBA is issuing this fourth notice to further revise program requirements as described more fully below.

2. Comments

Although the extension of and changes to the CA Pilot Program will be effective November 9, 2012, comments are solicited from interested members of the public on all aspects of the CA Pilot Program. Comments must be submitted on or before the deadline for comments listed in the **DATES** section. The SBA will consider these comments and the

need for making any revisions as a result of these comments.

3. Changes to the Community Advantage Pilot Program

Extension of the CA Pilot Program

The CA Pilot Program is currently set to expire on March 15, 2014. It was anticipated that this would be sufficient time to evaluate whether the CA Pilot Program was succeeding in expanding access to capital to small businesses in underserved markets and for SBA to determine whether to take the necessary steps to make the program permanent. In response to comments received from prospective applicants to the CA Pilot Program, SBA has made significant program modifications to increase the overall interest and participation in the program. However, CA Lenders have not had enough time to allow the program to gain the traction necessary to adequately measure whether the goals of the CA Pilot Program are being met. For these reasons and due to the significant investment in time and resources that is necessary to become a CA Lender, SBA is extending the CA Pilot Program through March 15, 2017.

Fidelity Insurance Requirement

When a CA Lender is approved to participate in the CA Pilot Program it is identified as either a Small Business Lending Company (SBLC) or a Non-Federally Regulated Lender (NFRL), depending on whether the lender is subject to regulation by a State. Accordingly, all CA Lenders are SBA Supervised Lenders, as that term is defined in 13 CFR 120.10, and are subject to all regulations applicable to such lenders unless specifically waived or modified in the regulatory waiver section of the notices identified above.

Agency regulations at 13 CFR 120.470(e) require an SBLC to ''maintain a Brokers Blanket Bond, Standard Form 14, or Financing Companies Blanket Bond, Standard Form 15, or such other form of coverage as SBA may approve, in a minimum amount of $2,000,000 executed by a surety holding a certificate of authority from the Secretary of the Treasury pursuant to 31 U.S.C. 9304–9308.'' SBA believes that this amount of coverage is unnecessary for most CA Lenders because the maximum amount of any one CA loan (currently $250,000) is significantly less than the maximum amount of any one 7(a) loan (currently $5,000,000). Therefore, SBA is modifying the regulation at 13 CFR 120.470(e) to reduce the minimum amount of coverage to $500,000 for CA Lenders identified as SBLCs with outstanding SBA guarantee exposure of $20 million or less. CA Lenders with outstanding SBA guarantee exposure of more than $20 million must maintain fidelity insurance coverage in a minimum amount of $2,000,000. SBLCs that are not CA Lenders must comply with the insurance requirement in the regulation.

Secondary Market Access

SBA is revising the approval process concerning secondary market access for CA Lenders. In the February 8, 2012 notice SBA modified the requirements for CA Lenders to sell loans in the secondary market by allowing CA Lenders to request authority ''either at the time of application or after one year of participation.'' (77 FR 6619). SBA is revising this requirement to allow a CA Lender to request access to the secondary market with its application to participate in the CA Pilot or at any time thereafter. If authority is not awarded as a result of the first request, the CA Lender should resolve any weakness or deficiency indicated as reasons for rejection for secondary market authority before submitting a request for reconsideration.

Loan Loss Reserve Requirements

CA Lenders are required to create and maintain a separate Loan Loss Reserve Account (LLRA) to cover potential losses arising from defaulted CA loans. In the February 18, 2011 **Federal Register** Notice introducing the CA Pilot Program (76 FR 9626), SBA required all CA Lenders to create and maintain the LLRA with a reserve amount equal to 15 percent of the outstanding amount of the unguaranteed portion of a CA Lender's CA loan portfolio. This level of loan loss reserve was based on the SBA Microloan Program's loan loss reserve requirements. Upon further review, however, SBA believes that the Microloan Program is not an appropriate comparison for the CA Pilot Program because the maximum loan size in the Microloan Program is $50,000, compared to a maximum loan size of $250,000 permitted in the CA Pilot Program. The United States Department of Agriculture's (USDA's) Intermediary Relending Program for loans in underserved rural areas, which has a maximum loan size of $250,000, requires a 6% cash reserve. (7 CFR 4274.332(b)(3)). SBA's Intermediary Lending Pilot Program, which has a maximum loan size of $200,000, requires a 5% cash reserve. (13 CFR 109.350). In addition, larger commercial lenders that provide warehouse lines of credit to non-profit, mission-oriented lenders for loans to small businesses typically require a reserve rate of 5% for their riskier credits. Finally, CA Lenders must also establish an additional reserve for the guaranteed portion of loans sold into the secondary market because secondary market loan sales create a direct risk to SBA. The total cash reserve required for CA Lenders needs to be at a level that does not provide a significant disincentive for CA Lenders to participate in the program. Therefore, SBA is revising the reserve requirement to permit CA Lenders to fund and maintain the LLRA with an amount equal to 5% of the outstanding amount of the unguaranteed portion of the CA Lender's CA loan portfolio. CA Lenders must deposit this required reserve amount in the LLRA no later than 45 days after the date of each CA loan disbursement. In order to ensure that the 5% reserve is adequate for each individual CA Lender, OCRM will review asset quality for each CA Lender as a part of the quarterly review process. This will include reviewing current delinquency and default rates, current and projected purchase rates, and risk rating for each lender. OCRM will also review compliance with the cash reserve requirements, including examination of bank statements to ensure that the reserve is adequately funded. OCRM reserves the right to increase this level in its discretion. The additional reserve requirement for loans sold on the secondary market is described in the next paragraph.

On February 8, 2012, SBA published a notice in the **Federal Register** that made changes to certain CA Pilot Program requirements, including among other things the requirements surrounding access to the secondary market for CA Lenders. (77 FR 6619). In that **Federal Register** notice, SBA stated that CA Lenders granted access to the secondary market must have additional reserves and must complete additional training in secondary market activities and requirements before initiating secondary market sales. The February 8, 2011 notice did not, however, state what the additional reserve requirement would be for CA Lenders with secondary market authority. With this Notice, SBA is establishing an additional reserve requirement of 3% of the outstanding amount of the guaranteed portion of each CA loan sold in the secondary market. This level of additional reserve is based upon the dollar rate of repairs and denials for all 7(a) loans purchased over the last two calendar years (2.75%). Because CA Lenders are generally inexperienced 7(a) lenders, the rate is set more conservatively. CA Lenders must deposit the required reserve amount

covering the guaranteed portion of the CA loan in the LLRA no later than 10 days after the CA loan has been sold in the secondary market. In addition, to address the concern that a CA Lender with an unacceptable purchase rate might use secondary market sales to significantly expand its CA loan portfolio, SBA is modifying its regulation at 13 CFR 120.660 for the duration of the pilot program, to allow the Director, Office of Credit Risk Management, discretion to suspend secondary market authority for any CA Lender based on the risk characteristics or performance of the CA Lender's portfolio.

The 5% loan loss reserve amount for the unguaranteed portion of CA loans and the 3% loan loss reserve amount for the guaranteed portion of CA loans sold in the secondary market may be kept in the same segregated bank account and must be carried as a restricted reserve on the CA Lender's balance sheet for use in meeting obligations the CA Lender has to cover losses from their CA lending activity including but not limited to defaults and guarantee repairs, denials, withdrawals or cancelations. This reserve may be used to repay SBA in the event of a repair or denial. If the CA Lender chooses to use the reserve to repay SBA, the CA Lender must ensure that the reserve is replenished to the required level within 45 days. All other requirements regarding the creation and maintenance of the LLRA stated in the February 18, 2011 notice and all subsequent notices remain unchanged. Failure to maintain the loan loss reserve account as required may result in removal from the CA Pilot Program, the imposition of additional controls or reserve amounts, and/or other action permitted by SBA regulation or otherwise by law. Based on the risk characteristics or performance of a CA Lender, OCRM in its discretion may require additional amounts to be included in the LLRA or may suspend secondary market privileges.

Refinancing of SBA Microloans

Currently, CA loans may not be used to refinance loans made by Microloan Intermediaries in SBA's Microloan Program. Because of the natural synergies that exist between the SBA Microloan Program and the CA Pilot Program, a number of CA Lenders have asked SBA to reconsider this prohibition. The CA Pilot Program was designed as a complement to the SBA Microloan Program, especially when small business borrowers' capital needs exceed the Microloan Program's $50,000 maximum loan limit. Allowing CA Lenders to refinance their SBA microloans or those of other Microloan Intermediaries into CA loans will not only free up microloan program resources to make more small dollar loans, but also will make both programs more attractive and thereby maximize lender participation and capital availability to underserved markets. Analysis indicates that this can be done without any significant additional risk to the 7(a) program. Loan performance data from the 7(a) loan program, (for loans less than $250,000) over the last 10 years show virtually identical cumulative default rates for loans that went to former micro borrowers versus similarly-sized 7(a) loans that went to other borrowers (a 0.2 percent difference). Therefore, SBA is revising its policy to permit CA loans to be used to refinance loans made by SBA Microlenders subject to the policies and procedures governing debt refinancing for 7(a) loans as set forth in SBA Loan Program Requirements and the CA Participant Guide. As such, the refinancing of same-institution debt cannot be processed on a delegated basis and must be submitted to the Standard 7(a) Loan Guaranty Processing Center. SBA will monitor the CA Pilot Program portfolio to ensure that such refinancings are in the best interest of the affected borrowers.

Financial Reports

SBA regulations at 13 CFR 120.464(b)(2) require an SBA Supervised Lender to prepare financial reports on an accrual basis. In the February 18, 2011 notice, however, SBA modified 13 CFR 120.463(a) to eliminate the requirement for CA Lenders to keep their books and records on an accrual basis. In order to be consistent with that modification, SBA is waiving 13 CFR 120.464(b)(2) for purposes of the CA Pilot Program.

CA Associate

The CA Pilot Program was originated under the basic premise that mission-based lenders are the optimal distribution tool to get capital to small businesses in underserved markets. While this premise remains true, SBA has recognized that there are many mission-based organizations that do not have the capacity to become CA Lenders but can nevertheless provide referral services to CA Lenders. Linking higher capacity CA Lenders with these other mission-based organizations should increase the flow of capital to small businesses in underserved markets. Current SBA regulations at 13 CFR part 103 and SBA's Standard Operating Procedure (SOP) 50 10 5(E) set forth the Agency's policy and procedures governing Referral Agents and apply with equal force and effect to organizations acting as agents for CA Lenders on CA loans. Mission-based organizations providing referral services to one or more CA Lenders may be referred to as ''Community Advantage Associates'' (''CA Associates'') for the purpose of the CA program and are subject to all of the same requirements as other agents. SBA may place additional reporting requirements on CA Lenders that utilize CA Associates.

Guarantee Purchase

Guarantee purchase requests for CA loans will be processed in SBA's Commercial Loan Servicing Centers (CLSCs) in Little Rock, AR and Fresno, CA. The CLSCs, which process similarly-sized loans, have a greater capacity to receive and process additional guarantee purchase requests than the National Guaranty Purchase Center, which processes the larger and more complex standard 7(a) guarantee purchase requests.

General Information

These changes are limited to the CA Pilot Program only. All other SBA guidelines and regulatory waivers related to the CA Pilot Program remain unchanged.

SBA has provided more detailed guidance in the form of a Participant Guide which has been updated and is available on SBA's Web site at *http://www.sba.gov.* SBA may provide additional guidance, through SBA notices, which may also be published on SBA's Web site at *http://www.sba.gov/category/lender-navigation/forms-notices-sops/notices.* Questions regarding the CA Pilot Program may be directed to the Lender Relations Specialist in the local SBA district office. The local SBA district office may be found at *http://www.sba.gov/about-offices-list/2.*

Authority: 15 U.S.C. 636(a)(25) and 13 CFR 120.3.

Dated: October 15, 2012.

Karen G. Mills,

Administrator.

[FR Doc. 2012–27334 Filed 11–8–12; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

Agency Information Collection Activities: Proposed Request and Comment Request

The Social Security Administration (SSA) publishes a list of information

collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions to OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB)

Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov.*

(SSA)

Social Security Administration, DCRDP, Attn: Reports Clearance Director, 107 Altmeyer Building, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.*

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than January 8, 2013. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Child Relationship Statement—20 CFR 404.355 & 404.731—0960–0116. To help determine a child's entitlement to Social Security benefits, SSA uses criteria under section 216(h)(3) of the Social Security Act (Act), deemed child provision. SSA may deem a child to an insured individual if: (1) The insured individual presents SSA with satisfactory evidence of parenthood and was living with or contributing to the child's support at certain specified times; or (2) the insured individual (a) acknowledged the child in writing; (b) was court decreed as the child's parent; or (c) was court ordered to support the child. To obtain this information, SSA uses Form SSA–2519, Child Relationship Statement. Respondents are people with knowledge of the relationship between certain individuals filing for Social Security benefits and their alleged biological children.

Type of Request: Revision of an OMB-approved information collection.

Modality of collection	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–2519	50,000	1	15	12,500

2. Pain Report-Child—20 CFR 404.1512 and 416.912—0960–0540. Before SSA can make a disability determination for a child, we require evidence from Supplemental Security Income (SSI) applicants or claimants to prove their disability. Form SSA–3371–BK provides disability interviewers, and SSI applicants or claimants in self-help situations, with a convenient way to record information claimants' pain or other symptoms. The State disability determination services adjudicators and administrative law judges then use the information from Form SSA–3371–BK to assess the effects of symptoms on function for purposes of determining disability under the Act. The respondents are applicants for, or claimants of, SSI payments.

Type of Request: Revision of an OMB-approved information collection.

Modality of collection	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–3371	250,000	1	15	62,500

3. Internet and Automated Telephone Request for Replacement Forms SSA–1099/SSA–1042S—20 CFR 401.45—0960–0583. Title II recipients use Forms SSA–1099 and SSA–1042S, Social Security Benefit Statement, to determine if their Social Security benefits are taxable and the amount they need to report to the Internal Revenue Service. In cases where the original forms are unavailable (e.g., lost, stolen, mutilated), an individual may use SSA's Internet request form or automated telephone application to request a replacement SSA–1099 and SSA–1042S. SSA uses the information from the Internet and automated telephone requests to verify the identity of the requestor and to provide replacement copies of the forms. The Internet and automated telephone options reduce requests to the National 800 Number Network (N8NN) and visits to local Social Security field offices. The respondents are title II recipients who wish to request a replacement SSA–1099 or SSA–1042S via the Internet and telephone.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Internet Requests	145,390	1	10	24,232
Automated Telephone Requests	190,413	1	2	6,347
N8NN	566,667	1	3	28,333
Calls to local field offices	783,333	1	3	39,167
Other (program service centers)	90,000	1	3	4,500

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Totals	1,775,803			102,579

4. Important Information About Your Appeal, Waiver Rights, and Repayment Options—20 CFR 404.502–521—0960–0779. When SSA accidentally overpays beneficiaries, the agency informs them of the following rights: (1) The right to reconsideration of the overpayment determination; (2) the right to request a waiver of recovery and the automatic scheduling of a personal conference if SSA cannot approve a request for waiver; and (3) the availability of a different rate of withholding when SSA proposes the full withholding rate. SSA uses Form SSA–3105, Important Information About Your Appeal, Waiver Rights, and Repayment Options, to explain these rights to overpaid individuals, and allow them to notify SSA of their decision(s) regarding these rights. The respondents are overpaid claimants requesting a waiver of recovery for the overpayment, reconsideration of the fact of the overpayment, or a lesser rate of withholding of the overpayment.

Type of Request: Extension of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–3105	80,000	1	15	20,000

II. SSA submitted the information collection below to OMB for clearance. Your comments regarding the information collection would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than December 10, 2012. Individuals can obtain copies of the OMB clearance packages by writing to *OR.Reports.Clearance@ssa.gov.*

Vocational Rehabilitation Provider Claim—20 CFR 404.2108(b), 404.2117(c)(1)&(2), 404.2101(a)&(b), 404.2121(a), 416.2208(b), 416.2217(c)(1)&(2), 416.2201(a)&(b), 416.2221(a), 34 CFR 361—0960–0310.

State vocational rehabilitation (VR) agencies submit Form SSA–199 to SSA to obtain reimbursement of costs incurred for providing VR services. SSA requires state VR agencies to submit reimbursement claims for the following categories:

(1) Claiming reimbursement for VR services provided; (2) certifying adherence to cost containment policies and procedures; and (3) preparing causality statements.

The respondents mail the paper copy of the SSA–199 to SSA for consideration and approval of the claim for reimbursement of cost incurred for SSA beneficiaries. For claims certifying adherence to cost containment policies and procedures, or for preparing causality statements, State VR agencies submit written requests as stipulated in SSA's regulations within the Code of Federal Regulations. In most cases, SSA requires adherence to cost containment policies and procedures as well as causality statements prior to determining whether to reimburse the State VR agencies. SSA uses the information on the SSA–199, along with the written documentation, to determine whether or not, and how much, to pay the State VR agencies under SSA's VR program. Respondents are State VR agencies who offer vocational and employment services to Social Security and SSI recipients.

Type of Request: Revision of an OMB-approved information collection.

Modality of collection	Number of respondents	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden (hours)
a. Claiming Reimbursement on SSA–199—20 CFR 404.2108(b) & 416.2208(b)	80	160	(12,800)	23	4,907
b. Certifying Adherence to Cost Containment Policy and Procedures—20 CFR 404.2117(c)(1)&(2), 416.2217(c)(1)&(2) & 34 CFR 361	80	1	(80)	60	80
c. Preparing Causality Statements—20 CFR 404.2121(a), 404.2101(a), 416.2201(a), & 416.2221(a)	80	2.5	(200)	100	333
Totals	80		(13,080)		5,320

Dated: November 5, 2012.

Faye Lipsky,

Reports Clearance Director, Social Security Administration.

[FR Doc. 2012–27358 Filed 11–8–12; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 8084]

Defense Trade Advisory Group; Notice of Open Meeting

SUMMARY: The Defense Trade Advisory Group (DTAG) will meet in open session from 1:00 p.m. until 5:00 p.m. on Wednesday, November 28, 2012, in the East Auditorium, U.S. Department of State, Harry S. Truman Building, Washington, DC. Entry and registration will begin at 12:00 p.m. Please use the building entrance located at 21st Street NW., Washington, DC, between C & D Streets. The membership of this advisory committee consists of private sector defense trade representatives, appointed by the Assistant Secretary of State for Political-Military Affairs, who advise the Department on policies, regulations, and technical issues affecting defense trade. The purpose of the meeting will be to discuss current defense trade issues and topics for further study. Specific agenda topics will be posted on the Directorate of Defense Trade Controls' Web site, at *www.pmddtc.state.gov* approximately 10 days prior to the meeting.

Members of the public may attend this open session and will be permitted to participate in the discussion in accordance with the Chair's instructions. Members of the public may, if they wish, submit a brief statement to the committee in writing.

As access to the Department of State facilities is controlled, persons wishing to attend the meeting must notify the DTAG Alternate Designated Federal Officer (DFO) by close of business Friday, November 23, 2012. If notified after this date, the Department's Bureau of Diplomatic Security may not be able to complete the necessary processing required to attend the plenary session. A person requesting reasonable accommodation should notify the Alternate DFO by the same date.

Anyone who wishes to attend this plenary session should provide: his/her name; company or organizational affiliation (if any); date of birth; and identifying data such as driver's license number, U.S. Government ID, or U.S. Military ID, to the DTAG Alternate DFO, Patricia Slygh, via email at *SlyghPC@state.gov.* A RSVP list will be provided to Diplomatic Security. One of the following forms of valid photo identification will be required for admission to the Department of State building: U.S. driver's license, passport, U.S. Government ID or other Government-issued photo ID.

Personal data is requested pursuant to Public Law 99–399 (Omnibus Diplomatic Security and Antiterrorism Act of 1986), as amended; Public Law 107–56 (USA PATRIOT Act); and Executive Order 13356. The purpose of the collection is to validate the identity of individuals who enter Department facilities. The data will be entered into the Visitor Access Control System (VACS–D) database. Please see the Security Records System of Records Notice (State-36) at *http://www.state.gov/documents/organization/103419.pdf* for additional information.

For additional information, contact Patricia Slygh, PM/DDTC, SA–1, 12th Floor, Directorate of Defense Trade Controls, Bureau of Political-Military Affairs, U.S. Department of State, Washington, DC 20522–0112; telephone (202) 663–2830; FAX (202) 261–8199; or email *SlyghPC@state.gov.*

Dated: November 6, 2012.

Robert S. Kovac,

Designated Federal Officer, Defense Trade Advisory Group, Department of State.

[FR Doc. 2012–27442 Filed 11–8–12; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2012–46]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of the FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number involved and must be received on or before November 29, 2012.

ADDRESSES: You may send comments identified by Docket Number FAA–2012–0405 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mark Forseth, ANM–113, (425) 227–2796, Federal Aviation Administration, 1601 Lind Avenue SW., Renton, WA 98057–3356, or Andrea Copeland (202) 267–8081, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 5, 2012.

Ida M. Klepper,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2012–0405.

Petitioner: The Boeing Company.

Section of 14 CFR Affected: § 25.562(b)(2) at Amendment 25–64.

Description of Relief Sought: Relief from the misalignment and roll test

requirement for flight-deck seats on Boeing Model 767–2C airplanes.

[FR Doc. 2012–27434 Filed 11–8–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[Docket Number FTA–2012–0054]

Fiscal Year 2013 Public Transportation on Indian Reservations Program

AGENCY: Federal Transit Administration, DOT.

ACTION: Request for comment; Announcement of public meetings.

SUMMARY: This notice announces changes in the Public Transportation on Indian Reservations program (Tribal Transit Program) in accordance with the Moving Ahead for Progress in the 21st Century Act (MAP–21) (Pub. L. 112–141), which authorizes the program for Federal fiscal years (FY) 2013 and 2014. MAP–21 was signed into law by President Barack Obama on July 6, 2012 and became effective on October 1, 2012. This notice responds to the new legislation under the Tribal Transit Program by: (1) Introducing FTA's consultation process and schedule for implementing changes due to MAP–21; (2) describing and seeking comment on the methodology for the formula allocation and the assumptions made regarding who is eligible for the formula program; (3) seeking comment on the terms and conditions for the formula and discretionary components of the program; and (4) seeking comments on how the discretionary program resources should be allocated.

DATES: Comments must be submitted by January 8, 2013. Late-filed comments will be considered to the extent practicable.

Outreach and Public Meeting: FTA will provide outreach in conjunction with the National Tribal Transportation Conference, sponsored by the Northwest Tribal Transit Assistance Program (TTAP). The meeting will be held on November 14–15, 2012 in Phoenix, Arizona at the Pointe Hilton Tapatio Cliffs Resort, 11111 North 7th Street. The first session is scheduled from 1:30 p.m. to 5:00 p.m. on November 14th and the second session on November 15th from 8:00 a.m. to 12:00 p.m. All participants must pre-register for the meeting and may register online at *http://ttap.colostate.edu.* Additionally, FTA will hold a public meeting in Washington, DC on December 10, 2012, at the U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. Please send an email to Élan Flippin at *Elan.Flippin@dot.gov* with your contact information if you plan to attend the December meeting in Washington, DC FTA encourages public participation at these meetings. However, comments must be submitted in writing directly to the official docket per the instructions found in the **ADDRESSES** section of this notice by January 7, 2013.

Details and updates regarding these meetings will be posted on the FTA Web site *www.fta.dot.gov,* Tribal Technical Assistance (TTAP) Program (*www.ltap.org*), and National RTAP Program *www.Nationalrta.org.*

FOR FURTHER INFORMATION CONTACT: Lorna Wilson, Federal Transit Administration, 1200 New Jersey Ave. SE., E46–305, Washington, DC 20590, phone: (202) 366–0893, fax: (202) 366–3809, or email, *Lorna.Wilson@dot.gov* or Élan Flippin at *Elan.Flippin@dot.gov.*

ADDRESSES: Comments should be submitted by one of the following methods, identifying your submission by docket number FTA–2012–0054.

(1) *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for submitting comments.

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

(3) *Hand Delivery or Courier:* Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M–30 West Building Ground Floor, Room W12–140, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9 a.m. and 5 p.m. Eastern time, Monday through Friday, except Federal holidays.

(4) *Fax:* 202–493–2251.

You must include the agency name (Federal Transit Administration) and docket number (FTA–2012–0054) for this notice at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA received your comments, include a self-addressed stamped postcard. Note that all comments received will be posted without change to *www.regulations.gov* including any personal information provided and will be available to internet users. You may review DOT's complete Privacy Act Statement published in the **Federal Register** on April 11, 2000 (65 FR 19477).

For access to the docket to read background documents and comments received, go to *www.regulations.gov* at any time or to the U.S. Department of Transportation, 1200 New Jersey Ave. SE., Docket Operations, M–30, West Building Ground Floor, Room W12–140, Washington, DC 20590 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Overview
II. Questions on Proposed Tribal Transit Formula Program Allocations
III. Questions on Proposed Tribal Transit Discretionary Program
IV. Questions on Proposed Cost Sharing, Matching, and Indirect Costs
V. Proposed Terms and Conditions of the Tribal Transit Program

I. Overview

Section 3013 of Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), (Pub. L. 109–59 (August 10, 2005)) established the Public Transportation on Indian Reservations Program (Tribal Transit Program). The program authorized direct grants ''under such terms and conditions as may be established by the Secretary'' to Indian tribes for any purpose eligible under FTA's Grants for Rural Areas Formula Program, 49 U.S.C. 5311 (Section 5311 program). The Tribal Transit Program was implemented by FTA in consultation with Indian tribes consistent with the principles and policies set forth in Presidential Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' and U.S. Department of Transportation Order 5301.1, ''Department of Transportation Programs, Policies, and Procedures affecting American Indians, Alaska Natives and tribes for programs affecting Indian tribal governments.'' Under SAFETEA–LU, the Tribal Transit Program was a discretionary program, and funded for a total of $42 million over the life of SAFETEA–LU and its extensions, with approximately $15 million available in each of the last four years.

This notice describes changes to the Tribal Transit Program as a result of the Moving Ahead for Progress in the 21st Century Act (MAP–21). MAP–21 modifies the Tribal Transit Program and provides $25 million for formula allocation and $5 million for discretionary allocation in each of fiscal years 2013 and 2014. Through this notice, FTA seeks comment on the data assumptions and methods FTA will use to allocate these formula funds. FTA will continue to allocate the $5 million

in discretionary funding competitively. This notice also seeks comment on how these funds will be competed. For both the formula and discretionary program, FTA seeks comments on the terms and conditions.

II. Questions on Proposed Tribal Transit Formula Program Allocations

The Tribal Transit Formula Program distributes $25 million to eligible Indian tribes providing public transportation on tribal lands. Since FY 2006, the National Transit Database (NTD) reporting requirement has applied to the Tribal Transit Program. FTA proposes to limit eligible recipients to those registered in the NTD. Tribes that operate public transportation services, but which do not yet participate in the Tribal Transit Program, may file a report with the NTD on a voluntary basis for inclusion in future apportionments (FY 2014 and beyond.) Apportionments will be based on a statutory formula which includes three tiers. Tiers 1 and 2 are based on historical data reported to the NTD by Indian tribes who received Section 5311 funding in prior years (including discretionary Tribal Transit Program funds); Tier 3 is based on 2010 U.S. Census data.

The statutory tiers for the formula are:

Tier 1—50 percent based on vehicle revenue miles as reported to the NTD.

Tier 2—25 percent apportioned equally amongst Indian tribes providing at least 200,000 vehicle revenue miles as reported to the NTD Secretary.

Tier 3—25 percent based on Indian tribes providing public transportation on reservations in which more than 1,000 low income individuals reside, with no tribe receiving more than $300,000 for this tier.

In establishing the apportionment methodology, FTA is proposing a number of key assumptions shown below. FTA seeks comment on the following questions:

a. Should FTA include vehicle revenue miles from Indian tribes in both the Tribal Transit Program formula apportionment and the Rural Area Formula Program apportionment? FTA proposes to allow vehicle revenue miles from Indian tribes to count towards both formula apportionments. Normally, FTA does not allow a single vehicle revenue mile to count twice towards different formulas (e.g., service between a rural area and an urbanized area (UZA) must be counted the Rural Area Formula Program apportionment or the Urbanized Area Formula Program apportionment, but not both). The Tribal Transit Program formula, however, refers to ''Indian tribe[s] providing public transportation,'' not where the service is being operated. Therefore, tribes may report their total vehicle revenue miles, regardless of funding source, to the NTD, and States may include tribal vehicle revenue miles in their reporting to the NTD.

b. When another local government entity pays an Indian tribe to operate service in an off-reservation jurisdiction, should 100% of that service operated by the Indian tribe count towards the Tribal Transit Program formula? FTA proposes to count 100% of service operated by Indian tribes towards the Tribal Transit Program apportionment. This interpretation is consistent with ''each Indian tribe providing public transportation service.''

c. When an Indian tribe pays another local government entity to extend service to the Reservation, should a pro-rated share of the local government's vehicle revenue miles be counted towards the Tribal Transit formula? FTA proposes to count a pro-rated share of the operator's vehicle revenue miles towards the Tribal Transit Program apportionment, based on the portion of the total operating expenses provided by the Indian tribe. This share then would count towards both the Rural and Tribal Transit program formulas.

d. Should FTA consider tribes that actually are providing public transportation on Indian reservations when no revenue miles are reported to the NTD for funding under Tier 3? FTA proposes that tribes that previously received capital assistance through the Tribal Transit Program should be included in Tier 3 of the Tribal Transit Program formula, which is based on low-income population on Tribal lands.

e. Should FTA consider allowing Tribal Transit Program grantees who were otherwise exempt from reporting based on grant dollar amount (under $50,000) be given an opportunity to report to the NTD or to FTA for inclusion in the FY 2013 apportionment?

f. For Indian tribes that have multiple operators, should FTA consolidate the service data for all operators into a single apportionment?

g. For Indian tribes that share reservation lands, such as in Oklahoma, how should FTA conduct the apportionment of funds?

h. In some instances tribal operators may serve multiple reservations. Should FTA combine poverty data for all reservations served into a single apportionment?

III. Questions on Proposed Tribal Transit Discretionary Program

$5 million in discretionary funds are authorized for grants to federally-recognized Indian tribes for any purpose under the Section 5311 program. The funds set aside for Indian tribes in the Tribal Transit Program are not meant to replace or reduce funds that Indian tribes receive from State through FTA's Section 5311 program. Tribal Transit funds are meant to complement Section 5311 funds that applicants may be receiving. In light of the $25 million formula program, FTA seeks comments on the eligibility of applicants, eligible projects, and cost sharing for the discretionary program. Program requirements of the Tribal Transit Program under SAFETEA–LU can be accessed at *http://www.fta.dot.gov/documents/06–6911.pdf.*

FTA seeks comments on the following questions:

a. Should eligible applicants under the discretionary program be restricted based on the availability of formula funds?

b. If the discretionary program should be restricted, should applicants and projects be limited based on the amount of formula allocation received?

c. Should a portion of discretionary program funds be set aside for

1. Start-up projects, or
2. Planning projects, or
3. Expansion of services?

d. Should FTA establish minimum and maximum grant awards to ensure that grant funding is large enough to aid Indian tribes?

e. Should operating assistance continue to be eligible under the discretionary program? If so, what type of operating expenses?

f. Should FTA prioritize projects for funding as a part of the evaluation criteria? If so, what factors should be used to prioritize projects (continuation services, start-ups, matching funds, etc.)?

IV. Questions on Proposed Cost Sharing, Matching, and Indirect Costs

FTA recognizes the particular challenges tribes may have providing a local match, but to ensure that participants in this program have a vested interest we propose requiring some local match. Matching funds may be provided from Federal agencies other than the Department of Transportation with the exception of Federal Lands Highways program funds, administered by the Federal Highway Administration and Indian Reservation Roads (IRR) Program.

FTA seeks comments on the following questions:

a. Should FTA require an 80/20 Federal/local match for tribes for both capital and operating assistance under

both the formula and discretionary Tribal Transit Programs?

b. Would an 80/20 match present a financial burden on tribes? If so, is there a proposed match amount that would be less burdensome?

c. Under SAFETEA–LU, FTA limited the indirect cost to not more than 10 percent of each Tribal Transit grant award. Should FTA retain the condition that indirect costs not exceed 10 percent of each Tribal Transit grant award under MAP–21?

V. Proposed Terms and Conditions of the Tribal Transit Program

Section 5311(c) of Title 49 U.S.C., as amended by MAP–21, provides that available funds shall be apportioned for grants to Indian tribes, ''under such terms and conditions as may be established by the Secretary.'' The term ''Secretary'' in this provision refers to the Secretary of Transportation. The Secretary of Transportation possesses the authority to limit the applicability of certain substantive and procedural requirements that are set forth in Title 49 (Transportation) of the United States Code. This includes the Federal transit assistance provisions in Chapter 53 (Public Transportation) of Title 49, which are administered by FTA. The Secretary of Transportation, however, does not possess the authority to limit the applicability of government-wide grant requirements (commonly referred to as cross-cutting requirements) that apply to all Federal grants. Recipients of Federal assistance are subject to many requirements regardless of the source of funds, for example, restrictions on lobbying. Recipients under the Tribal Transit Program are subject to these government-wide grant requirements, which are not all named in this document. In addition, some Federal requirements are applicable regardless of whether Federal assistance is provided. For example, the requirement for drivers of vehicles over a certain size is to hold a Commercial Driver's License.

To the extent permitted by law and in recognition of the unique status and autonomy of Indian tribes, FTA has made every effort in establishing the terms and conditions to balance the objectives of this program, which will directly benefit transit projects for Indian tribes, with other national objectives (*e.g.,* safety) that are important not only to Indian tribes but also to the general public. Other applicable program requirements were established for the Tribal Transit Program under SAFETEA–LU.

Therefore, FTA seeks guidance on the following terms and conditions, which are being considered for both the formula and discretionary programs.

a. Common Grant Rule (49 CFR Part 18), ''Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.'' This is a government-wide regulation that applies to all Federal assistance programs.

b. Civil Rights Act of 1964. Unless Indian tribes are specifically exempted from civil rights statutes, compliance with civil rights statutes will be required, including compliance with equity in service. Title VI of the Civil Rights Act prohibits discrimination on the basis of race, color, and national origin in programs and activities receiving Federal financial assistance. Title VII of the Civil Rights Act prohibits discrimination in employment in any business on the basis of race, color, religion, sex, or national origin. Indian tribes are specifically excluded from the definition of an ''employer'' under the Act. Thus, to the extent that Tribal Employment Rights Offices (TERO) are consistent with Federal statutes that authorize a general preference for Indians in employment or contracting for federally funded work on or around Indian reservations, FTA of course will comply with applicable law. However, although Indian tribes will not be subject to FTA's program-specific requirements under Title VI and Title VII of the Civil Rights Act, Indian tribes under the Tribal Transit Program nonetheless still will be subject to the provisions of Title VI and Title VII of the Civil Rights Act, unless they are specifically exempt from the Act.

c. Section 504 of the Rehabilitation Act of 1973 and Americans with Disabilities Act (ADA) requirements in 49 CFR parts 27, 37, and 38 are government-wide requirements that apply to all Federal programs.

d. Drug and Alcohol Testing requirements (49 CFR Part 655). Should FTA continue to apply this requirement because it addresses a national safety issue for operators of public transportation?

e. National Environmental Policy Act. This is a government-wide requirement that applies to all Federal programs.

f. Charter Service and School Bus transportation requirements in 49 CFR parts 604 and 605. The definition of ''public transportation'' in 49 U.S.C. 5302 specifically excludes school bus and charter service.

g. NTD Reporting requirement. 49 U.S.C. 5335 requires NTD reporting for all direct recipients of section 5311 funds. The Tribal Transit Program is a section 5311 program that will provide funds directly to Indian tribes and this reporting requirement therefore will apply.

h. Bus Testing (49 CFR part 665) requirement. To ensure that vehicles acquired under this program will meet adequate safety and operational standards, should FTA now apply this requirement?

i. Labor Protection requirement. The U.S. Department of Labor (DOL) will, pursuant to 49 U.S.C. 5333(b), apply the section 5311 special warranty. Congress amended section 5311(i) to apply section 5333(b) ''if the Secretary of Labor utilizes a special warranty that provides a fair and equitable arrangement to protect the interests of employees.'' Congress did not exempt the Tribal Transit Program from this requirement. FTA therefore intends to continue to apply the special warranty to the Tribal Transit Program.

j. Buy America requirements. FTA did not apply the Buy America requirements to the Tribal Transit program prior to FY 2012. However, FTA proposes including Buy America requirements on the formula and discretionary programs under MAP–21.

k. MAP–21, Section 5329 requires all grantees to develop comprehensive agency safety management plans that at a minimum include methods for identifying and evaluating safety risks, strategies to minimize exposure to hazards and unsafe conditions, and performance targets for safety performance criteria and state of good repairs standards established in a forthcoming National Public Transportation Safety plan. A rulemaking is forthcoming to further explain the requirements for the development and certification of agency safety plans and following that rulemaking, FTA will be finalizing requirements through a rulemaking at a later date. In the interim, we are seeking comment on whether to apply these provisions to the Tribal Transit Program.

l. Transit Asset Management Provisions. MAP–21 requires each recipient and subrecipient of FTA grants to establish a ''transit asset management'' (TAM) plan for its transit system. This requirement, however, would not be a condition for receiving FTA grants until FTA issues its rule-making. Further, depending on the outcome of that rule-making, FTA would propose that so long as tribes have a system for maintaining their capital asset inventory and a basis for prioritizing and replacing capital assets, it would not require the tribe to prepare a TAM plan. FTA seeks comment on whether to apply this requirement to the Tribal Transit Program.

m. Pre-award and post-delivery audits (49 CFR part 633). FTA seeks comment on whether to apply this requirement.

n. Should U.S. DOT's DBE regulation, 49 CFR part 26, continue not to apply to the Tribal Transit Program?

A comprehensive list and description of all of the statutory and regulatory terms and conditions that FTA applied to the SAFETEA–LU Tribal Transit Program are set forth in FTA's Master Agreement for the Tribal Transit Program available on FTA's Web site at: *www.fta.dot.gov/.* Annual certifications and assurances are also available on FTA's Web site.

Issued in Washington, DC, this 6th day of November, 2012.

Peter M. Rogoff,

Administrator.

[FR Doc. 2012–27458 Filed 11–8–12; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35690]

Northern Plains Railroad, Inc.—Temporary Trackage Rights Exemption—Soo Line Railroad Company

Soo Line Railroad Company (Soo Line), pursuant to a written agreement dated October 4, 2012, has agreed to grant temporary overhead trackage rights to Northern Plains Railroad, Inc. (NPR) between milepost 128.9 at Mahnomen, Minn., and milepost 153.6 at Erskine, Minn., a distance of approximately 24.7 miles.[1]

The transaction may be consummated on or after November 25, 2012, and the temporary trackage rights are scheduled to expire on or about December 24, 2012. The purpose of the temporary trackage rights is to permit NPR to operate bridge train service during certain programmed track, roadbed and structural maintenance on trackage it leases from Soo Line.

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk and Western Railway—Trackage Rights—Burlington Northern, Inc.,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease and Operate—California Western Railroad,* 360 I.C.C. 653 (1980), and any employees affected by the discontinuance of those trackage rights will be protected by the conditions set out in *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

This notice is filed under 49 CFR 1180.2(d)(8). If it contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than November 16, 2012 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35690, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Roy J. Christensen, Johnson, Killen & Seiler, P.A., 230 W. Superior Street, Suite 800, Duluth, MN 55802.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

Decided: November 5, 2012.

By the Board, Richard Armstrong, Acting Director, Office of Proceedings.

Derrick A. Gardner,

Clearance Clerk.

[FR Doc. 2012–27535 Filed 11–8–12; 8:45 am]

BILLING CODE 4915–01–P

[1] In a letter filed on November 1, 2012, NPR provided the specific mileposts.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35687]

Soo Line Railroad Company—Temporary Trackage Rights Exemption—BNSF Railway Company

BNSF Railway Company (BNSF), pursuant to a written trackage rights agreement (Agreement), has agreed to grant temporary overhead trackage rights to Soo Line Railroad Company d/b/a Canadian Pacific (Soo Line) over BNSF's line of railroad between Ardoch, N.D., and Erskine, Minn., a distance of approximately 84.6 miles.

The transaction may be consummated on or after November 24, 2012, the effective date of the exemption (30 days after the verified notice of exemption was filed). The temporary trackage rights are scheduled to expire on or about December 24, 2012. The purpose of the temporary trackage rights is to permit Soo Line to bridge its train service while its main lines are out of service due to certain programmed track, roadbed, and structural maintenance.

As a condition to this exemption, any employees affected by the acquisition of the temporary trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease & Operate—California Western Railroad,* 360 I.C.C. 653 (1980), and any employees affected by the discontinuance of those trackage rights will be protected by the conditions set out in *Oregon Short Line Railroad & The Union Pacific Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

This notice is filed under 49 CFR 1180.2(d)(8). If it contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 USC 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction. Petitions for stay must be filed no later than November 16, 2012 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 35687, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on W. Karl Hansen, Leonard, Street and Deinard, 150 South Fifth Street, Suite 2300, Minneapolis, MN 55402.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

Decided: November 1, 2012.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2012–27412 Filed 11–8–12; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

Proposed Information Collections; Comment Request

AGENCY: Alcohol and Tobacco Tax and Trade Bureau; Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of our continuing effort to reduce paperwork and respondent burden, and as required by the Paperwork Reduction Act of 1995, we invite comments on the proposed or

continuing information collections listed below in this notice.

DATES: We must receive your written comments on or before January 8, 2013.

ADDRESSES: You may send comments to Mary A. Wood, Alcohol and Tobacco Tax and Trade Bureau, at any of these addresses:

- *U.S. mail:* 1310 G Street NW., Box 12, Washington, DC 20005;
- *Hand delivery/courier in lieu of mail:* 1310 G Street NW., Suite 200E, Washington, DC 20005;
- 202–453–2686 (facsimile); or
- *formcomments@ttb.gov* (email).

Please send separate comments for each specific information collection listed below. You must reference the information collection's title, form or recordkeeping requirement number, and OMB number (if any) in your comment. If you submit your comment via facsimile, please send no more than five 8.5 × 11 inch pages in order to ensure our equipment is not overburdened.

FOR FURTHER INFORMATION CONTACT: To obtain additional information, copies of the information collection and its instructions, or copies of any comments received, contact Mary A. Wood, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; or telephone 202–453–2265.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Department of the Treasury and its Alcohol and Tobacco Tax and Trade Bureau (TTB), as part of their continuing effort to reduce paperwork and respondent burden, invite the general public and other Federal agencies to comment on the proposed or continuing information collections listed below in this notice, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Comments submitted in response to this notice will be included or summarized in our request for Office of Management and Budget (OMB) approval of the relevant information collection. All comments are part of the public record and subject to disclosure. Please do not include any confidential or inappropriate material in your comments.

We invite comments on: (a) Whether this information collection is necessary for the proper performance of the agency's functions, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the information collection's burden; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the information collection's burden 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 the requested information.

Information Collections Open for Comment

Currently, we are seeking comments on the following TTB forms and recordkeeping requirements:

Title: Brewer's Report of Operations and Brewpub Report of Operations.

OMB Control Number: 1513–0007.

TTB Form Numbers: 5130.9 and 5130.26.

Abstract: The Internal Revenue Code (IRC) requires brewers to file periodic reports of their brewing and associated operations. TTB uses these reports to determine whether the brewer's operations are in compliance with the requirements of Federal law and regulations. We also use this information to assist us in determining whether the brewer pays the proper Federal excise taxes in a timely and accurate manner.

Current Actions: We are submitting this information collection as a revision. TTB is revising TTB F 5130.9, Brewers Report of Operations and TTB F 5130.26, Brewpub Report of Operations. We are revising these forms primarily to ease the regulatory burden on brewers, particularly small brewers, without compromising our mandates under the Internal Revenue Code of 1986. On both forms, TTB proposes to remove two parts, ''Part 2–Report Period Tax Payments'' and ''Part 3–Summary of Materials Used and Wort Produced'' and to add directions for filing electronically through the ''Pay.gov'' system to the Instructions section.

TTB also proposes to make additional changes to TTB F 5130.26 so that it is applicable to a majority of small brewers. For example, this quarterly form, which is considerably less detailed than TTB F 5130.9, is currently restricted to brewpubs who remove 5,000 barrels or less per calendar year and who do not bottle. The proposed changes to TTB F 5130.26 provide that all brewers producing less than 10,000 barrels per calendar year may use this form to report quarterly, and, as a result, we propose to change the name of this form from ''Brewpub Report of Operations'' to ''Small Brewers Report.''

We estimate these changes will reduce the time it takes brewers to complete either form by 15 minutes. We also believe that the changes to TTB F 5130.26 will significantly increase its use, which would reduce a qualifying brewer's reporting requirements from 12 times a year to just 4. We estimate these changes will affect the estimated number of respondents and estimated total annual burden.

For more information on these and additional minor proposed changes to these two forms, see the TTB announcement posted on the beer page of the TTB Web site at *http://www.ttb.gov/beer/index.shtml.*

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 2,026.

Estimated Total Annual Burden Hours: 9,114.

Title: Application to Establish and Operate Wine Premises and Wine Bond.

OMB Control Number: 1513–0009.

TTB Form Numbers: 5120.25 and 5120.36, respectively.

Abstract: TTB F 5120.25, Application to Establish and Operate Wine Premises, is the form used to establish the qualifications of a person applying to establish and operate a wine premises. The applicant certifies their intention to produce and/or store a specified amount of wine and to take certain precautions to protect it from unauthorized use. TTB F 5120.36, Wine Bond, is the form used by the proprietor and a surety company as a contract to ensure the payment of the Federal wine excise tax.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 1,720.

Estimated Total Annual Burden Hours: 2,050.

Title: Formula and/or Process for Article Made With Specially Denatured Spirits.

OMB Control Number: 1513–0011.

TTB Form Number: 5150.19.

Abstract: TTB F 5150.19 is completed by persons who use specially denatured spirits in the manufacture of certain articles. TTB uses the information provided on the form to ensure the manufacturing formulas and processes conform to statutory requirements (see 26 U.S.C. 5273).

Current Actions: We are submitting this information collection as a revision. The information collection and

estimated number of respondents remain unchanged. However, the burden hours decreased slightly because this form is included in our Formulas Online (FONL) system which allows it to be submitted electronically. It takes less time to complete the form using FONL.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 2,683.

Estimated Total Annual Burden Hours: 2,415.

Title: User's Report of Denatured Spirits.

OMB Number: 1513–0012.

TTB Form Number: 5150.18.

Abstract: Submitted annually by holders of permits to use specially denatured spirits, TTB F 5150.18 summarizes the permittee's manufacturing activities during the preceding year. The information is used by TTB to pinpoint unusual activities that could indicate a threat to the Federal revenue or possible dangers to the public.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 3,778.

Estimated Total Annual Burden Hours: 1,133.

Title: Power of Attorney.

OMB Number: 1513–0014.

TTB Form Number: 5000.8.

Abstract: TTB F 5000.8 delegates the authority to a specific individual to sign documents on behalf of an applicant or a principal. The Internal Revenue Code at 26 U.S.C. 6061 authorizes our regulations requiring that an individual signing returns, statements, or other required documents filed by industry members under the provisions of the Code or the Federal Alcohol Administration Act have that signature authority on file with TTB.

Current Actions: We are submitting this information collection as a revision. The burden hours decrease slightly because this form is included in our Permits Online system which allows it to be submitted electronically. It takes less time to complete this form electronically. Also, the supporting statement and form reflects changes to regulatory section numbers as recodified in the final rule for the revision of 27 CFR Part 19, Distilled Spirits Plants.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 5,000.

Estimated Total Annual Burden Hours: 3,250.

Title: Report—Proprietor of Export Warehouse.

OMB Control Number: 1513–0024.

TTB Form Number: 5220.4.

Abstract: Proprietors account for taxable articles on this report. TTB uses this information to ensure that proprietors have complied with Federal laws and regulations and to protect against diversion.

Current Actions: We are submitting this information collection as a revision. We are updating this collection as a result of changes made to the form as a result of the regulations implementing the Children's Health Insurance Program Reauthorization Act of 2009 (see T.D. TTB–104, published in the **Federal Register** of June 21, 2012, at 77 FR 37287). The estimated number of respondents and estimated total annual burden hours remain unchanged.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 80.

Estimated Total Annual Burden Hours: 1,920.

Title: Certificate of Tax Determination—Wine.

OMB Control Number: 1513–0029.

TTB Recordkeeping Number: 5120.20.

Abstract: Wine that has been manufactured, produced, bottled, or packaged in bulk containers in the U.S. and then exported is eligible for a drawback (refund) of the excise tax paid on that wine. TTB F 5120.20 supports the exporter's claim for drawback, as the producing winery verifies that the wine being exported was in fact exported.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 1,000.

Estimated Total Annual Burden Hours: 500.

Title: Application to Receive Spirits and/or Denatured Spirits by Transfer in Bond.

OMB Control Number: 1513–0038.

TTB Form Number: 5100.16.

Abstract: TTB F 5100.16 is completed by distilled spirits plant proprietors who wish to receive spirits in bond from other distilled spirits plants. TTB uses the information to determine if the applicant has sufficient bond coverage for the additional tax liability assumed when spirits are received through a transfer in bond.

Current Actions: We are submitting this information collection as a revision. The burden hours decrease slightly because this form is included in our Permits Online system which allows it to be submitted electronically. It takes less time to complete this form electronically. Also, the supporting statement and form reflects changes to regulatory section numbers as recodified in the final rule for the revision of 27 CFR Part 19, Distilled Spirits Plants (see T.D. TTB–92, published in the **Federal Register** on February 16, 2011, at 76 FR 9080).

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 1,508.

Estimated Total Annual Burden Hours: 302.

Title: Distilled Spirits Plants Warehousing Record, and Monthly Report of Storage Operations.

OMB Control Number: 1513–0039.

TTB Form Number: 5110.11.

TTB Recordkeeping Number: 5110/02.

Abstract: TTB uses this information collection to account for a proprietor's tax liability and adequacy of bond coverage, and to protect the revenue. The information also provides data to analyze trends, audit operations, monitor industry activities and compliance in order to provide for efficient allocation of field personnel, and provide for economic analysis.

Current Actions: We are submitting this information collection as a revision. The supporting statement and form reflects changes to regulatory section numbers as recodified in the final rule for the revision of 27 CFR Part 19, Distilled Spirits Plants. The estimated number of respondents and estimated total annual burden hours remain unchanged.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for profit.

Estimated Number of Respondents: 230.

Estimated Total Annual Burden Hours: 5,520.

Title: Distilled Spirits Plants—Excise Taxes.

OMB Control Number: 1513–0045.

TTB Recordkeeping Number: 5110/06.

Abstract: The collection of information is necessary to account for and verify taxable removals of distilled spirits. The data is used to audit tax payments.

Current Actions: We are submitting this information collection as a revision. The supporting statement reflects changes to regulatory section numbers as recodified in the final rule for the revision of 27 CFR Part 19, Distilled Spirits Plants (see T.D. TTB–92, published in the **Federal Register** on February 16, 2011, at 76 FR 9080). The estimated number of respondents and estimated total annual burden hours remain unchanged.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 133.

Estimated Total Annual Burden Hours: 3,458.

Title: Formula for Distilled Spirits under the Federal Alcohol Administration Act.

OMB Control Number: 1513–0046.

TTB Form Number: 5110.38.

Abstract: TTB F 5110.38 is used to determine the classification of distilled spirits for labeling and for consumer protection purposes. The form describes the person filing, type of product to be made, and restrictions to the label and/or manufacturing process. The form is used by TTB to ensure that a product is made and labeled properly, and to audit distilled spirits operations. Records are kept indefinitely for this information collection.

Current Actions: We are submitting this information collection as a revision. The supporting statement and form reflect changes to regulatory section numbers as recodified in the final rule for the revision of 27 CFR Part 19, Distilled Spirits Plants (see T.D. TTB–92, published in the **Federal Register** on February 16, 2011, at 76 FR 9080). The estimated number of respondents and estimated total annual burden hours remain unchanged.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 200.

Estimated Total Annual Burden Hours: 4,000.

Title: Distilled Spirits Plant (DSP) Denaturation Records, and Monthly Report of Processing (Denaturing) Operations.

OMB Control Number: 1513–0049.

TTB Form Number: 5110.43.

TTB Recordkeeping Number: 5110/04.

Abstract: This information collection is necessary to account for and verify the denaturation of distilled spirits. It is used to audit plant operations, monitor the industry for the efficient allocation of personnel resources, and compile statistics for government economic planning.

Current Actions: We are submitting this information collection as a revision. The supporting statement and form reflect changes to regulatory section numbers as recodified in the final rule for the revision of 27 CFR Part 19, Distilled Spirits Plants. The estimated number of respondents and estimated total annual burden hours remain unchanged.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 98.

Estimated Total Annual Burden Hours: 1,176.

Title: Distilled Spirits Plants—Transaction and Supporting Records.

OMB Control Number: 1513–0056.

TTB Recordkeeping Number: 5110/5.

Abstract: Transaction records provide the source data for accounts of distilled spirits in all DSP operations. They are used by TTB to verify those accounts and consequent tax liabilities.

Current Actions: We are submitting this information collection as a revision. The supporting statement reflects changes to regulatory section numbers as recodified in the final rule for the revision of 27 CFR Part 19, Distilled Spirits Plants. The estimated number of respondents and estimated total annual burden hours remain unchanged.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 278.

Estimated Total Annual Burden Hours: 6,060.

Title: Letterhead Applications and Notices Relating to Tax-Free Alcohol.

OMB Number: 1513–0060.

TTB Recordkeeping Number: 5150/4.

Abstract: Tax-free alcohol is used for nonbeverage purposes by educational organizations, hospitals, laboratories, and the like in scientific research and for medicinal purposes. Permits/Applications control the authorized uses and flow of tax-free alcohol. TTB Letterhead Applications and Notices are designed to protect tax revenue and public safety.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Not-for-profit institutions; Federal Government; State, local, or tribal government.

Estimated Number of Respondents: 4,444.

Estimated Total Annual Burden Hours: 2,222.

Title: Stills—Retail Liquor Dealers Records of Receipts of Alcoholic Beverages and Commercial Invoices.

OMB Number: 1513–0066.

TTB Recordkeeping Number: 5170/3.

Abstract: The primary objective of this recordkeeping requirement is revenue protection, by making accountability data available for audit purposes. Another objective is consumer protection, by affording the subject record traceability of alcoholic beverages to the retail liquor dealer level of distribution in the event of defective products. The record retention requirement for this information collection is three years.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for profit; State, local, or tribal government.

Estimated Number of Respondents: 455,000.

Estimated Total Annual Burden Hours: 455,000.

Title: Wholesale Dealers Applications, Letterheads, and Notices Relating to Operations. (Variations in Format or Preparation of Records).

OMB Control Number: 1513–0067.

TTB Recordkeeping Number: 5170/6.

Abstract: This recordkeeping requirement pertains only to those wholesale liquor and beer dealers submitting applications for a variance from the regulations dealing with preparation, format, type, or place of retention of records of receipt or disposition of alcoholic beverages.

Current Actions: We are submitting this information collection for extension purposes only. The information

collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 1,029.

Estimated Total Annual Burden Hours: 515.

Title: Equipment and Structures.

OMB Control Number: 1513–0080.

TTB Recordkeeping Number: 5110/12.

Abstract: Marks, signs, and calibrations are necessary on equipment and structures at a distilled spirits plant in order to identify the plant's major equipment and to accurately determine the plant's contents.

Current Actions: We are submitting this information collection as a revision. The supporting statement reflects changes to regulatory section numbers as recodified in the final rule for the revision of 27 CFR Part 19, Distilled Spirits Plants. The estimated number of respondents and estimated total annual burden hours remain unchanged.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 281.

Estimated Total Annual Burden Hours: One (1).

Title: Alternative Methods or Procedures and Emergency Variations from Requirements for Exports of Liquors.

OMB Control Number: 1513–0082.

TTB Recordkeeping Number: 5170/7.

Abstract: When an exporter seeks to use an alternate method or procedure or seeks an emergency variation from the regulatory requirements of 27 CFR part 28, such exporter requests a variance by letter, following the procedure in 27 CFR 28.20. TTB uses the provided information to determine if the requested variance is allowed by statute and does not jeopardize the revenue. The applicant is informed of the approval or disapproval of the request. TTB also uses the information to analyze what changes should be made to existing regulations. Records will be maintained only while the applicant is using the authorization.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 500.

Estimated Total Annual Burden Hours: 200.

Title: Labeling of Sulfites in Alcoholic Beverages.

OMB Control Number: 1513–0084.

TTB Form/Recordkeeping Number: None.

Abstract: As mandated by Federal law, and in accordance with our consumer protection responsibilities, TTB requires label disclosure statements on all alcoholic beverage products released from U.S. bottling premises or customs custody that contain 10 parts per million or more of sulfites. Sulfating agents have been shown to produce allergic-type responses in humans, particularly asthmatics, and the presence of these ingredients in alcohol beverages may have serious health implications for those who are intolerant of sulfites. Disclosure of sulfites on labels of alcohol beverages will minimize their exposure to these ingredients.

Current Actions: We are submitting this information collection as a revision. We updated the estimated number of respondents and estimated total annual burden hours.

Type of Review: Revision of a currently approved collection.

Estimated Number of Respondents: 18,163.

Estimated Total Annual Burden Hours: 12,109.

Title: Notices Relating to Payment of Firearms and Ammunition Excise Tax.

OMB Control Number: 1513–0097.

TTB Form/Recordkeeping Number: None.

Abstract: Federal excise taxes are collected on the sale or use of firearms and ammunition by firearms or ammunition manufacturers, importers, or producers. Taxpayers who elect to pay excise taxes by electronic fund transfer must furnish a written notice upon election and discontinuance. This notice protects the tax revenue.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 10.

Estimated Total Annual Burden Hours: One (1).

Title: Applications, Notices, and Permits Relating to Importation and Exportation of Distilled Spirits, Wine and Beer, Including Puerto Rico and Virgin Islands.

OMB Control Number: 1513–0100.

TTB Form/Recordkeeping Number: None.

Abstract: Distilled spirits, beer, wine, and industrial alcohol are subject to Federal alcohol excise tax when imported into the United States. The taxes on these commodities coming from the Virgin Islands and Puerto Rico are largely returned to the two insular governments. Exports of these products from the United States are largely tax free. These documents ensure that the proper taxes are collected or returned according to law.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 20.

Estimated Total Annual Burden Hours: 180.

Title: Information Collected in Support of Small Producer's Wine Tax Credit.

OMB Control Number: 1513–0104.

TTB Recordkeeping Number: 5120/11.

Abstract: TTB is responsible for the collection of the Federal excise tax on wines. Certain small wine producers are eligible for a credit which may be taken to reduce the tax they pay on wines removed from their own premises. In addition, small producers can authorize bonded warehouses, which store their wine and ship it on their instructions, to take the credit on their behalf. The transferee will use the information provided by the small producer under the regulations to take the appropriate credit on behalf of the small producer, and the producer will use this information to monitor its own tax payments to ensure it does not exceed the authorized annual credit. The information is used by taxpayers in preparing their returns and by TTB to verify tax computation.

Current Actions: We are submitting this information collection for extension purposes only. The information collection, estimated number of respondents, and estimated total annual burden hours remain unchanged.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 280.

Estimated Total Annual Burden Hours: 2,800.

Dated: November 6, 2012.

Amy R. Greenberg,

Assistant Director, Regulations and Rulings Division.

[FR Doc. 2012–27464 Filed 11–8–12; 8:45 am]

BILLING CODE 4810–31–P

FEDERAL REGISTER

Vol. 77 Friday,

No. 218 November 9, 2012

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 417

Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for All Medicare Providers; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 417

[CMS–1352–F]

RIN 0938–AR13

Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for All Medicare Providers

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

ACTION: Final rule.

SUMMARY: This final rule updates and makes revisions to the end-stage renal disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2013. This rule also sets forth requirements for the ESRD quality incentive program (QIP), including for payment year (PY) 2015 and beyond. In addition, this rule implements changes to bad debt reimbursement for all Medicare providers, suppliers, and other entities eligible to receive Medicare payment for bad debt and removes the cap on bad debt reimbursement to ESRD facilities. (See the Table of Contents for a listing of the specific issues addressed in this final rule.)

DATES: *Effective Date:* These regulations are effective on January 1, 2013.

Applicability Date: The regulations setting forth the reductions in Medicare bad debt pursuant to section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 112–96) are applicable for cost reporting periods beginning October 1, 2012.

FOR FURTHER INFORMATION CONTACT: Michelle Cruse, (410) 786–4533, for issues related to ESRD.

Heidi Oumarou, (410) 786–7942, for issues related to the ESRD market basket.

Anita Segar, (410) 786–4614, for issues related to the QIP.

Kellie Shannon, (410) 786–0416 for information regarding Medicare bad debt.

SUPPLEMENTARY INFORMATION:

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents. Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the Code of Federal Regulations (CFR).

I. Executive Summary
A. Purpose
1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)
2. ESRD QIP
3. Reductions to Bad Debt Payments for All Medicare Providers and Elimination of the Cap on Bad Debt Reimbursement to ESRD Facilities
B. Summary of Major Provisions
1. ESRD PPS
2. ESRD QIP
3. Reductions to Bad Debt Payments for All Medicare Providers and Elimination of the Cap on Bad Debt Reimbursement to ESRD Facilities
C. Summary of Cost and Benefits
1. Impacts of the Final ESRD PPS
2. ESRD QIP
3. Impacts of Bad Debt Provisions
II. Calendar Year (CY) 2013 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)
A. Background on the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)
B. Summary of the Proposed Provisions and Responses to Comments on the CY 2013 ESRD PPS
C. Routine Updates and Proposed Policy Changes to the CY 2013 ESRD PPS
1. Composite Rate Portion of the ESRD PPS Blended Payment
a. Update to the Drug Add-on to the Composite Rate Portion of the ESRD Blended Payment Rate
i. Estimating Growth in Expenditures for Drugs and Biologicals in CY 2013
ii. Estimating Per Patient Growth
iii. Applying the Growth Update to the Drug Add-On Adjustment
iv. Update to the Drug Add-On Adjustment for CY 2013
2. ESRD PPS Base Rate
3. ESRD Bundled Market Basket
a. Overview and Background
b. Market Basket Update Increase Factor and Labor-Related Share for ESRD Facilities for CY 2013
c. Productivity Adjustment
d. Calculation of the ESRDB Market Basket Update Adjusted for Multifactor Productivity for CY 2013
4. Transition Budget-Neutrality Adjustment for CY 2013
5. Updates to the Wage Index Values and Wage Index Floor for the Composite Rate Portion of the Blended Payment and the ESRD PPS Payment
a. Reduction to the ESRD Wage Index Floor
b. Policies for Areas With No Wage Data
c. Wage Index Budget-Neutrality Adjustment
d. ESRD PPS Wage Index Tables
6. Drug Policy Changes
a. Daptomycin
b. Alteplase and Other Thrombolytics
c. Part B Drug Pricing
7. Revisions to the Outlier Policy
a. Impact of Changes to the Outlier Policy
b. Outlier Policy Percentage
D. Clarifications Regarding the ESRD PPS
1. Reporting Composite Rate Items and Services
2. ESRD Facility Responsibilities for ESRD-Related Drugs and Biologicals
3. Use of AY Modifier
E. Miscellaneous Comments
III. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for Payment Year (PY) 2015
A. Background
B. Summary of the Proposed Provisions and Responses to Comments on the ESRD QIP for PY 2015
C. Considerations in Updating and Expanding Quality Measures Under the ESRD QIP for PY 2015 and Subsequent PYs
1. Value-Based Purchasing (VBP) Overview
2. Brief Overview of Proposals
3. Measures Application Partnership Review
4. PY 2014 Mineral Metabolism Measure
D. Proposed Measures for the PY 2015 ESRD QIP and Subsequent PYs of the ESRD QIP
1. PY 2014 Measures Continuing for PY 2015 and Subsequent PYs
a. Hemoglobin Greater Than 12 g/dL
b. Vascular Access Type (VAT) Measure Topic
c. In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS)
2. Expansion of Two PY 2014 Measures for PY 2015 and Subsequent PYs
a. Expanded National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure
b. Expanded Mineral Metabolism Reporting Measure
3. New Measures for PY 2015 and Subsequent PYs of the ESRD QIP
a. Kt/V Dialysis Adequacy Measure Topic
i. Adult Hemodialysis Adequacy
ii. Peritoneal Dialysis Adequacy
iii. Pediatric, In-center Hemodialysis Adequacy
b. Hypercalcemia
c. Anemia Management Reporting Measure
4. Measures Under Consideration for Future PYs of the ESRD QIP
a. Standardized Hospitalization Ratio (SHR)
b. Standardized Mortality Ratio (SMR)
c. Public Reporting of SHR and SMR Measures
5. Other Potential Future Measures Under Development
a. Thirty-Day Hospital Readmissions
b. Efficiency
c. Population/Community Health
6. Scoring Background and General Considerations for the PY 2015 ESRD QIP
7. Performance Period for the PY 2015 ESRD QIP
8. Performance Standards for the PY 2015 ESRD QIP
a. Clinical Measure Performance Standards
b. Performance Standards
c. Performance Standards for the PY 2015 Reporting Measures
9. Scoring for the PY 2015 ESRD QIP Measures
a. Scoring Facility Performance on Clinical Measures Based on Achievement
b. Scoring Facility Performance on Clinical Measures Based on Improvement
c. Calculating the Reporting Measure Scores

10. Weighting the PY 2015 ESRD QIP Measures and Calculation of the PY 2015 ESRD QIP Total Performance Score
a. Weighting Individual Measures To Compute Measure Topic Scores for the Kt/V Dialysis Adequacy Measure Topic and the Vascular Access Type Measure Topic
b. Weighting the Total Performance Score
c. Examples of the PY 2015 ESRD QIP Scoring Methodology
11. Minimum Data for Scoring Measures for the PY 2015 ESRD QIP
a. Minimum Data for Scoring Clinical Measures for the PY 2015 ESRD QIP
b. Minimum Data Requirements for Reporting Measures by New Facilities
12. Payment Reductions for the PY 2015 ESRD QIP
13. Data Validation
14. Scoring Facilities Whose Ownership has Changed
15. Public Reporting Requirements
IV. Limitation on Payments to All Providers, Suppliers and Other Entities Entitled to Bad Debt
A. Background
B. Section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. No. 112–96)
C. Summary of Provisions of This Final Rule
1. Section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. No. 112–96)
2. ESRD Bad Debt Cap and Remove and Reserve § 413.178
3. Technical Corrections
D. Changes to Medicare Bad Debt Policy
1. Changes to 42 CFR 413.89(h)
2. Rationale for Removing 42 CFR 413.178
3. Technical Corrections to 42 CFR 417.536(f)(1)
V. Collection of Information Requirements
A. Legislative Requirement for Solicitation of Comments
B. Requirements in the Regulation Text
C. Additional Information Collection Requirements
1. ESRD QIP
a. Display of Certificates for the PY 2015 ESRD QIP
b. NHSN Dialysis Event Reporting Requirement for the PY 2015 ESRD QIP
c. ICH CAHPS Survey Attestation Requirement for the PY 2015 ESRD QIP
d. Data Validation Requirements
2. Reductions to Bad Debt Payments for All Medicare Providers
VI. Economic Analyses
A. Regulatory Impact Analysis
1. Introduction
2. Statement of Need
3. Overall Impact
B. Detailed Economic Analysis
1. CY 2013 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)
a. Effects on ESRD Facilities
b. Effects on Other Providers
c. Effects on the Medicare Program
d. Effects on Medicare Beneficiaries
e. Alternatives Considered
2. ESRD QIP
a. Effects of the PY 2015 ESRD QIP
b. Alternatives Considered for the PY 2015 ESRD QIP
3. Reductions to Bad Debt Payments for All Medicare Providers
C. Accounting Statement
VII. Regulatory Flexibility Act Analysis
VIII. Unfunded Mandates Reform Act Analysis
IX. Federalism Analysis
X. Files Available to the Public via the Internet
Regulations Text

Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

AMCC Automated Multi-Channel Chemistry
ASP Average Sales Price
AV Arteriovenous
BLS Bureau of Labor Statistics
BMI Body Mass Index
BSA Body Surface Area
CAH Critical Access Hospital
CBSA Core-Based Statistical Area
CCN CMS Certification Number
CDC Centers for Disease Control and Prevention
CLABSI Central Line Access Bloodstream Infections
CFR Code of Federal Regulations
CIP Core Indicators Project
CMHC Community Mental Health Center
CMP Competitive Medical Plans
CMS Centers for Medicare & Medicaid Services
CPM Clinical Performance Measure
CPT Current Procedural Terminology
CROWNWeb Consolidated Renal Operations in a Web-Enabled Network
CY Calendar Year
DFC Dialysis Facility Compare
DFR Dialysis Facility Report
DME Durable Medical Equipment
ESA Erythropoiesis stimulating agent
ESRD End-Stage Renal Disease
ESRDB End-Stage Renal Disease Bundled
FDA Food and Drug Administration
FI/MAC Fiscal Intermediary/Medicare Administrative Contractor
FQHC Federally Qualified Health Center
FY Fiscal Year
GDP Gross Domestic Product
HAI Healthcare-associated Infections
HCPCS Healthcare Common Procedure Coding System
HCPP Health Care Prepayment Plan
HD Hemodialysis
HHD Home Hemodialysis
HMO Health Maintenance Organization
ICD–9–CM International Classification of Diseases, 9th Edition, Clinical Modifications
ICH CAHPS In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems
IGI IHS Global Insight
IPPS Inpatient Prospective Payment System
KDIGO Kidney Disease: Improving Global Outcomes
KDOQI Kidney Disease Outcome Quality Initiative
Kt/V A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume
LDO Large Dialysis Organization
MAP Medicare Allowable Payment
MCP Monthly Capitation Payment
MIPPA Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275)
MMA Medicare Prescription Drug, Improvement and Modernization Act of 2003
MMEA Medicare and Medicaid Extenders Act of 2010 Pub. L. 111–309
MFP Multifactor Productivity
NHSN National Healthcare Safety Network
NQF National Quality Forum
PD Peritoneal Dialysis
PFS Physician Fee Schedule
PPS Prospective Payment System
PSR Performance Score Report
PY Payment Year
QIP Quality Incentive Program
REMIS Renal Management Information System
RFA Regulatory Flexibility Act
RHC Rural Health Clinic
RRF Residual Renal Function
RUL Reasonable Useful Lifetime
SBA Small Business Administration
SHR Standardized Hospitalization Ratio
SIMS Standard Information Management System
SMR Standardized Mortality Ratio
SNF Skilled Nursing Facility
SSA Social Security Administration
TEP Technical Expert Panel
The Act Social Security Act
The Affordable Care Act The Patient Protection and Affordable Care Act
URR Urea Reduction Ratio
VAT Vascular Access Type
VBP Value Based Purchasing

I. Executive Summary

A. Purpose

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

This final rule updates and makes revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2013. In accordance with section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), the Centers for Medicare & Medicaid Services (CMS) implemented a case-mix adjusted bundled PPS for Medicare outpatient ESRD dialysis services beginning January 1, 2011. The ESRD PPS replaced the basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD services.

Also, section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act (Pub. L. 111–148), established that beginning CY 2012, and each subsequent year, the Secretary shall reduce the market basket increase factor by a productivity

adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. In addition, the application of the productivity adjustment may result in the increase factor being less than 0.0 percent for a year.

2. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

This final rule also sets forth requirements for the ESRD quality incentive program (QIP), including for payment year (PY) 2015. The program is authorized under section 153(c) of MIPPA, which added section 1881(h) to the Social Security Act (the Act). The ESRD QIP is the most recent step in fostering improved patient outcomes by establishing incentives for dialysis facilities to meet performance standards established by CMS.

3. Reductions to Bad Debt Payments for all Medicare Providers and Elimination of the Cap on Bad Debt Reimbursement to ESRD Facilities

This final rule also implements the changes to the limitations on payments for bad debt reimbursement set forth in section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 112–96) by revising 42 CFR 413.89, Bad debts, charity, and courtesy allowances. Additionally, this rule will remove the cap on bad debt reimbursement to ESRD facilities.

B. Summary of the Major Provisions

1. ESRD PPS

• *Update to the composite and ESRD PPS base rate for CY 2013:* For CY 2013, the ESRD PPS base rate is $240.36. This amount reflects the application of the ESRD bundled (ESRDB) market basket reduced by the productivity adjustment, or 2.3 percent, and the wage index budget-neutrality adjustment factor of 1.000613 to the CY 2012 ESRD PPS base rate of $234.81. The base rate is applicable to both the ESRD PPS portion of the blended payment under the transition and payments under the full PPS. During the transition, we are required to update the composite rate for ESRD facilities receiving a blended payment. For CY 2013, the composite base rate is $145.20. This amount reflects the CY 2012 composite rate of $141.94, increased by the ESRDB market basket reduced by the productivity adjustment.

• *Update to the composite rate drug add-on for CY 2013:* There are no changes to the methodology used to compute the drug add-on for CY 2013; we are only updating the data used to calculate the drug add-on for CY 2013. Using 6 years of average sales price (ASP) drug expenditure data and other data, we estimate a 2.9 percent decrease in aggregate drug expenditures and a 4.0 percent increase in enrollment. Using these estimates, we project a 6.6 percent decrease in per patient growth of drug expenditures for CY 2013. Thus, we are projecting that the combined growth in per patient utilization and pricing for CY 2013 will result in a decrease to the drug add-on equal to 0.9 percentage points. We will apply a zero update to the drug add-on adjustment and maintain the $20.33 per treatment drug add-on amount for CY 2013. Because the market basket minus productivity that is applied to the composite rate increases the composite rate, the add-on adjustment of 14.3 percent is reduced to 14.0 percent to maintain the drug add-on at $20.33.

• *Market basket and productivity adjustment:* Under section 1881(b)(14)(F) of the Act, beginning in CY 2012, ESRD PPS payment amounts and the composite rate portion of the transition blended payment amounts shall be annually increased by an ESRD market basket percentage increase factor reduced by a multi-factor productivity (MFP) adjustment. The CY 2013 ESRDB market basket increase factor is 2.9 percent. The current forecast of the CY 2013 MFP adjustment is 0.6 percent. The resulting final CY 2013 MFP-adjusted ESRDB market basket update is equal to 2.3 percent.

• *The transition budget-neutrality adjustment factor:* For CY 2013, we are applying the transition budget-neutrality adjustment methodology established in CY 2011. This results in a 0.1 percent adjustment. Therefore, for CY 2013, a 0.1 percent increase will be applied to both the blended payments made under the transition and payments made under the full ESRD PPS for renal dialysis services furnished January 1, 2013 through December 31, 2013.

• *Updates to the wage index and wage index floor:* We adjust wage indices on an annual basis using the most current hospital wage data to account for differing wage levels in areas in which ESRD facilities are located. In CY 2013, we are not making any changes to the application of the wage index budget-neutrality adjustment factor and will continue to apply the budget-neutrality adjustment to the pre-floor, pre-reclassified wage index values for the composite rate portion of the blended payment and to the base rate for the ESRD PPS. Over the past several years, we have been gradually decreasing the wage index floor by 0.05 in an effort to gradually phase out the floor, and in CY 2013 we will continue to do so. Therefore, in CY 2013, we are reducing the wage index floor from 0.550 to 0.500. We also applied the wage index budget-neutrality adjustment factor to the wage index floor of 0.500, which results in an adjusted wage index floor of 0.501 (0.500×1.001141) for CY 2013.

• *Update to the outlier policy:* We are updating the outlier services fixed dollar loss amounts and Medicare Allowable Payments (MAPs) for CY 2013 using 2011 data. Based on the use of more current data, the fixed dollar loss amount for pediatric patients will decrease from $71.64 to $47.32 and the MAP amount will decrease from $45.44 to $41.39 as compared to CY 2012 values. For adult patients, the fixed-dollar loss amount drops from $141.21 to $110.22 and the MAP amount drops from $78.00 to $59.42. Because of the decline in utilization associated with the implementation of the expanded bundle, the 1 percent target for outlier payments was not achieved in CY 2011. Use of 2011 data to recalibrate the thresholds, reflecting lower utilization of epoetin and other outlier services, is expected to result in aggregate outlier payments close to the 1 percent target in CY 2013. We believe this update to the outlier MAPs and fixed dollar loss amounts for CY 2013 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier policy.

• *Policy reiteration (composite rate drugs and AY modifier):* Under the composite and basic case-mix adjusted composite rate payment systems, certain drugs were included in the composite rate and were not eligible for separate payment. Our analyses of claims show that ESRD facilities are continuing to report composite rate drugs on ESRD claims. In this rule, we are reiterating that any item or service included in the composite rate should not be identified on ESRD claims. An AY modifier can be appended to claims for drugs and laboratory tests that are not ESRD-related to allow for separate payment. Our analyses of claims show that there are ESRD facilities and laboratories that are appending the AY modifier to drugs and laboratory tests that we believe are ESRD-related, resulting in separate payment. In this rule, we reiterate the purpose of the AY modifier and emphasize that we are continuing our monitoring efforts. We also indicate that we may consider eliminating the AY modifier in future rulemaking if we believe that the AY modifier is not being used for the purpose intended.

2. ESRD QIP

This final rule also implements new requirements for the ESRD QIP. It will continue some of the previous ESRD QIP measures, add new measures, and expand the scope of some of the existing measures to cover the measure topics as follows:

- To evaluate anemia management:
  - Hemoglobin Greater Than 12 g/dL, a clinical measure.
  - Anemia Management, a reporting measure.*
- To evaluate dialysis adequacy:
  - A clinical Kt/V measure for adult hemodialysis patients.*
  - A clinical Kt/V measure for adult peritoneal dialysis patients. *
  - A clinical Kt/V measure for pediatric in-center hemodialysis patients. *
- To determine whether patients are treated using the most beneficial type of vascular access:
  - Vascular Access Type, a clinical measure topic comprised of an arteriovenous fistula and a catheter measure.
- To address effective bone mineral metabolism management:
  - Mineral Metabolism, a reporting measure.
- To address safety:
  - National Healthcare Safety Network (NHSN) Dialysis Event reporting measure.
- To assess patient and caregiver experience:
  - In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey reporting measure.

* Denotes that this measure is new to the ESRD QIP.

This final rule also establishes CY 2013 as the performance period for the PY 2015 ESRD QIP. It also establishes performance standards for each measure and adopts scoring and payment reduction methodologies that are similar to those finalized for the PY 2014 ESRD QIP.

3. Reductions to Bad Debt Payments for all Medicare Providers and Elimination of the Cap on Bad Debt Reimbursement to ESRD Facilities

This rule also implements the statutory changes to the limitations on payments for bad debt reimbursement by revising 42 CFR 413.89, Bad debts, charity, and courtesy allowances. We are also moving 42 CFR 413.178(a) to 42 CFR 413.89(h)(3), and moving 42 CFR 413.178(d)(2) to 42 CFR 413.89(i)(2) and removing and reserving the remainder of 42 CFR 413.178. Additionally, we are making a technical correction to the cross reference in 42 CFR 417.536(f)(1) to Medicare bad debt reimbursement policy. Finally, this final rule will eliminate the cap on bad debt reimbursement to an ESRD facility at its unrecovered costs.

C. Summary of Costs and Benefits

In section VI.B of this final rule, we set forth a detailed analysis of the impacts that the changes will have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact chart in section VI.B of this final rule displays the estimated change in payments to ESRD facilities in CY 2013 as compared to estimated payments in CY 2012. The overall impact of the CY 2013 changes is projected to be a 3.0 percent increase in payments. Hospital-based ESRD facilities have an estimated 3.6 percent increase in payments compared with freestanding facilities with an estimated 2.9 percent increase. Urban facilities are expected to receive an estimated payment increase of 3.0 percent compared to an estimated 2.9 percent increase for rural facilities. We expect a 2.4 percent decrease in estimated payments as a result of wage index adjustments for Puerto Rico and the Virgin Islands. However, this decrease is offset primarily by the impact of the market basket increase, resulting in an estimated 0.6 percent increase in payment. The estimated 3.0 percent overall payment increase will result in a $250 million cost to Medicare and a $60 million cost to beneficiaries. In 2013, a 2.3 percent market basket increase will result in a $190 million cost to Medicare and a $50 million cost to beneficiaries. The outlier fixed dollar loss and MAP adjustments in CY 2013 will result in a $30 million cost to Medicare and a $10 million cost to beneficiaries. The difference in cost to Medicare is due to the effects of changing the blend of payments from 50/50 to 25/75 and the 0.1 percent transition budget-neutrality adjustment.

2. Impacts for ESRD QIP

The overall economic impact of the ESRD QIP is an estimated $24.6 million for PY 2015. We expect the total payment reductions to be approximately $12.1 million, and the costs associated with the collection of information requirements for certain measures to be approximately $12.4 million.

The estimated payment reduction will continue to incentivize facilities to provide higher quality care to beneficiaries. The reporting measures that result in costs associated with the collection of information are critical to better understanding the quality of care beneficiaries receive, particularly a patient's experience of care, and will be used to incentivize improvements in the quality of care provided.

3. Impacts of Bad Debt Provisions

We are codifying the provisions of section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 that requires reductions in bad debt reimbursement to all providers eligible to receive bad debt reimbursement; these provisions are specifically prescribed by statute and thus, are generally self-implementing. There will be a $10.92 billion savings to the program over 10 years resulting from these self-implementing reductions in bad debt reimbursement. We are also removing the cap on reimbursement for bad debt to ESRD facilities for cost reporting periods beginning on or after January 1, 2013, which will result in a cost to the Medicare program of $170 million over 10 years.

II. Calendar Year (CY) 2013 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background on the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On August 12, 2010, we published in the **Federal Register** a final (75 FR 49030) titled, ''End-Stage Renal Disease Prospective Payment System'', hereinafter referred to as the CY 2011 ESRD PPS final rule. In the CY 2011 ESRD PPS final rule, we implemented a case-mix adjusted bundled PPS for Medicare outpatient ESRD dialysis services beginning January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA.

On April 6, 2011, we published in the **Federal Register** an interim final rule with comment period (76 FR 18930) titled, ''Changes in the End-Stage Renal Disease Prospective Payment System Transition Budget-Neutrality Adjustment'', which revised the ESRD transition budget-neutrality adjustment for CY 2011. In the interim final rule, we revised the 3.1 percent transition budget-neutrality adjustment reduction to a zero percent transition budget-neutrality adjustment for renal dialysis services furnished on April 1, 2011 through December 31, 2011 (76 FR 18933). On November 10, 2011, we published in the **Federal Register**, a final rule (76 FR 70228 through 70316) titled, ''Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program;

Ambulance Fee Schedule; Durable Medical Equipment; and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (hereinafter referred to as the CY 2012 ESRD PPS final rule). In that final rule, for the ESRD PPS, we made a number of routine updates for CY 2012, implemented the second year of the transition to the ESRD PPS, made several policy changes, clarifications, and technical changes. In the CY 2013 ESRD PPS proposed rule (77 FR 40956), we summarize the updates, changes, and clarifications that were finalized in the CY 2012 ESRD PPS final rule (76 FR 70228).

B. Summary of the Proposed Provisions and Responses to Comments on the CY 2013 ESRD PPS

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for All Medicare Providers'' (77 FR 40952), hereinafter referred to as the CY 2013 ESRD PPS proposed rule appeared in the **Federal Register** on July 11, 2012, with a comment period that ended on August 31, 2012. In that proposed rule, for the ESRD PPS, we proposed to (1) make a number of routine updates for CY 2013, (2) implement the third year of the transition, and (3) make several policy changes and clarifications. We received approximately 40 public comments on the ESRD PPS proposals, including comments from ESRD facilities; national renal, nephrologist and patient organizations; patients; manufacturers; health care systems; and nurses. In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2013 ESRD PPS.

C. Routine Updates and Proposed Policy Changes to the CY 2013 ESRD PPS

1. Composite Rate Portion of the ESRD PPS Blended Payment

Section 1881(b)(14)(E)(i) of the Act requires a 4-year transition under the ESRD PPS. This final rule implements the third year of the transition for those ESRD facilities that did not elect to receive 100 percent of the payment amount under the ESRD PPS. For CY 2013, under 42 CFR 413.239(a)(3), facilities that are transitioning will receive a blended rate equal to the sum of 75 percent of the full ESRD PPS amount and 25 percent of the basic case-mix adjusted composite payment amount. Accordingly, we continue to update the composite rate portion of the blended payment during the transition, (that is, CY 2011 through 2013), which includes updates to the drug add-on adjustment required by section 1881(b)(12)(F) of the Act, discussed in section II.C.1.a of this final rule, as well as the wage index values (which includes a budget-neutrality factor) used to adjust the labor component of the composite rate discussed in section II.C.5 of this final rule. For CY 2013, we proposed to update the second part of the transition budget-neutrality adjustment to reflect updated data. The transition budget-neutrality adjustment is applied to both the blended payments under the transition and payments under the ESRD PPS. The discussion regarding the transition budget-neutrality adjustment can be found in section II.C.4 of this final rule.

As discussed in the CY 2013 ESRD PPS proposed rule (76 FR 40957), section II.C.3 of this final rule, and in section 1881(b)(14)(F)(ii) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, for the years in which the transition applies, the composite base rate shall be annually increased by the ESRDB market basket and, for CY 2012 and each subsequent year, the ESRDB market basket shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. In the CY 2013 ESRD PPS proposed rule (77 FR 40957), we proposed for CY 2013 a composite rate of $145.49, which reflected the CY 2012 composite rate of $141.94 increased by an ESRDB market basket of 3.2 reduced by the productivity adjustment of 0.7 percent, resulting in an update of 2.5 percent, based on the first quarter 2012 IGI forecast of the ESRDB market basket.

We received four public comments supporting our proposal to increase the composite base rate by 2.5 percent for ESRD services furnished in CY 2013 and paid under the blended payment methodology during the transition period.

In section II.C.3.b of this final rule, we finalize the CY 2013 ESRDB market basket update of 2.9 percent, and the MFP adjustment of 0.6 percent, which results in a forecasted rate of increase to the base rate of 2.3 percent. This final update is based on the third quarter 2012 IGI forecast of the ESRDB market basket. Consequently for CY 2013, we are finalizing the composite base rate under the ESRD PPS payment of $145.20 for ESRD services furnished during CY 2013 and paid under the blended payment methodology. This amount reflects the CY 2012 composite rate of $141.94 increased by the CY 2013 ESRD market basket increase factor of 2.9 percent reduced by the productivity adjustment of 0.6 percent. The resulting CY 2013 MFP-adjusted ESRD market basket update is 2.3 percent ($141.94 × 1.023 = $ 145.20).

a. Update to the Drug Add-On to the Composite Rate Portion of the ESRD Blended Payment Rate

Section 1881(b)(14)(E)(i) of the Act requires a 4-year transition under the ESRD PPS. Under 42 CFR 413.239, ESRD facilities were permitted to make a one-time election by November 1, 2010, to be excluded from the transition and receive full payment under the ESRD PPS. Under § 413.239(a)(3), in CY 2013, ESRD facilities that elected to receive payment under the transition will be paid a blended amount consisting of 25 percent of the basic case-mix adjusted composite payment system payment and 75 percent of the ESRD PPS payment. Thus, we must continue to update the composite rate portion of the blended payment amount during the ESRD PPS transition (CY 2011 through 2013), which includes an update to the drug add-on.

As required under section 1881(b)(12) of the Act, the basic case-mix adjusted composite payment system includes the services in the composite rate and an add-on to the composite rate portion of the blended payment to account for the difference between pre-Medicare Modernization Act payments for separately billed drugs and the revised drug pricing specified in the statute. For the drug add-on for CY 2013 (77 FR 40957 through 40959), we did not propose any changes to the drug add-on methodology, but merely updated the data used in computing the drug add-on as described below.

i. Estimating Growth in Expenditures for Drugs and Biologicals in CY 2013

Section 1881(b)(12)(F) of the Act specifies that the drug add-on increase must reflect ''the estimated growth in expenditures for drugs and biologicals (including erythropoietin) that are separately billable * * *''. By referring to ''expenditures'', we believe the statute contemplates that the update would account for both increases in drug prices, as well as increases in utilization of those drugs.

As we indicated in the CY 2013 ESRD PPS proposed rule (77 FR 40957), we continue to estimate growth in drug expenditures based on the trends in available data. To account for increases in drug prices and utilization for CY 2013 we used the 6 years of available drug expenditure data based on ASP pricing. We then removed growth in

enrollment for the same time period from the expenditure growth so that the residual reflects the per patient expenditure growth (which includes price and utilization combined).

To estimate drug expenditure growth using trend analysis, for CY 2013, we looked at the average annual growth in total drug expenditures between 2006 and 2011. First, we estimated the total drug expenditures for all ESRD facilities in CY 2011. We used the final CY 2006 through CY 2010 ESRD claims data and the latest available CY 2011 ESRD facility claims, updated through December 31, 2011 (that is, claims with dates of service from January 1 through December 31, 2011, that were received, processed, paid, and passed to the National Claims History File as of December 31, 2011). We indicated in the CY 2013 ESRD PPS proposed rule (77 FR 40958) that for the CY 2013 PPS final rule, we would use additional updated CY 2011 claims with dates of service for the same timeframe. This updated CY 2011 data file would include claims received, processed, paid, and passed to the National Claims History File as of June 30, 2012. We further stated that while the CY 2011 claims file used in the proposed rule was the most current available, we recognize that it does not reflect a complete year, as claims with dates of service towards the end of the year have not all been processed. To more accurately estimate the update to the drug add-on, completed aggregate drug expenditures are required.

In the CY 2013 ESRD PPS proposed rule (77 FR 40958), we inflated the CY 2011 drug expenditures to estimate the June 30, 2012 update of the 2011 claims file. We used the relationship between the December 2010 and the June 2011 versions of 2010 claims to estimate the more complete 2011 claims that were available in June 2012 and applied that ratio to the 2011 claims data from the December 2011 claims file. The net adjustment to the CY 2011 claims data was an increase of 9.7 percent to the 2011 expenditure data. This adjustment allows us to more accurately compare the 2010 and 2011 drug expenditure data to estimate per patient growth.

We further stated in the CY 2013 ESRD PPS proposed rule (77 FR 40958), that using the completed full-year 2011 drug expenditure figure, we calculated the average annual change in drug expenditures from 2006 through 2011. This average annual change showed a decrease of 3.0 percent in drug expenditures from 2006 through 2011. We used this 3.0 percent decrease to project drug expenditures for both 2012 and 2013.

For this CY 2013 final rule, using the full year 2011 drug expenditure figure based on the June 2012 update of the CY 2011 National Claims History File, we calculated the average annual change in drug expenditure from 2006 through 2011. This average annual change showed a decrease of 2.9 percent in drug expenditures from 2006 through 2011. We used this 2.9 decrease to project drug expenditures for both 2012 and 2013. We note that the decrease in the drug expenditures percentage is a result of our use of updated data.

ii. Estimating Per Patient Growth

In the CY 2013 ESRD PPS proposed rule (77 FR 40958), we explained that once we had the projected growth in drug expenditures from 2012 to 2013, we calculated per patient growth between CYs 2012 and 2013 by removing the estimated growth in enrollment data between CYs 2012 and 2013. We had estimated a 4.6 percent growth in fee-for-service Medicare dialysis beneficiary enrollment between CYs 2012 and 2013. To obtain the per-patient estimated growth in expenditures, we divided the total drug expenditure change of a 3 percent decrease between 2012 and 2013 (0.97) by enrollment growth of 4.6 percent (1.046) for the same timeframe. The result was a per-patient growth factor equal to 0.927 (0.97/1.046 = 0.927). Thus, we are projecting a 7.3 percent decrease ($-7.3\% = -.073 = 0.927 - 1$) in per patient growth in drug expenditures between CYs 2012 and 2013.

For this final rule, we estimate a 4.0 percent estimated growth in enrollment between CYs 2012 and 2013. To obtain the per-patient estimated growth in expenditures, we divided the total drug expenditure change of a 2.9 percent decrease between CYs 2012 and 2013 (0.971) by enrollment growth of 4.0 percent (1.04) for the same timeframe. The result is a per-patient growth factor equal to 0.934 (.971/1.04=.934). Thus, in this final rule, for CY 2013 we are projecting a 6.6 percent decrease (-6.6% percent $= -.063 = .934 - 1$) in per patient growth in drug expenditures between CYs 2012 and 2013.

iii. Applying the Proposed Growth Update to the Drug Add-On Adjustment

We explained in the CY 2013 ESRD PPS proposed rule (77 FR 40958), that in the CY 2012 ESRD PPS proposed and final rules, we provided an incorrect citation to the CY 2006 PFS final rule with comment in the discussion of the application of the projected growth update percentages. The correct citation to this discussion in the CY 2006 PFS final rule with comment is 70 FR 70166 and 70167. In the CY 2006 rule, we applied the projected growth percentage to the total amount of drug add-on dollars established for CY 2005 to establish a dollar amount for the CY 2006 growth. In addition, we projected the growth in dialysis treatments for CY 2006 based on the projected growth in ESRD enrollment. We divided the projected total dollar amount of the CY 2006 growth by the projected total dialysis treatments to develop the per treatment growth update amount. This growth update amount, combined with the CY 2005 per treatment drug add-on amount, resulted in a 14.7 percent adjustment to the composite rate for CY 2006.

We further explained in the CY 2013 ESRD PPS proposed rule (77 FR 40958), that subsequent to the publication of the CY 2006 PFS final rule with comment, the Deficit Reduction Act (DRA) of 2005 (Pub. L. 109–171) was enacted on February 8, 2006. Section 5106 of the DRA amended section 1881(b)(12) of the Act to require the Secretary to increase the amount of the composite rate component of the basic case-mix adjusted system for dialysis services furnished on or after January 1, 2006 by 1.6 percent above the amount of the composite rate for such services furnished on December 31, 2005. We issued Change Request 4291, Transmittal 849, entitled, ''Update to the ESRD Composite Payment Rates'' on February 10, 2006 to instruct contractors to implement this change. We stated in Change Request 4291 that because the drug add-on adjustment is determined as a percentage of the composite rate, it was necessary to adjust the drug add-on percentage to account for the 1.6 percent increase in the composite payment rate. Therefore, the total drug add-on adjustment to the composite payment rate for 2006 was 14.5 percent instead of 14.7 percent.

Finally, we explained in the CY 2013 ESRD PPS proposed rule (77 FR 40958) that in the CY 2007 PFS final rule with comment period (71 FR 69683 and 69684), we revised our update methodology by applying the growth update to the per treatment drug add-on amount. That is, for CY 2007, we applied the growth update factor of 4.03 percent to the $18.88 per treatment drug add-on amount resulting in an updated per treatment drug add-on amount of $19.64 per treatment (71 FR 69684). For CY 2008, the per treatment drug add-on amount was updated to $20.33. In the CYs 2009, 2010, and 2011 PFS final rule with comment period (73 FR 69755 through 69757, 74 FR 61923, and 75 FR 73485, respectively) and the CY 2012

ESRD PPS final rule (76 FR 70239), we applied a zero update to the per treatment drug add-on amount resulting in a per treatment drug add-on amount of $20.33. For CY 2013, we did not make any update to the per treatment drug add-on amount of $20.33 established in CY 2008.

As discussed in detail below, in this final rule, for CY 2013, we are finalizing a zero update to the per treatment drug add-on amount of $20.33 established in CY 2008.

iv. Update to the Drug Add-On Adjustment for CY 2013

As discussed above, in the CY 2013 ESRD PPS proposed rule (77 FR 40958), we estimated a 3.0 percent decrease in drug expenditures between CYs 2012 and 2013. Combining this decrease with a 4.6 percent increase in enrollment, as described above, we projected a 7.3 percent decrease in per patient growth of drug expenditures between CYs 2012 and CY 2013. Therefore, in the CY 2013 ESRD PPS proposed rule, we projected that the combined growth in per patient utilization and pricing for CY 2013 would result in a decrease to the drug add-on equal to 1.0 percentage points (out of the revised 14.0 percent add-on for 2013). This figure was derived by applying the 7.3 percent decrease to the CY 2012 drug add-on of $20.33. This resulted in a revised drug add-on of $18.85, which is 13.0 percent of the proposed CY 2013 base composite rate of $145.49. We indicated that if we were to apply no decrease to the drug add-on of $20.33, this would result in a 14.0 percent drug add-on. However, similar to last year and as indicated above, we proposed a zero update to the drug add-on adjustment. We believe this approach is consistent with the language under section 1881(b)(12)(F) of the Act, which states in part that ''the Secretary shall annually increase'' the drug add-on amount based on the growth in expenditures for separately billed ESRD drugs. Therefore, we proposed to apply a zero update and maintain the $20.33 per treatment drug add-on amount for CY 2013. We sought comment on our proposed zero update to the drug add-on.

We further stated in the CY 2013 ESRD PPS proposed rule (77 FR 40959), that the current $20.33 per treatment drug add-on reflected a 14.3 percent drug add-on adjustment to the composite rate in effect for CY 2012. As discussed in section II.3.a of the CY 2013 ESRD PPS proposed rule, section 1881(b)(14)(F) of the Act requires that an ESRDB market basket minus productivity adjustment be used to update the composite rate portion of the ESRD PPS payment resulting in a decrease to the CY 2013 drug add-on adjustment from 14.3 to 14.0 percent, to maintain the drug add-on at $20.33. This decrease occurs because the drug add-on adjustment is a percentage of the composite rate. Since the proposed CY 2013 composite rate is higher than the CY 2012 composite rate and since the drug add-on remains at $20.33, the percentage decreases. Therefore, we proposed a drug add-on adjustment to the composite rate for CY 2013 of 14.0 percent.

We did not receive any comments on our proposals to use a zero update to the drug add-on or on the proposed drug-add on adjustment to the composite rate for CY 2013 of 14.0 percent.

In this final rule, for CY 2013, we estimate a 2.9 percent decrease in drug expenditures between CYs 2012 and 2013. Combining this increase with a 4.0 percent increase in enrollment, we project a 6.6 percent decrease in per patient growth of drug expenditures between CYs 2012 and 2013. Therefore, we project that the combined growth in per patient utilization and pricing for CY 2013 results in a decrease to the drug add-on equal to 0.9 percentage points. This figure is derived by applying the 6.6 percent decrease to the CY 2012 drug add-on of $20.33. This results in a revised drug add-on of $18.98, which is 13.1 percent of the final CY 2013 base composite rate of $145.20. Applying no decrease to the drug add-on of $20.33 results in a 14.0 percent drug add-on. Similar to last year and as discussed above, for CY 2013, we are finalizing a zero update to the drug add-on and maintaining the $20.33 per treatment drug add-on amount.

The current $20.33 per treatment drug add-on reflected a 14.3 percent drug add-on adjustment to the composite rate in effect for CY 2012. Using the latest ESRDB market basket minus productivity adjustments to update the composite rate portion of the ESRD PPS payment (forecast of 2.3 percent in CY 2013 effective January 1, 2013, as discussed in section II.C.3 of this final rule), results in a decrease to the CY 2013 drug add-on adjustment from 14.3 to 14.0 percent in order to maintain the drug add-on amount of $20.33. This decrease occurs because the drug add-on adjustment is a percentage of the composite rate. Because the final CY 2013 composite rate is higher than CY 2012 composite rate, and since the drug add-on remains at $20.33, the percentage decreases. Therefore, we are finalizing for CY 2013 the drug add-on adjustment of 14.0 to the composite rate.

2. ESRD PPS Base Rate

In the CY 2013 ESRD PPS proposed rule (77 FR 40959) and CY 2012 ESRD PPS final rule (76 FR 70231), we discussed the development of the ESRD PPS per treatment base rate that is codified in the Medicare regulations at 42 CFR 413.220 and 413.230. We explained that the CY 2011 ESRD PPS final rule (75 FR 49071 through 49082) provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget-neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year), updated to CY 2011, and represented the average per treatment Medicare Allowable Payment (MAP) for composite rate and separately billable services. We further explained that in accordance with 42 CFR 413.230, the ESRD PPS base rate is adjusted for the patient-specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, as well as any outlier payment or training payments (if applicable). For CY 2012, the ESRD PPS base rate was $234.81 (76 FR 70231).

We also indicated in the CY 2013 ESRD PPS proposed rule (77 FR 40959) that section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually adjusted by the rate of increase in the ESRD market basket, reduced by the productivity adjustment. Accordingly, in the CY 2013 ESRD PPS proposed rule, we applied the 2.5 percent increase to the CY 2012 ESRD PPS base rate of $234.81, which resulted in a proposed CY 2013 ESRD PPS base rate of $240.68 ($234.81 × 1.025 = $240.68). The ESRD PPS base rate is applicable to both the ESRD PPS portion of the blended payment under the transition and payments under the full ESRD PPS.

In addition, for CY 2013, we proposed a wage index budget-neutrality adjustment factor of 1.000826 to be applied to the CY 2013 ESRD PPS base rate (that is, $240.68), which yielded a proposed CY 2013 ESRD PPS wage index budget-neutrality adjusted base rate of $240.88 ($240.68 × 1.000826 = $240.88).

Comment: All commenters supported our CY 2013 ESRD PPS wage index budget-neutrality adjusted base rate. Two commenters thanked CMS for providing an update to the base rate, and one commenter specifically appreciated the base rate increase at a time when the Medicare ESRD program is undergoing significant changes and noted that it is important to retain savings where applicable.

Response: We thank the commenters for their support. In this final rule, using updated data for CY 2013, we applied the 2.3 percent increase (ESRDB market basket update less productivity) to the CY 2012 ESRD PPS base rate of $234.81, which results in an ESRD PPS base rate for CY 2013 of $240.21 ($234.81 × 1.023 = $240.21). In addition, we applied the wage index budget-neutrality adjustment factor of 1.000613 to the updated base rate of $240.21, yielding an ESRD PPS wage index budget-neutrality adjusted base rate for CY 2013 of $240.36 ($240.21 × 1.000613 = $240.36).

3. ESRD Bundled Market Basket

a. Overview and Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD bundled payment amounts are required to be annually increased by an ESRD market basket increase factor that is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment described may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute further provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services. Under section 1881(b)(14)(F)(ii) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, the ESRDB market basket increase factor will also be used to update the composite rate portion of ESRD payments during the ESRD PPS transition period from CYs 2011 through 2013; though beginning in CY 2012, such market basket increase factor will be reduced by the productivity adjustment. Therefore, a full market basket was applied to the composite rate portion of the blended payment in CY 2011 during the first year of the transition.

b. Market Basket Update Increase Factor and Labor-related Share for ESRD Facilities for CY 2013

As required under section 1881(b)(14)(F) of the Act, CMS developed an all-inclusive ESRDB input price index (75 FR 49151 through 49162). Although ''market basket'' technically describes the mix of goods and services used to produce ESRD care, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from that market basket. Accordingly, the term ''ESRDB market basket'', as used in this document, refers to the ESRDB input price index.

We proposed to use the same methodology described in the CY 2011 ESRD PPS final rule (75 FR 49151 through 49162) to compute the CY 2013 ESRDB market basket increase factor and labor-related share based on the best available data (76 FR 40503). Consistent with historical practice, we estimated the ESRDB market basket update based on IHS Global Insight (IGI), Inc.'s forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Using this methodology and the IGI forecast for the third quarter of 2012 of the CY 2008-based ESRDB market basket (with historical data through the second quarter of 2012), and consistent with our historical practice of estimating market basket increases based on the best available data, the CY 2013 ESRDB market basket increase factor is 2.9 percent.

For the CY 2013 ESRD payment update, we will continue to use a labor-related share of 41.737 percent for the ESRD PPS payment and the ESRD PPS portion of the blended payment, which was finalized in the CY 2011 ESRD final rule (75 FR 49161). We will also continue to use a labor-related share of 53.711 percent for the ESRD composite rate portion of the blended payment for all years of the transition. This labor-related share was developed from the labor-related components of the 1997 ESRD composite rate market basket that was finalized in the CY 2006 Physician Fee Schedule (PFS) final rule (70 FR 70168), and is consistent with the mix of labor-related services paid under the composite rate, as well as the method finalized in the CY 2011 ESRD PPS final rule (75 FR 49116).

c. Productivity Adjustment

The ESRDB market basket must be annually adjusted by changes in economy-wide productivity. Specifically, under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) (the ''MFP adjustment''). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please see *http://www.bls.gov/mfp* to obtain the BLS historical published MFP data.

CMS notes that the methodology for calculating and applying the MFP adjustment to the ESRD payment update is similar to the methodology used in other payment systems, as required by section 3401 of the Affordable Care Act.

The projection of MFP is currently produced by IGI. The details regarding the methodology for forecasting MFP and how it is applied to the market basket was finalized in the CY 2012 ESRD PPS final rule (76 FR 70232 through 70234). Using this method and the IGI forecast for the third quarter of 2012 of the 10-year moving average of MFP, the CY 2013 MFP factor is 0.6 percent.

d. Calculation of the ESRDB Market Basket Update, Adjusted for Multifactor Productivity for CY 2013

Under section 1881(b)(14)(F) of the Act, beginning in CY 2012, ESRD PPS payment amounts and the composite rate portion of the transition blended payment amounts shall be annually increased by an ESRD market basket percentage increase factor reduced by a productivity adjustment. We proposed to follow the same methodology for calculating the ESRDB market basket updates adjusted for MFP that was finalized in the CY 2012 ESRD PPS final rule (76 FR 70234).

Thus, in accordance with section 1881(b)(14)(F)(i) of the Act, the market basket increase factor for CY 2013 for the ESRDB market basket is based on the 3rd quarter 2012 forecast of the CY 2008-based ESRDB market basket

update, which is estimated to be 2.9 percent. This market basket percentage is then reduced by the MFP adjustment (the 10-year moving average of MFP for the period ending CY 2013) of 0.6 percent, which is based on IGI's 3rd quarter 2012 forecast. The resulting MFP-adjusted ESRDB market basket update for CY 2013 is equal to 2.3 percent, or 2.9 percent less 0.6 percentage point.

We received two comments in support of the market basket update. We are finalizing the update to the ESRDB market basket of 2.3 percent for CY 2013.

4. Transition Budget-Neutrality Adjustment for CY 2013

Section 1881(b)(14)(E)(i) of the Act requires the Secretary to provide a 4-year phase-in of the payments under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011, with payments under the ESRD PPS fully implemented for renal dialysis services furnished on or after January 1, 2014. Although the statute uses the term ''phase-in,'' we use the term ''transition'' in our discussions in order to be consistent with other Medicare payment systems.

Section 1881(b)(14)(E)(ii) of the Act permitted ESRD facilities to make a one-time election to be excluded from the transition. An ESRD facility that elected to be excluded from the transition receives payment for renal dialysis services furnished on or after January 1, 2011, based on 100 percent of the payment rate under the ESRD PPS rather than a blended payment based in part on the payment under the basic case-mix adjusted composite payment system and in part on the payment under the ESRD PPS. Section 1881(b)(14)(E)(iii) of the Act also requires that we make an adjustment to payments during the transition so that the estimated total amount of payments under the ESRD PPS, including payments under the transition, equals the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition. We refer to this provision as the transition budget-neutrality adjustment.

In the CY 2012 ESRD PPS final rule (76 FR 70235), we discussed the two parts that comprise the transition budget-neutrality adjustment factor. For the first part, we created a one-time payment adjustment to the composite rate portion of the blended payment during the transition to account for the per treatment costs of ESRD drugs with an injectable equivalent that were paid under Part D. We finalized the one-time addition of the CY 2011 Part D per treatment amount of $0.49 to the composite rate (76 FR 70231). For the second part, we explained that we computed a factor that would make the estimated total amount of payments under the ESRD PPS, including payments under the transition, equal to the estimated total amount of payments that would otherwise occur without such a transition.

Given that the transition budget-neutrality adjustment required under section 1881(b)(14)(E)(iii) of the Act applies in each year of the transition, we must update the transition budget-neutrality adjustment for CY 2013, the third year of the transition. As discussed in detail below, and in accordance with section 1881(b)(14)(E)(iii) of the Act, an adjustment is made to payments so that estimated total payments under the transition equal estimated total payment amounts without such a transition.

In the CY 2013 ESRD PPS proposed rule, we did not propose to change the methodology used to calculate either part of the transition budget-neutrality adjustment factor. We did, however, propose to use updated data to calculate the second part of the transition budget-neutrality adjustment factor. The first part, which is the Part D payment amount added to the composite rate, is updated annually by the ESRDB market basket reduced by the productivity adjustment. The second part is updated as described below.

For CY 2013, we started with 2011 utilization data from claims, as 2011 is the latest complete year of claims data available. In the CY 2013 ESRD PPS proposed rule, we used the December 2011 claims file. In this final rule, we used the June 2012 claims file. We updated the CY 2011 utilization data to CYs 2012 and 2013 payments by using the price growth factors for CYs 2012 and 2013, as discussed in the impact analysis in section VI.C of this final rule. We then took the estimated payments under the full CY 2013 ESRD PPS and the blended payments under the transition based on actual facility election data and compared these estimated payments to the total estimated payments in CY 2013 as if all facilities had elected to receive payment under the ESRD PPS. We then calculated the transition budget-neutrality factor to be 1 minus the ratio of estimated payments under the ESRD PPS as if there were no transition to the total estimated payments under the transition, which results in a zero percent reduction factor for CY 2013. In the CY 2013 ESRD PPS proposed rule, we proposed a zero percent reduction to all payments made to ESRD facilities (that is, the zero percent adjustment would be applied to both the blended payments made under the transition and payments made under the 100 percent ESRD PPS) for renal dialysis items and services furnished January 1, 2013 through December 31, 2013 (77 FR 40957). We solicited comments on the proposed second part of the CY 2013 transition budget-neutrality adjustment.

We received three comments as set forth below.

Comment: All of the commenters supported using updated data and maintaining a zero percent budget-neutrality transition adjustment for CY 2013.

Response: We thank the commenters for their support of our proposed use of updated data and a transition budget-neutrality factor of zero percent for renal dialysis services furnished during January 1, 2013 through December 31, 2013. As we indicated above, for the proposed rule, we used the December 2011 claims file to compute the transition budget-neutrality adjustment factor. For this final rule, we used the June 2012 claims file. As a result of using the June 2012 claims file, we calculated the transition budget-neutrality factor to be a reduction of 1 minus the ratio of estimated payments under the ESRD PPS as if there were no transition to the total estimated payments under the transition, which results in a 0.1 percent increase factor for CY 2013. We believe the claims data we used to perform our analysis resulted in the change in the transition budget-neutrality adjustment factor from the zero factor used in previous years to the 0.1 percent increase factor for CY 2013. We note that in past years, the transition budget-neutrality factor has not always been an absolute zero, but was rounded to zero percent. The June 2012 claims file represents 2011 data, the first year of the PPS. In 2011, the utilization for separately billable drugs, laboratory tests and other items dropped significantly. For ESRD facilities that are paid under the transition, the decrease in utilization contributed to the payment for the composite rate portion of the blended payment being lower than the payment for the ESRD PPS portion of the blended payment. Therefore, total payments for all facilities under the transition were lower than what payments would have been under the ESRD PPS, if there were no transition. This widening difference resulted in the transition budget-neutrality adjustment rounding to 0.1 for CY 2013. We are finalizing for CY 2013 a transition budget-neutrality adjustment of 0.1 percent.

5. Updates to the Wage Index Values and Wage Index Floor for the Composite Rate Portion of the Blended Payment and the ESRD PPS Payment

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment by a geographic wage index, such as the index referred to in section 1881(b)(12)(D) of the Act. In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized the use of the OMB's core-based statistical area (CBSA) based geographic area designations to define urban/rural areas and corresponding wage index values. In the CY 2012 ESRD PPS final rule (76 FR 70241), we finalized the wage index policy that is used under the ESRD PPS. Under the ESRD PPS, we have adopted the same method and source of wage index values used previously to compute the wage index values for the basic case-mix adjusted composite payment system. Specifically, we finalized our policies to continue to utilize the methodology established under the composite payment system for updating the wage index values using the OMB's CBSA-based geographic area designations to define urban and rural areas and corresponding wage index values; the gradual reduction of the wage index floor during the transition; and the policies for areas with no hospital data. For CY 2013, we did not propose any changes to the methodology finalized in the CY 2012 final rule and will update the wage index values using the FY 2013 Inpatient Prospective Payment System (IPPS) pre-floor, pre-reclassified hospital wage data.

In the CY 2012 ESRD PPS final rule (76 FR 70242), we explained that we would continue to use the labor-related share of 53.711 finalized in the 2005 PFS final rule (70 FR 70168) for the composite rate portion of the blended payment during the transition and continue to use a labor-related share of 41.737 for the ESRD PPS payment for CY 2012. We also discussed that the wage data used to construct the wage index under the ESRD PPS is updated annually, based on the most current data available and based on the Office of Management and Budget's (OMB's) urban and rural definitions and corresponding wage index values. Additional discussion on the labor-related share can be found in section II.c.3 of this final rule. For CY 2013, we did not propose to change the labor-related shares, as finalized in the CY 2012 rule, as discussed in section II.C.3 of this final rule.

In the CY 2012 ESRD PPS final rule (76 FR 70240), we discussed that during the transition we would continue to update the composite rate portion of the ESRD PPS blended payment, including adjusting payments for geographic differences in area wage levels, as noted above. We also discussed the application of the wage index budget-neutrality adjustment factor to the area wage index values for the composite rate portion of the ESRD PPS blended payment. In the proposed rule, for CY 2013 we did not propose any changes to the methodology for the wage index used to adjust the composite rate portion of the ESRD PPS blended payment.

a. Reduction to the ESRD Wage Index Floor

In the CY 2012 ESRD PPS final rule (76 FR 70239 through 70241), we finalized that we will continue to reduce the wage index floor by 0.05 for each of the remaining years of the transition. That is, we finalized the 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.550 and 0.500, respectively. The wage index floor value is used in lieu of wage index values below the floor. The wage index floor is applied to both the composite rate portion of the blend and to the ESRD PPS. In the CY 2013 ESRD PPS proposed rule, we did not propose any changes to the wage index floor methodology or reduction. Consequently, for CY 2013 we indicated in the proposed rule that we would continue to reduce the wage index floor by 0.05, which will reduce the wage index value for the wage index floor from 0.550 to 0.500. For CY 2013, the wage index floor of 0.500 only applies to areas located in Puerto Rico because those are the only areas that have wage index values below the wage index floor value of 0.500. In the CY 2012 ESRD PPS final rule (76 FR 70241), we explained that continuing to artificially adjust the wage index values after the transition by substituting a wage index floor is not an appropriate method to address low wages in certain geographic locations. Therefore, we would no longer apply a wage index floor beginning January 1, 2014.

b. Policies for Areas With No Wage Data

In the CY 2012 ESRD PPS final rule (76 FR 70241), we explained that we adopted the CBSA designations for the basic case-mix adjusted composite rate payment system and for the ESRD PPS. We also discussed and finalized the methodologies we use to calculate wage index values for ESRD facilities that are located in urban and rural areas where there are no hospital data. That is, for urban areas with no hospital data we compute the average wage index value of all urban areas within the State and use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. For rural Puerto Rico, we use the wage index floor as the wage index value, since all rural Puerto Rico areas are below the floor.

We further explained that for rural Massachusetts, we determined that the borders of Dukes and Nantucket Counties are contiguous with Barnstable and Bristol counties. Under the methodology, the values for these counties are averaged to establish the wage index value for rural Massachusetts.

After the CY 2012 ESRD PPS final rule was published, we determined that for CY 2012 there was a rural hospital with wage data on which to base an area wage index for rural Massachusetts. We note that the wage index value for rural Massachusetts was correctly identified on the wage index table for CY 2012 based on the wage data for that rural hospital. Consequently, in the CY 2013 ESRD PPS proposed rule we corrected the statement in the CY 2012 final rule that ''For rural Massachusetts, we determined that the borders of Dukes and Nantucket Counties are contiguous with Barnstable and Bristol counties. Under the methodology, the values for these counties are averaged to establish the wage index value for rural Massachusetts'' (76 FR 70241). Therefore, for CY 2012 and subsequent years, the area wage index value for rural Massachusetts is based on wage data of the rural hospital.

For CY 2013, we will continue to use the statewide urban average based on the average of all urban areas within the state for urban areas without hospital data. We note that Yuba City, California now has hospital data to calculate a wage index. Therefore, the methodology for computing a wage index for urban areas without hospital data no longer applies to that area. The only urban area without wage index data is Hinesville-Fort Stewart, GA.

c. Wage Index Budget-Neutrality Adjustment

In the CY 2012 ESRD PPS final rule (76 FR 70241 and 70242), we explained that we have broad discretion under section 1881(b)(14)(D)(iv)(II) of the Act to develop a geographic wage index. We explained that in addition to being

given broad discretion, the section cites the wage index under the basic case-mix adjusted composite payment system as an example. We have previously interpreted the statutory requirement in section 1881(b)(12)(D) of the Act for the geographic adjustment for the basic case-mix adjusted composite payment system as requiring that the geographic adjustment be made in a budget-neutral manner.

In the CY 2012 ESRD PPS final rule (76 FR 70241 and 70242), we finalized the policy to apply the wage index in a budget-neutral manner under the ESRD PPS using a wage index budget-neutrality adjustment factor. We further explained that in the first year of the ESRD PPS, CY 2011, we did not apply a wage index budget-neutrality adjustment factor under the ESRD PPS because budget-neutrality was achieved through the overall 98 percent budget-neutrality requirement in section 1881(b)(14)(A)(ii) of the Act. In the CY 2012 ESRD PPS final rule (76 FR 70242), we finalized that for CYs 2012 and 2013 we will apply the wage index budget-neutrality adjustment to the wage index values for the composite rate portion of the blended payment and that for CY 2012 and subsequent years we will apply the wage index budget-neutrality adjustment to the ESRD PPS base rate for purposes of the ESRD PPS portion of the blended payment during the transition and the ESRD PPS payment. We did not propose any changes to the wage index budget-neutrality adjustment methodology for CY 2013.

In the CY 2012 ESRD PPS final rule (76 FR 70242), we also finalized the methodology for computing the wage index budget-neutrality adjustment factor for CY 2012 and subsequent years. For CY 2013, we did not propose any changes to the methodology. Consequently, for the CY 2013 wage index budget-neutrality adjustment factors, we use the fiscal year (FY) 2013 pre-floor, pre-reclassified, non-occupational mix-adjusted hospital data to compute the wage index values, 2011 outpatient claims (paid and processed as of December 31, 2011), and geographic location information for each facility, which can be found through Dialysis Facility Compare (DFC). The DFC can be found at the Dialysis Facility Compare Web page on the Medicare.gov Web site at *www.Medicare.gov/Dialysis.* The FY 2013 hospital wage index data for each urban and rural locale by CBSA may also be accessed on the CMS Web site at *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp*. The wage index data are located in the section entitled, ''FY 2013 Proposed Rule Occupational Mix Adjusted and Unadjusted Average Hourly Wage and Pre-Reclassified Wage Index by CBSA''.

To compute the CY 2013 wage index budget-neutrality adjustment factor for this final rule, we used treatment counts from the 2011 claims and facility-specific CY 2012 payment rates; we computed the estimated total dollar amount that each ESRD facility would have received in CY 2012. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2013. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the final ESRD wage index for CY 2013. The total of these payments becomes the new CY 2013 amount of wage-adjusted expenditures for all ESRD facilities.

After comparing these two dollar amounts (target amount divided by the new CY 2013 amount), we calculated two wage index budget-neutrality adjustment factors that, when multiplied by the applicable CY 2013 estimated payments, would result in aggregate payments to ESRD facilities that would remain budget-neutral when compared to the target amount of expenditures. The first factor was applied to the ESRD PPS base rate. The second factor was applied to the wage index values for the composite rate portion of the blended payment. Therefore, in this final rule, we are finalizing for CY 2013, the wage index budget-neutrality adjustment factor for the composite portion of the ESRD PPS blended payment of 1.001141, which is applied directly to the ESRD wage index values. For the ESRD PPS (that is, for the full ESRD PPS payments and the ESRD PPS portion of the blended payments during the transition), we are finalizing the wage index budget-neutrality adjustment factor of 1.000613 that will be applied to the ESRD PPS base rate. Because we apply the wage index budget-neutrality adjustment factor to the wage index values to ensure budget-neutrality under the composite rate portion of the blended payment, we also apply the wage index budget-neutrality adjustment factor to the wage index floor. We note that this would apply to areas in Puerto Rico, subject to the floor. Therefore, for the composite rate portion of the blended payment, we are finalizing for CY 2013, to apply the wage index budget-neutrality adjustment factor to the wage index floor of 0.500 which results in an adjusted wage index floor of 0.501 (1.001141×0.500) because under the composite rate, the wage index budget-neutrality adjustment is applied to the wage index value. Under the ESRD PPS, the wage index budget-neutrality adjustment factor is applied to the base rate.

d. ESRD PPS Wage Index Tables

The CY 2013 ESRD PPS proposed wage index tables, referred to as Addendum A (ESRD facilities located in urban areas), and Addendum B (ESRD facilities located in rural areas) are posted on the CMS Web site at *http://www.cms.gov/vESRDPayment/PAY/list.asp.* The wage index tables list two separate columns of wage index values. One column represents the wage index values for the composite rate portion of the blended payment to which the wage index budget-neutrality adjustment factor has been applied. The other column lists the wage index values for the ESRD PPS, which does not reflect the application of the wage index budget-neutrality adjustment factor, because we finalized for CY 2012 and subsequent years that we will apply the wage index budget-neutrality adjustment factor to the ESRD PPS base rate.

We received one comment. The comment and our response are set forth below.

Comment: We received a comment from an LDO that expressed concern about the negative impact of the wage index floor on dialysis providers in Puerto Rico. The commenter expressed concern that wages for dialysis facilities in Puerto Rico are not accurately captured by the current hospital wage index methodology. The commenter urged CMS to determine an alternate basis for calculating the wage index floor in Puerto Rico, stating that it does not believe that the wage index as reported for Puerto Rico is representative of the wage levels of dialysis providers in Puerto Rico relative to a sample of other states. Specifically, the commenter provided its own analysis of its random sampling of cost report salaries comparing ESRD facilities in Puerto Rico with ESRD facilities in Florida, Georgia, Ohio, South Carolina and Virginia. The commenter recommended that reimbursement for Puerto Rico be based on ''some measure other than the hospital wage index, such as basing the wage index on cost report salaries relative to other state salaries.'' The commenter further explained that Puerto Rico requires that only registered nurses (RN) provide dialysis therapy, and therefore, in the dialysis setting, the occupational mix would be weighted more toward RNs than the mix for hospital.

Response: We understand that the commenter is concerned about wage

index values in Puerto Rico, however, it is our policy to use wage indices for all ESRD facilities that are based on the IPPS pre-floor, pre-reclassified hospital wage data. We discuss this in detail above. We believe that this is an appropriate mechanism for obtaining wage index values to be used to geographically adjust the ESRD PPS base rate for all ESRD facilities. It has been the same method that we have used previously for the basic case-mix adjusted composite rate payment system. We refer the commenter to the discussion on the methodology used to determine wage index values in the CY 2013 IPPS final rule (77 FR 53365 through 55367). We will, however, consider the commenter's recommended approach if we determine in the future that a change to the methodology for determining geographic wage index values is warranted.

In the CY 2012 ESRD PPS proposed rule (76 FR 40509 and 40510), we proposed to continue to reduce the wage index floor by 0.50 for each of the remaining years of the transition (that is, CYs 2012 and 2013). We also stated that ''we continue to believe that artificially adjusting wage index values by substituting a wage index floor is not an appropriate method to address low wages in certain geographic locations'' and that, accordingly, we will no longer apply a wage index floor beginning January 1, 2014 (76 FR 70241). We will include in the CY 2014 ESRD PPS proposed rule, the methodology we propose to use to address wages in rural Puerto Rico when we no longer apply the wage index floor.

Therefore, we are finalizing the wage index floor value of 0.500 for CY 2013.

6. Drug Policy Changes

a. Daptomycin

In the CY 2011 ESRD PPS final rule (75 FR 49050 through 49052), we stated that antibiotics used for the treatment of vascular access infections and peritonitis are renal dialysis services under the ESRD PPS. Payments for anti-infective drugs in injectable forms (covered under Part B) and oral or other forms of administration (formerly covered under Part D) used for the treatment of ESRD, were included in computing the final ESRD PPS base rate and, therefore, would not be separately paid under the ESRD PPS. We further stated that any anti-infective drug or biological used for the treatment of ESRD-related conditions would be considered a renal dialysis service and not eligible for separate payment. We noted that this policy also applies to any drug or biological that may be developed in the future.

In the CY 2012 ESRD PPS final rule (76 FR 70243), we explained that subsequent to the publication of the CY 2011 ESRD PPS final rule, we received numerous comments indicating that vancomycin is indicated in the treatment of both ESRD and non-ESRD conditions, such as skin infections. In the CY 2012 ESRD PPS final rule (76 FR 70243), we allowed ESRD facilities to receive separate payment for vancomycin when furnished to treat non-ESRD related conditions. When ESRD facilities furnish vancomycin to treat non-ESRD related conditions, they place the AY modifier on the claim. We stipulated that in accordance with ICD–9–CM guidelines as described in the CY 2011 ESRD PPS final rule (75 FR 49107), an ESRD facility must report on the claim the diagnosis code for which vancomycin is indicated. We also reiterated that treatment of any skin infection that is related to renal dialysis access management would be considered a renal dialysis service paid under the ESRD PPS, and that no separate payment would be made (76 FR 70243). Finally, in response to comments, we stated that we would consider allowing separate payment for daptomycin (76 FR 70243).

In the CY 2013 ESRD PPS proposed rule (77 FR 40963), we explained that after consultation with our medical experts, we proposed to allow ESRD facilities to receive separate payment for daptomycin when furnished to treat non-ESRD related conditions for CY 2013 and subsequent years. When ESRD facilities furnish daptomycin to treat non-ESRD-related conditions, they would place the AY modifier on the claim. We also explained that if ESRD facilities submitted claims for daptomycin with the AY modifier, then the ESRD facility would also be required to report the diagnosis code for which the daptomycin is indicated in accordance with ICD–9–CM diagnostic coding guidelines. We sought public comments on our proposal to permit separate payment for daptomycin when furnished to treat non-ESRD-related conditions. As we discussed in the proposed rule, we will continue to monitor the use of anti-infectives furnished by ESRD facilities including those that are identified as non-ESRD related (77 FR 40963). The comments we received and our responses are set forth below.

Comment: We received eight comments in support of our proposal to allow for separate payment for daptomycin when furnished for non-ESRD related conditions. One commenter encouraged CMS to consider the appropriateness of other anti-infective drugs and biologicals which could be used in the future for both ESRD and non-ESRD conditions, with the primary goal to help reduce drug resistance in this compromised and susceptible patient population.

Response: We thank the commenters for their support. We believe that the commenter is suggesting that CMS should frequently consider whether other drugs should be included in the ESRD PPS. We will consider allowing separate payment for other anti-infective drugs and biologicals as we may determine appropriate.

We are finalizing the proposal to eliminate the restriction on daptomycin to allow ESRD facilities to receive separate payment by placing the AY modifier on the claim for daptomycin when furnished to treat non-ESRD related conditions. In accordance with ICD–9–CM diagnostic coding guidelines as described in the CY 2011 ESRD PPS final rule (75 FR 49107), the ESRD facility must indicate on the claim the diagnosis code for which the daptomycin is indicated.

During our monitoring of claims we have noted that there are ESRD facilities that are indicating a type of organism rather than a diagnosis that would indicate that the anti-infective was furnished for non-ESRD-related conditions. We reiterate that the diagnosis code for which vancomycin or daptomycin is used must be indicated on the claim. We also reiterate that treatment of any skin infection that is related to renal dialysis access management will be considered a renal dialysis service and will continue to be paid under the ESRD PPS, and no separate payment will be made. We will continue to monitor the use of anti-infectives furnished by ESRD facilities including those that are identified as non-ESRD related to ensure proper billing of these drugs.

b. Alteplase and Other Thrombolytics

In the CY 2012 ESRD PPS final rule (76 FR 70246 through 70247), we explained that after the CY 2011 ESRD PPS final rule was published, our clinical review of the 2007 ESRD claims used to develop the ESRD PPS revealed that dialysis facilities routinely used alteplase and other thrombolytic drugs for access management purposes. We explained that under the Medicare Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1, drugs used as a substitute for any of the listed items or used to accomplish the same effect were covered under the composite rate. We further explained that because

heparin is a composite rate drug and could be used for access management, any drug or biological used for the same purpose may not be separately paid. Medicare regulations at 42 CFR 413.237(a)(2) through (a)(6), and (b) specify the methodology used to calculate outlier payments. An ESRD facility is eligible for an outlier payment if its actual or imputed Medicare Allowable Payment (MAP) amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The discussion on the outlier policy is in section II.C.7 of this final rule. Section 413.237(a)(1) provides the definition of ESRD outlier services. Specifically, § 413.237(a)(1)(i) includes ''ESRD related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.''

Because outlier payments are restricted under § 413.237(a) to those items or services that were or would have been separately billable prior to January 1, 2011, in the CY 2012 ESRD PPS final rule (76 FR 70249), we excluded thrombolytic drugs from the outlier policy and we recomputed the outlier MAP amounts to reflect this change. However, we noted in the CY 2012 ESRD PPS final rule (76 FR 70249), that for CY 2012 we had not proposed to exclude separate payment of thrombolytic drugs under the composite rate portion of the blended payment and therefore, separate payment would be made for thrombolytics for the composite rate portion of the blended payment in CY 2012.

For CY 2013, we proposed that thrombolytic drugs would not be considered eligible for separate payment under the composite rate portion of the blended payment for those ESRD facilities that are receiving a blended payment under the transition (77 FR 40963). We believe that this is consistent with the changes we made to our outlier policy regarding excluding thrombolytic drugs from outlier eligibility as discussed above. We note that these conclusions are specific to ESRD. We solicited comments on our proposal to exclude thrombolytic drugs from separate payment under the composite rate portion of the blended payment during the transition.

The comments and our responses are set forth below.

Comment: We received five comments pertaining to our proposal to no longer provide separate payment for thrombolytic drugs under the composite rate portion of the blended payment in CY 2013. In general, commenters agreed with CMS that both heparin and alteplase or other thrombolytic drugs are used for access management, but a few commenters disagreed with our assertion that heparin and alteplase are used for the same purpose. Some commenters specifically noted that CMS's proposal not to allow separate payment for alteplase and thrombolytic drugs under the composite rate portion of the blended payment during the transition period for CY 2013 is flawed because the drugs are used to achieve different clinical results and utilize different mechanisms of action. In particular, the commenters noted that heparin is used to prevent clotting whereas alteplase is used to avoid a poorly functioning catheter. Some commenters provided examples of the efficacy of alteplase and thrombolytics, as compared to heparin. Some commenters, including a renal organization and a pharmaceutical manufacturer, disagreed that heparin can be used as a substitute for alteplase, citing the different mechanisms of action for the two drugs. One commented that because heparin and thrombolytics achieve different clinical results, they should not be treated as substitutes for payment purposes.

Response: We believe alteplase and heparin are used for the same renal dialysis-related purpose, namely, vascular access management. In the CY 2012 ESRD PPS final rule (76 FR 70246 through 70249), we addressed similar comments regarding the use of alteplase and heparin in the context of our proposal to eliminate thrombolytics from the outlier policy. We noted that in the development of the ESRD PPS, we recognized that alteplase and heparin were pharmacologically different (that one is a thrombolytic that lyses clots and the other is an anticoagulant that prevents clots, respectively) (76 FR 70248). We further stated, however, that we believed that both drugs enable the catheter or graft to function either through clot prevention or clot degradation, thereby providing effective dialysis vascular access. We further believe that, for purposes of payment for renal dialysis services, it is sufficient that these products can be used for the purpose of providing dialysis vascular access. Consistent with the ESRD Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1, drugs used as substitutes for any of the listed items, or used to accomplish the same effect, are covered under the composite rate and are not separately payable. Because heparin is a composite rate drug and thrombolytics are used to achieve the same renal dialysis-related clinical outcome, we believe it is appropriate to exclude thrombolytic drugs from separate payment under the composite rate portion of the blended payment during the transition.

Comment: One ESRD facility commented that the high cost of alteplase compared to heparin would prevent substitution of alteplase for heparin. The commenter argued that CMS's policy in the ESRD Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1 of covering under the composite rate drugs used as substitutes for composite rate drugs, or used to accomplish the same effect, is without regard to innovation, cost, effectiveness, and efficiencies, and may result in increased cost to the Medicare program. The commenter also noted that the cost of thrombolytics is included in the ESRD PPS for those not in the transition and that elimination of separate payment for those in the transition would negatively impact reimbursement. A pharmaceutical company stated that the proposed changes may negatively affect catheter care because disallowing outlier payments and separate payment for thrombolytics creates a financial incentive for facilities to avoid restoring patency with alteplase.

Response: In the CY 2012 ESRD PPS final rule (76 FR 70247), we explained that the ESRD PPS provides an opportunity for ESRD facilities to make decisions based on the medical needs of patients and not on the basis of financial gain. We further explained that we are not implying that thrombolytics or any access management drug should not be used when clinically indicated. We noted that Medicare payment policy is not intended to dictate, determine, or influence clinical practice or favor one course of treatment over another. Rather, by accounting in the ESRD PPS base rate for the cost of drugs and biologicals that had been separately payable under the composite rate system, we believe that we provide adequate payment to maintain patency of the access site regardless of whether patency is maintained using heparin or a thrombolytic. For additional information regarding this issue, we refer the commenters to the comment responses in the CY 2012 ESRD PPS final rule (76 FR 70247 through 70249).

We disagree with the commenter that ESRD facilities receiving blended payments during the transition are unfairly disadvantaged because they will not receive separate payment for thrombolytics for the portion of the

blended payment based on the composite rate. Even when the composite rate system was in place before the ESRD PPS was implemented, it was our policy not to pay separately for drugs that could be used to accomplish the same effect as composite rate drugs. Accordingly, it is consistent with that policy not to provide separate payment for thrombolytics for the composite rate portion of blended payments during the remainder of the transition.

For all of the reasons stated above, we continue to believe that alteplase and other thrombolytics should not be eligible for separate payment under the composite rate portion of the blended payment. After consideration of public comments, we are finalizing our CY 2013 proposal to exclude alteplase and other thrombolytics from separate payment, which we believe is consistent with the CY 2012 ESRD PPS changes made to the outlier policy to exclude thrombolytic drugs from outlier payments.

c. Part B Drug Pricing

In the CY 2011 ESRD PPS proposed rule (74 FR 49991), with respect to estimating the imputed MAP amounts of ESRD outlier services that are separately billable under Part B, we proposed to use Average Sales Price (ASP) data for Part B ESRD-related drugs (which is updated quarterly). We did not make any changes to this proposed methodology in the CY 2011 final rule. In the CY 2012 ESRD PPS final rule (76 FR 70243), we explained that ESRD facilities receiving blended payments under the transition would receive payments based on ASP for separately billable ESRD drugs and biologicals for the composite rate portion of the blend. In the CY 2012 ESRD PPS final rule (76 FR 70244), we stated that under the outlier policy, we will use the ASP methodology.

In the CY 2013 ESRD PPS proposed rule (77 FR 40963), we proposed for CY 2013 and subsequent years to continue to use the ASP methodology, including any modifications finalized in the PFS final rules, to compute our outlier MAP amounts, the drug add-on, and any other policy that requires the use of payment amounts for drugs and biologicals that would be separately paid absent the ESRD PPS and for the composite rate portion of the blended payment during the transition. We explained that we would use this methodology for payment analyses that CMS may perform. We did not receive public comments on our proposal to apply the ASP methodology or any modifications to the ASP for these purposes, as updated in the PFS rule or in updating the ASP pricing. Therefore, we are finalizing that for CY 2013 and subsequent years we will continue to use the ASP methodology, including any modifications finalized in the Physician Fee Schedule (PFS) final rules, to compute outlier MAP amounts, the drug add-on, and any other policy that requires the use of payment amounts for drugs and biologicals that would be separately paid absent the ESRD PPS and for the composite rate portion of the blended payment during the transition.

7. Revisions to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Our regulations at 42 CFR 413.237(a)(1) provide that ESRD outlier services include: (i) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iii) medical/surgical supplies, including syringes used to administer ESRD-related drugs, that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and (iv) renal dialysis service drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, excluding ESRD-related oral-only drugs.

In the CY 2011 ESRD PPS final rule, we stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item on the monthly claim (75 FR 49142).

In the CY 2013 ESRD PPS proposed rule (77 FR 40964), we explained that drugs, laboratory tests, and medical/surgical supplies that we would recognize as outlier services are specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010 and rescinded and replaced by Transmittal 2094, dated November 17, 2010. We also explained that with respect to the outlier policy, Transmittal 2094 identified additional drugs and laboratory tests that may be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011 which was issued to correct the subject on the Transmittal page and made no other changes.

In the CY 2012 ESRD PPS final rule (76 FR 70246), we finalized our proposal to stop issuing a specific list of eligible outlier service drugs which were or would have been separately billable under Medicare Part B prior to January 1, 2011. We stated in that rule that we planned to use separate guidance to continue to identify renal dialysis service drugs which were or would have been covered under Part D for outlier eligibility purposes in order to provide unit prices for calculating imputed outlier services. In the CY 2013 ESRD PPS proposed rule (77 FR 40964), we explained that we planned to identify, through our monitoring efforts, those items and services that are incorrectly being identified as eligible outlier services. Any updates to the list of renal dialysis items and services that qualify as outlier services will be made through administrative issuances, if necessary.

We indicated in the CY 2013 ESRD PPS proposed rule (77 FR 40964), that Medicare regulations at 42 CFR 413.237(a)(2) through (a)(6), and (b) specify the methodology used to calculate outlier payments. We explained that an ESRD facility is eligible for an outlier payment if its actual or imputed Medicare Allowable Payment (MAP) amount per treatment for ESRD outlier services exceeds a threshold. We further explained that the MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. We also stated that the threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the fixed dollar loss amount. Finally, we explained that in accordance with 42 CFR 413.237(c), facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold and that ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule, using 2007 data, we established the outlier percentage at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the fixed dollar loss amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and fixed dollar loss amounts are different for adult and pediatric patients due to

differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140).

As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 and 49139), the predicted outlier services MAP amounts for a patient would be determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments. The average outlier services MAP amount per treatment for CY 2011 was based on payment amounts reported on 2007 claims and adjusted to reflect projected prices for 2011. For CY 2012, the outlier services MAP amounts and fixed dollar loss amounts were based on 2010 data (76 FR 70250). That is, for CYs 2011 and 2012, the MAP and fixed dollar loss amounts were computed based on pre-ESRD PPS claims data and utilization.

Comment: Several commenters agreed that no changes need to be made to the methodology and commended CMS for its transparency regarding the data and methodology used to update the MAP and fixed dollar loss thresholds. Some commenters expressed appreciation of CMS's clear explanation of eligible outlier services.

Response: We thank the commenters for their support. We will continue to issue guidance regarding the renal dialysis items and services that could qualify for outlier payment.

a. Impact of Changes to the Outlier Policy

In the CY 2013 ESRD PPS proposed rule (77 FR 40964), we explained that we did not propose any changes to the methodology used to compute the MAP or fixed dollar loss amounts. Rather, we explained that we were updating the outlier services MAP amounts and fixed dollar loss amounts to reflect the utilization of outlier services reported on the 2011 claims using the December 2011 claims file. In this final rule, for CY 2013, we used the June 2012 update of the CY 2011 National Claims History File to update the outlier services MAP amounts and fixed dollar loss amounts. That is, for CY 2013, the MAP and fixed dollar loss amounts are based on utilization data from the 2011 ESRD PPS claims. For this final rule, the impact of this update is shown in Table 1, which compares the outlier services MAP amounts and fixed dollar loss amounts used for the outlier policy in CY 2012 with the updated estimates. The estimates for the CY 2013 outlier policy, which are included in Column III of Table 1, were inflation-adjusted to reflect projected 2013 prices for outlier services.

TABLE 1—OUTLIER POLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY

	Column I Outlier policy for CY2012 (based on 2010 data price inflated to 2012) *		*Column II* Updated outlier estimates based on 2011 data price inflated to 2012 *		*Column III* Final outlier policy for CY2013 (based on 2011 data price inflated to 2013) *	
	Age < 18	Age > = 18	Age < 18	Age > = 18	Age < 18	Age > = 18
Average outlier services MAP amount per treatment [1]	$46.26	$81.73	$37.84	$59.49	$38.65	$61.38
Adjustments						
Standardization for outlier services [2]	1.0024	0.9738	1.0927	0.9878	1.0927	0.9878
MIPPA reduction	0.98	0.98	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount [3]	$45.44	$78.00	$40.52	$57.59	$41.39	$59.42
Fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold [4]	$71.64	$141.21	$44.16	$103.47	$47.32	$110.22
Patient months qualifying for outlier payment	5.7%	5.4%	7.8%	5.2%	7.6%	5.1%

* The outlier services MAP amounts and fixed dollar loss amounts were inflation adjusted to reflect updated prices for outlier services (that is, 2012 prices in Columns I and II and projected 2013 prices in Column III).

[1] Excludes patients for whom not all data were available to calculate projected payments under an expanded bundle. The outlier services MAP amounts are based on 2011 data. The medically unbelievable edits of 400,000 units for epoetin and 1,200 mcg for Aranesp that are in place under the ESA claims monitoring policy were applied.

[2] Applied to the average outlier MAP per treatment. Standardization for outlier services is based on existing Case Mix Adjusters for adult and pediatric patient groups.

[3] This is the amount to which the separately billable (SB) payment multipliers are applied to calculate the predicted outlier services MAP for each patient.

[4] The fixed dollar loss amounts were calculated using 2011 data to yield total outlier payments that represent 1% of total projected payments for the ESRD PPS.

As seen in Table 1, the estimated fixed dollar loss amounts that determine the 2013 outlier threshold amounts (Column III) are lower than those used for the 2012 outlier policy (Column I). The main reason for these reductions is the lower utilization of epoetin and other outlier services in CY 2011, the first year of the PPS. This can be seen by comparing the outlier service MAP amounts in Column I (which are based on 2010 data) with the outlier service MAP amounts in Column II (which are based on 2011 data).

The fixed dollar loss amounts which are added to the predicted MAP amounts per treatment to determine the outlier thresholds are being updated from the CY 2012 amount. Based on the use of the most recently available data, the fixed-dollar loss amount for pediatric patients will decrease from $71.64 to $47.32 and the MAP amount will decrease from $45.44 to $41.39 as compared to CY 2012 values. For adult patients, the fixed-dollar loss amount drops from $141.21 to $110.22 and the MAP amount drops from $78.00 to $59.42.

We estimate that the percentage of patient months qualifying for outlier payments under the current policy will be 5.1 percent and 7.6 percent for adult and pediatric patients, respectively, based on our use of 2011 data. The pediatric outlier MAP and fixed dollar loss amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of epoetin and other injectable drugs).

Comment: All of the commenters supported CMS's decision to lower the threshold for both the fixed dollar loss

and MAP amounts for pediatric and adult patients. The commenters stated that they believed that outlier payment mechanisms are fundamental to the long-term success of prospective payment systems to ensure patients get the care they need, even when there are financial disincentives. The commenters further expressed that it is important for CMS to ensure that the information it uses to determine the outlier thresholds each year is as current as possible and agreed with CMS in using the 2011 ESRD claims and utilization for CY 2013.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern that some ESRD facilities may not have the necessary resources available to identify outlier services on the claim, and therefore are not receiving the outlier payments to which they are entitled. One commenter suggested that CMS make available data indicating that the outlier policy is beneficial to small ESRD facilities. The commenter further explained that this policy could be detrimental to small facilities because, although the facilities' base rate is reduced by 1 percent to account for outlier services, the facilities may be unable recoup this amount because of resource limitations.

Response: Outlier services are the items and services that were separately paid prior to the implementation of the ESRD PPS and are also separately paid under the composite rate portion of the blended payment for those ESRD facilities under the transition. We do not believe that it should be difficult for small facilities to identify outlier services on claims because these facilities should have had experience identifying these items on claims before the PPS was implemented. Specifically, the items eligible for outlier payments under the ESRD PPS are the same items that had been separately paid under the basic case-mix adjusted composite rate system and are separately paid under the composite rate portion of the blended payment for ESRD facilities receiving payment under the transition. Consequently, we believe that identifying items eligible for outlier payment is not an additional burden nor do we believe that it is difficult for small ESRD facilities.

In terms of demonstrating that the outlier policy is beneficial to small ESRD facilities, we note that the outlier policy is intended to account for the cost of beneficiaries with high resource utilization; it is not intended to account for facility size. Instead, our low-volume adjustment accounts for facility size by adjusting for the cost of treating a low volume of ESRD patients. Although we will continue to monitor the impact of our outlier policy, as noted above, we believe that all facilities, regardless of size, should be able to identify outlier services on claims and be compensated for the cost of treating beneficiaries with high resource utilization.

b. Outlier Policy Percentage

In the CY 2013 ESRD PPS proposed rule (77 FR 40965), we explained that 42 CFR 413.220(b)(4) stipulates that the per treatment base rate is reduced by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments. We further explained that because of the decrease in utilization associated with the implementation of the ESRD PPS, the 1 percent target for outlier payments was not achieved in CY 2011. For this final rule, using the June 2012 update of the CY 2011 National Claims History File, we found that outlier payments represented approximately 0.3 percent of total payments. That is, the historical data previously used to set the outlier thresholds for CY 2011 projected greater use of outlier services than was observed under the expanded ESRD PPS, leading to lower outlier payments than expected. Use of 2011 data to recalibrate the thresholds, reflecting lower utilization of epoetin and other outlier services, will result in aggregate outlier payments close to the 1 percent target in CY 2013. We believe this update to the outlier MAP and fixed dollar loss amounts for CY 2013 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier policy.

We note that recalibration of the fixed dollar loss amounts in this final rule for CY 2013 outlier payments results in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but raises payments to providers for beneficiaries with renal dialysis items and services that are eligible for outlier payments. Therefore, beneficiary co-insurance obligations would increase for renal dialysis services eligible for outlier services and would remain unchanged for those not eligible.

Comment: One commenter recommended that CMS estimate and publish the amount of the shortfall in outlier payments paid during CY 2011. The commenters recommended that CMS develop a mechanism to return these funds to the ESRD facilities so that these funds may be used to offset the costs associated with numerous ''unfunded mandates'' imposed on these facilities. One commenter suggested that CMS set less than 1 percent aside for outliers and allocate the leftover funds to the ESRD PPS base rate.

Response: We disagree that the shortfall in outlier payments should be used to make additional payments to ESRD facilities to account for not achieving the 1 percent threshold. The 1 percent outlier policy is a prospective payment mechanism in which thresholds are established and adjusted on a yearly basis based on historical data. In the FY 1997 Inpatient Prospective Payment System (IPPS) final rule (61 FR 46229 and 46230), we explained that we believe our outlier policies are consistent with the statute and the goals of the prospective payment system. Many of the factors used to set prospective payment amounts for a given year are based on estimates. These factors include not only the outlier thresholds, but also the market basket rate of increase, the update factors and the required budget-neutrality provisions. We do not believe that Congress intended that the standardized amounts should be adjusted (upward or downward) to reflect differences between projected and actual outlier payments for a given year. Moreover, retroactive adjustments would be extremely difficult or impracticable (if not impossible) to administer. We further explained that the thresholds for a given year reflect certain levels of costs, so that if costs are held down, fewer cases qualify for outlier payments and outlier payments are lower than expected. We believe that the same explanation applies to the ESRD PPS.

D. Clarifications Regarding the ESRD PPS

1. Reporting Composite Rate Items and Services

In the CY 2011 ESRD PPS final rule (75 FR 49036), we explained that section 1881(b)(14)(B)(i) of the Act requires that the ESRD PPS payment bundle include composite rate items and services. The basic case-mix adjusted composite payment system represented a limited PPS for a bundle of routine outpatient maintenance renal dialysis services. We defined composite rate services at § 413.171 as ''items and services used in the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite payment system established under section 1881(b)(7) [of the Act] and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.'' In 42 CFR 413.171 we also defined renal

dialysis services as including, ''items and services included in the composite rate for renal dialysis services as of December 31, 2010.'' We further explained that currently services that are billed on the ESRD claim do not provide any detail of the composite rate items and services that are furnished to the patient. We indicated that, as we discussed in the Medicare Claims Processing Manual, Pub. 100–04, chapter 8, sections 50.1 and 50.2, laboratory tests and drugs covered under the facility's composite rate may not be billed separately (75 FR 49173). We stated in the CY 2013 ESRD PPS proposed rule that the composite rate represented the routine items and services provided to Medicare beneficiaries for outpatient maintenance dialysis and therefore was full payment for those items and services. Therefore, it would not have been appropriate for ESRD facilities to bill for items and services in the composite rate because this would result in duplicate payments by Medicare (77 FR 40965).

We also explained in the CY 2011 ESRD PPS final rule (75 FR 49048), that in our analysis of the ESRD claims we identified drugs and biologicals that were included in the composite payment rate but for which ESRD facilities received separate payment in addition to the composite rate payment. Because these composite rate drugs and biologicals were listed separately on the ESRD claims, separate payment was inadvertently made. We further explained that we excluded those inadvertent payments from the final ESRD PPS base rate calculation. We also noted that the Medicare Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1 lists the drugs and fluids that were included under the composite payment system and explicitly states, ''* * * drugs used in the dialysis procedure are covered under the facility's composite rate and may not be billed separately. Drugs that are used as a substitute for any of these items, or are used to accomplish the same effect, are also covered under the composite rate.'' The manual further provides that ''administration of these items (both the staff time and supplies) is covered under the composite rate and may not be billed separately'' (75 FR 49048).

In the CY 2012 ESRD PPS final rule (76 FR 70243), with regard to antibiotics, we provided for separate payment for vancomycin when furnished to treat non-ESRD related conditions. We also eliminated the payment distinction for antibiotics furnished in an ESRD facility or in the home used to treat access infections or peritonitis. We finalized that antibiotics furnished in the home to treat access site infections and peritonitis would be eligible for outlier payment (76 FR 70246). In the CY 2013 ESRD PPS proposed rule (77 FR 40963), we proposed to allow for separate payment for daptomycin if furnished for non-ESRD-related conditions and finalized in section II.C.6.2 of this final rule.

As described at 42 CFR 413.239, there are ESRD facilities receiving reimbursement under the transition, that is, receiving a blended payment of the basic case-mix adjusted composite rate payment system and the ESRD PPS. If an ESRD facility receives payment under the transition and reports a drug, biological, or laboratory test that was included in the composite rate on the ESRD claim, it could inadvertently receive separate payment for that item or service within the portion of the blended payment that is based on the basic case-mix adjusted composite payment system.

As mentioned above and defined at 42 CFR 413.237, ESRD-related drugs, biologicals, and laboratory tests that were or would have been separately payable under the basic case-mix adjusted composite payment system qualify as eligible outlier services. In the CY 2012 ESRD PPS final rule (76 FR 70246), we finalized that as of CY 2012, we would no longer issue a specific list of eligible outlier service drugs which were or would have been separately billable under Medicare Part B prior to January 1, 2011. If an ESRD facility reports a drug or biological that was included in the basic case-mix adjusted composite payment system on the ESRD claim, it would inappropriately be applied toward an outlier calculation because all drugs and biologicals with a rate available on the ASP pricing file when the modifier AY is not present may be eligible for outlier consideration.

We explained in the CY 2013 ESRD PPS proposed rule, that as a result of our monitoring efforts, we continue to find composite rate drugs reported on ESRD claims and reiterated that composite rate items and services are not to be reported on the ESRD facility claims. We noted that we are instituting measures to ensure that composite rate drugs are prevented from being applied to the outlier payment. These measures will be discussed through administrative issuances, as appropriate. We also noted that we would continue to monitor the reporting of composite rate items and services on ESRD claims and plan to take actions to recoup inappropriate and duplicative payments. Finally, we noted that if the inclusion of composite rate items and services such as laboratory tests, drugs and supplies on claims will be required to be reported, we will discuss this requirement in future rulemaking (77 FR 40966).

We received one comment on this issue. The comment and our response are set forth below.

Comment: One commenter concluded that any action to recoup inappropriate and duplicative payments for reporting composite rate items and services should be pursued on a going forward basis rather than retrospectively.

Response: CMS has a fiduciary responsibility to ensure that accurate payments are made. If we were to identify inappropriate payments that had been made because composite rate items and services were reported on claims for the purpose of receiving separate payment we would pursue recoupment of those payments in accordance with applicable laws and regulations.

2. ESRD Facility Responsibilities for ESRD-Related Drugs and Biologicals

In the CY 2013 ESRD PPS proposed rule (77 FR 40966), we indicated that we had become aware that some ESRD facilities are requiring ESRD beneficiaries to purchase renal dialysis drugs from the ESRD facility and are instructing beneficiaries not to use their Part D plan for their purchases. We explained that section 1866(a)(1)(A) of the Act, as codified in regulations at 42 CFR 489.21, prohibits providers from billing beneficiaries for services for which the beneficiary would have been entitled to have payment made under Medicare if the provider appropriately filed claims for those services. Furthermore, section 1881(b)(2)(A) of the Act states that payments shall be made to an ESRD facility only if it agrees to accept such payments as payment in full for covered services except for the beneficiary co-insurance and deductible amounts.

Furthermore, in the CY 2011 ESRD PPS final rule (75 FR 49045), we explained that the ESRD PPS bundled base rate reflects Medicare payment for the average ESRD patient. We stated that we had incorporated payments under the basic case-mix adjusted composite rate payment system as well as payments for separately billable items and services into the ESRD PPS base rate. As a result, we believe the ESRD PPS payments are sufficient and reflect the average cost of providing care to the average patient with ESRD and therefore, we expect that, on average, high cost patients would be offset by low cost patients. In the CY 2011 ESRD PPS final rule (75 FR 49045), we also explained that we had provided for

higher acuity patients with patient case-mix adjusters and outlier payments for high-cost patients. We further cited 42 CFR 494.90 of the ESRD Conditions for Coverage which requires the development of an individualized patient plan of care to address patient needs and concluded that we believe ESRD facilities should make medical decisions based on patient needs and not solely on a financial basis.

In the CY 2011 ESRD PPS final rule (75 FR 49050), we stipulated that any drug or biological (that is, injectable, oral or other forms of administration) furnished for the purpose of access management, anemia management, vascular access or peritonitis, cellular management or bone and mineral metabolism would be considered renal dialysis services under the ESRD PPS. Any drug or biological used as a substitute for a drug or biological that was included in the ESRD PPS bundled base rate would also be a renal dialysis service and would not be eligible for separate payment. Antiemetics, anti-infectives, antipruritics, anxiolytic, excess fluid management, fluid and electrolyte management and pain management drugs and biologicals could be used for dialysis purposes and therefore, are considered ESRD-related when used for those purposes. We indicated that we presumed these drugs and biologicals to be renal dialysis services in whatever form they are furnished, unless indicated on the claim that they are used for non-ESRD-related conditions. Drugs and biologicals paid under Part D that are furnished by an ESRD facility for ESRD-related purposes are considered renal dialysis services (75 FR 49050 and 49051).

In the CY 2013 ESRD PPS proposed rule, we reiterated that ESRD facilities are responsible for furnishing renal dialysis items and services that are required to meet patient needs. This would include oral or other forms of administration of injectable drugs and biologicals that are furnished for ESRD-related conditions. We also expect that ESRD facilities will not restrict access to necessary drugs for financial purposes by requiring patients to purchase medically necessary drugs and biologicals. We expect that ESRD facilities will furnish drugs and biologicals that had been considered medically necessary prior to the implementation of the ESRD PPS and not exclude them because the ESRD facility is now financially responsible for these drugs and biologicals. Because of the reasons cited above, ESRD facilities may not require, induce or coerce beneficiaries to purchase any renal dialysis item or service.

We received no comments on the clarification of our policy regarding ESRD facility responsibilities for ESRD-related drugs and biologicals.

3. Use of AY Modifier

As we indicated in the CY 2013 ESRD PPS proposed rule (77 FR 40967), in the CY 2011 ESRD PPS final rule, we developed a mechanism to be used by ESRD facilities to identify and be paid separately for non-ESRD-related items and services, such as drugs, biologicals, and equipment and supplies (75 FR 49052 and 75 FR 49168). We provided this mechanism in order to support a Medicare beneficiary's need for non-ESRD-related items and services (that is, predominantly drugs and laboratory tests) during a dialysis treatment and to mitigate the need for the beneficiary to receive additional injections or health care visits. We further stated that in the event that supplies or equipment are not ESRD-related, ESRD facilities would be required to place a modifier on the claim for those supplies and equipment, signifying that they were used for services that were not ESRD-related and eligible for separate payment outside of the ESRD PPS (75 FR 49168). Change Request 7064, Transmittal 2033, titled ''End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services'', issued on August 20, 2010, re-issued November 17, 2010 under Transmittal 2094, and re-issued January 14, 2011 under Transmittal 2134, provided instructions on the use of the modifier. In that Change Request, we indicated that the claim lines for laboratory tests and drugs provided to a beneficiary for reasons other than the treatment of ESRD must be submitted with the AY modifier to signal separate payment outside of the ESRD PPS. In the CY 2012 ESRD PPS final rule, we provided for the use of the AY modifier with vancomycin if used for non-ESRD-related conditions and with the requirement that the ESRD facilities include the diagnosis code of the condition on the claim (76 FR 70243). In the CY 2013 ESRD PPS proposed rule (77 FR 40967), we proposed to allow the use of the AY modifier for separate payment when daptomycin is furnished by an ESRD facility to an ESRD Medicare beneficiary for non-ESRD related conditions. We are finalizing this policy above. ESRD facilities are required to indicate an appropriate diagnosis code on the claim that reflects the condition requiring the use of daptomycin.

We explained in the CY 2013 ESRD PPS proposed rule (77 FR 40967) that our monitoring activities have identified that ESRD facilities and clinical laboratories are appending the AY modifier for items that we believe are ESRD-related. We noted in the proposed rule (77 FR 40967) that some ESRD facilities and clinical laboratories appear to be appending the AY modifier on many items and services reported on claims. We reiterated in the proposed rule that the purpose of the AY modifier is to allow beneficiaries the convenience to receive non-ESRD-related items (for example, drugs and laboratory tests) during their dialysis treatment and to allow the ESRD facility to receive a separate payment for furnishing those items. The AY modifier is also intended to allow separate payment to laboratories in the event an ESRD-related laboratory test is required for non-ESRD-related conditions. The AY modifier is not intended to be used to receive a separate payment for items that are ESRD-related and therefore included in the ESRD PPS base rate. We further stated that we would continue to monitor the use of the AY modifier and intend to take steps to recoup inappropriate payments. In the event that we believe the AY modifier is not being used for the purpose intended, we may be forced to discontinue the AY modifier and cease to provide separate payment for any non-ESRD-related drug or laboratory test furnished.

We received several comments on our clarification of this policy and our responses are set forth below.

Comment: We received six comments regarding the AY modifier. Commenters supported maintaining the AY modifier for non-ESRD conditions. Several commenters provided reasons for supporting the AY modifier. For example, some commenters concurred that the AY modifier is intended to allow Medicare beneficiaries the convenience of receiving non-ESRD related items and services during the course of dialysis treatment; and to allow the ESRD facility or laboratory to receive a separate payment when furnishing non-ESRD items or services. It also enables optimal coordinated care to Medicare beneficiaries by minimizing their need for additional doctor visits and duplicative or unnecessary lab tests. Five commenters largely encouraged CMS to continue the use of the modifier for reporting non-ESRD related items or services for payment and to furnish supporting data on AY modifier misuse. A few commenters suggested that CMS should consider drafting guidance on the appropriate use of the AY modifier.

A few commenters expressed concern over the possible elimination of the AY modifier and identified possible resulting hardships for Medicare ESRD

beneficiaries. One commenter noted that the elimination of the AY modifier would force facilities to send dialysis patients to labs or infusion centers to receive IV medications that would risk the vascular access and add transportation and time burdens for the beneficiary.

Response: We thank commenters for their support of the use of the AY modifier. We agree that the elimination of the AY modifier could result in additional hardships for ESRD beneficiaries.

Comment: One commenter suggested that, rather than eliminating the AY modifier, CMS should rely upon the contractors to educate providers, audit payments for AY items, and request documentation when appropriate. Another commenter encouraged CMS to provide data on the exact abuses or the scope of modifier misuse noting that patients should not suffer because of modifier abuse, but rather CMS should work with facilities and providers to ensure policy compliance.

Response: With regard to the suggestion that the responsibility for AY modifier monitoring education should rest on the CMS contractors (that is, the Medicare Administrative Contractors (MACs)), we note that we do provide education and instructions to the A/B MACs through administrative issuances and MedLearn articles that they can then use to educate providers. For example, CMS Change Request #7064 and subsequent Medicare Learning Network Matters (MLN) article # MM7064, published on January 14, 2011, notifies contractors that ESRD-related laboratory services, drugs and supplies will be subject to Part B consolidated billing edits and no longer separately payable when furnished to ESRD beneficiaries. However, these consolidated billing edits do not apply when the items and services are not ESRD-related. When items and services are furnished to an ESRD beneficiary for conditions other than ESRD, the AY modifier must be present on the claim to bypass billing edits and allow for a separate payment outside of the ESRD PPS. CMS MLN #MM7064 may be viewed at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM7064.pdf.* Finally, we are in the process of updating the ESRD Benefit Policy Manual, Pub 100–02, chapter 11, to reflect the policy requirements under the ESRD PPS, including the use of the AY modifier.

With regard to the comment concerning monitoring the use of the AY modifier and the suggested functions to be performed by the MACs, as we discussed in the CY 2013 ESRD PPS proposed rule (77 FR 40967), we are continuing to monitor the use of the AY modifier and intend to take steps to recoup inappropriate payments. Although we are updating our manual, we believe that we have provided adequate instructions as to the appropriate use of the AY modifier. We expect that the contractors will convey information regarding the proper use of the AY modifier to the ESRD facilities, and will also audit payments and request documentation as necessary. However, CMS has the responsibility to ensure that payments are made appropriately. Therefore, we will continue to monitor the use of the AY modifier. If we believe that the AY modifier is not being used as intended, or it is being used in order to receive separate payment for renal dialysis items and services that are in the bundled payment, we will be forced to reconsider its use.

E. Miscellaneous Comments

We received thirty-five comments from Medicare beneficiaries, family members, ESRD facilities, nurses, physicians, professional organizations, renal organizations, and manufacturers related to issues that were not specifically addressed in the CY 2013 ESRD PPS proposed rule.

Comment: We received comments from patients, their families, renal associations and manufacturers requesting changes in how CMS pays for home dialysis and home dialysis training. Many of these commenters described the benefits of home dialysis. Most commenters asked CMS to increase the number of weekly allowable dialysis sessions and eliminate the medical justification requirement for additional sessions. One commenter questioned why payment for in-facility dialysis was the same as for home dialysis, noting the differences between staff and supply use between in-facility and home dialysis. Some commenters contended that patient requests for home dialysis are being denied. Commenters also stated that beneficiaries with ESRD are not provided with the same home training opportunities as beneficiaries whose care is covered by other payment sources. Many of the commenters stated that payment for home dialysis training is insufficient and does not reflect the true cost of training. Some commenters indicated various ranges of time required for home training in terms of time per day and number of training sessions. One home dialysis organization stated that ESRD facilities only receive payment for 18, rather than 25, training sessions for new patients.

Response: CMS developed a reimbursement mechanism with the 2011 implementation of the ESRD PPS that we believe supports home-based dialysis. That is, the ESRD PPS payment, which includes drugs, laboratory tests, staff time, supplies, patient-level adjustments, facility-level adjustments and outlier payments, is the same regardless of the location where the dialysis services are furnished or the dialysis modality, which we believe supports beneficiaries' ability to elect to receive dialysis at home, where appropriate. It is not, however, CMS's intent to encourage, discourage or require any particular dialysis modality. Rather, we believe that decisions regarding whether to receive dialysis and which dialysis modality to use should be made by beneficiaries in consultation with their physicians. This includes the decision whether to receive home hemodialysis or home peritoneal dialysis, rather than in-facility dialysis. We believe that the decision to perform home dialysis includes determining the beneficiary's abilities, the beneficiary's desire to perform home dialysis and the beneficiary's physical and emotional status.

With regard to the comment asking why the payment is the same for in-facility as home dialysis, we believe that our policy to pay the same amount, including the patient-level and facility-level adjustments, as well as the outlier policy for home and in-facility dialysis, provides adequate payment to account for the short-term increase in staff time necessary to train beneficiaries for home dialysis. Training costs are included in the ESRD PPS base rate, however, we also provide an add-on adjustment for each training session that represents one hour of nursing time to conduct one-on-one training treatments for each training treatment furnished by a Medicare certified home dialysis training facility. The add-on payment for one hour of training per training session does not imply that it takes only one hour per training session to properly educate a beneficiary to perform home dialysis. We believe that our payment is adequate for training and home dialysis.

We have been and will continue to monitor and analyze trends in home dialysis and home dialysis training. We have seen a continuing increase in overall home dialysis since mid-2009, including in 2011. In particular, we have observed an increase in home hemodialysis and a decline in home peritoneal dialysis with an overall higher rate of home peritoneal dialysis. In addition, our monitoring shows that

ESRD facilities receive payments for more treatments for home hemodialysis than for in-facility hemodialysis. We also have seen an increase in home training in 2011, particularly in retraining. Consequently, we do not believe that the ESRD PPS and our training adjustment discourage beneficiaries from receiving home dialysis.

Commenters also requested that we increase the maximum number of dialysis sessions and eliminate the medical justification requirement for dialysis treatments after a beneficiary has received three sessions in one week. We note that, although three is the maximum number of sessions that we will cover without a showing of medical necessity, we will cover additional sessions where those sessions are medically necessary. We are aware that there are observational studies that support additional weekly dialysis treatments and that there is some industry support for additional treatments. We have and will continue to monitor and analyze the number of dialysis treatments that Medicare beneficiaries receive to determine whether a change in this longstanding policy is warranted.

In addition, in the CY 2011 ESRD PPS final rule (75 FR 49064) we stated in response to a MedPAC comment that we would consider whether it would be appropriate to utilize a larger unit of payment, rather than a per treatment payment, after the transition period. We further stated that ''we may evaluate whether the ERSD PPS has resulted in improved outcomes, the degree to which home dialysis has increased, and whether interested stakeholders would favor an alternative to the per treatment approach.'' We will continue to monitor the impact of the ESRD PPS and will take these comments into consideration if we determine that any changes to the per treatment payment approach are warranted.

With regard to the comment that ESRD facilities receive payment for 18 rather than 25 training treatments for new patients, we believe that the commenter is confusing the adjustment for beneficiaries who are receiving home dialysis training but are not in their first four months of dialysis, with beneficiaries who have been newly diagnosed with ESRD and are receiving their first four months of dialysis. The home dialysis training adjustment applies to those beneficiaries who are not in their first four months of dialysis treatments. This adjustment does not apply for those beneficiaries newly diagnosed with ESRD. Instead, facilities receive the onset of dialysis adjustment for these beneficiaries. As we explained in the CY 2011 ESRD PPS final rule (75 FR 49094), we believe that the costs associated with the onset of dialysis adjustment and the training add-on adjustment overlap (that is, costs for services could be accounted for in both adjustments). Accordingly, we finalized a policy that ESRD facilities will not receive the home dialysis training adjustment when they are receiving the onset of dialysis adjustment. This does not mean that an ESRD facility may not furnish home training services during the onset period. Rather, the onset of dialysis payment adjustment of 51 percent per treatment accounts for the administrative and labor costs associated with new patients, including the costs to train patients.

We are unable to address the comment contending that ESRD beneficiaries are not offered the same home dialysis training opportunities as those offered to ESRD beneficiaries covered by private payers because we are not familiar with these payment sources.

Comment: One patient support group recommended that CMS use revenue code 0820 when reporting home dialysis instead of revenue code 0821, which is currently used to describe both in-facility and home dialysis services. The commenter contends that this will correctly identify patients on home dialysis in Medicare claims data.

Response: Our current Medicare policy for reporting home dialysis services with revenue code 0821 appended with ESRD condition code 74 (Dialysis in the Home) allows us to distinguish beneficiaries receiving dialysis at home from those receiving treatment in an ESRD facility.

Comment: We received twelve comments regarding the Agency's plan to include oral-only drugs in the ESRD PPS bundled payment for CY 2014. Commenters expressed concern about the administrative burden, compliance with state laws, and associated costs in furnishing oral-only drugs within the scope of the ESRD service. A few commenters requested that CMS ask for community input so that the inclusion of the oral-only drugs will be an uneventful transition for patients. ESRD industry associations cautioned that the inclusion of oral-only drugs into the ESRD PPS CY 2014 bundled payment may limit patient access to the most clinically appropriate drugs and threaten optimal health outcomes for ESRD Medicare beneficiaries. Some commenters recommended that CMS include patient protections to ensure patient care is not compromised and that oral-only drugs continue to be furnished at the recommended doses. Many commenters requested that the Agency share advance information about the methodology and data sources that the Agency will use to calculate the reimbursement rates for drugs and therapies and encouraged CMS to use the most recent year of available data to establish a payment rate for oral-only drugs. Other commenters requested that CMS adopt a methodology that measures the actual utilization on a per treatment basis and includes costs associated with drug administration when reimbursing oral-only drugs as part of the ESRD PPS.

Response: We thank the commenters for their comments. In the CY 2011 ESRD PPS final rule (75 FR 49038 through 49044), we responded to comparable comments regarding the inclusion of oral-only drugs in CY 2014. We received many suggestions from stakeholders on how oral-only drugs should be included in the ESRD PPS bundled payment. We have reviewed and will continue to review all of the comments, which we will consider as we formulate our proposals on this issue. We intend to address the inclusion of oral-only drugs in the ESRD PPS in the CY 2014 ESRD PPS proposed rule.

Comment: We received three comments from industry associations requesting that CMS release the rate-setting file to allow the industry to test the Agency's assumptions and complete its own analysis of the payment policies set forth in the CY 2013 ESRD PPS proposed rule. One commenter encouraged CMS to make data available to the public generally, not just dialysis facilities in particular, to allow for a more complete assessment of the ESRD PPS program.

Response: We received comparable requests and comments in response to the CY 2012 ESRD PPS proposed rule and responded to those comments in the CY 2012 ESRD PPS final rule (76 FR 70254 to 70255). We believe that we have provided and will provide data sufficient to analyze the payment policies included in the proposed rule, by posting the impact file for CY 2012 on the ESRD PPS Payment Web site. We will also post a provider-level impact file and the wage index file for CY 2013 shortly after publication of this final rule. We also explained that we have not made the rate setting file available ''because the release of patient identifiable data is not necessary to accomplish the purpose of analyzing our proposals. Applicable Federal privacy laws and regulations, including the Privacy Act and HIPPA Privacy Rule only permit us to disclose personal

identifiable information when it is necessary to administer the program, or for health care operations and payment.''

Comment: We received 8 comments requesting modification to the standardization factor methodology and calculation for CY 2013. Many of these commenters encouraged CMS to use the most current data available in order to establish the standardization factor, rather than historical estimates. Some commenters indicated that because we had adjusted the outlier fixed dollar loss and MAP amounts to account for outlier payments below the 1 percent threshold in CY 2011, we should provide a comparable adjustment to the standardization factor and the ESRD PPS base rate to account for payments for patient- and facility-level adjusters that were not utilized. Some commenters continue to contend that the ESRD PPS base rate established in CY 2011 is incorrect and that CMS should return the payment amounts removed from the base rate to account for the adjusters, thereby increasing the base rate. Other commenters stated that the ESRD PPS base rate should be adjusted to account for payments allocated for the patient- and facility-level adjusters that had not ultimately been paid to the ESRD facilities. A few commenters requested that CMS modify the payment for case-mix and co-morbidity adjustments.

Response: In the CY 2011 ESRD PPS final rule, we described the data sources that were used in constructing the ESRD PPS payment bundle, the development of the ESRD PPS base rate, and the payment adjusters (75 FR 49064 through 49127). In the CY 2013 ESRD PPS proposed rule, we proposed to update the base rate by the rate of increase in the ESRD market basket, reduced by the productivity adjustment (77 FR 40959). The base rate was developed using 2007 claims, in accordance with section 1881(b)(14)(A)(ii) of the Act, which requires CMS to use the lowest per patient utilization year. We also explained the methodology used to determine the case-mix adjustment amount, including co-morbidities (75 FR 49087 through 49116). In the CY 2013 ESRD PPS proposed rule, we stated that we were not proposing any changes to the methodology used to compute the MAP or fixed dollar loss amounts, but were updating the outlier services MAP amounts and fixed dollar loss amounts to reflect the utilization of outlier services reported on the 2011 claims, using the December 2011 claims file (77 FR 40964). The methodology for calculating and updating the base rate was finalized last year through notice and comment rulemaking, as were the methodologies for updating the outlier threshold. In the CY 2013 ESRD PPS proposed rule, we did not propose to change how the base rate is calculated or updated. We also did not propose in the CY 2013 ESRD PPS proposed rule to modify the payment adjusters. We do not believe that because we lowered the MAP and fixed dollar loss amounts to adjust for outlier payment expenditures that were below the 1 percent target, we must adjust the standardization factor for the ESRD PPS base rate. We will, however, continue to monitor our payments and consider if any changes need to be made in the future.

Comment: One commenter requested clarification when billing Medicare for Lipid Profile laboratory services furnished to ESRD beneficiaries. Another commenter encouraged CMS to furnish guidance for blood draws and laboratory collections under the ESRD PPS.

Response: ESRD-related laboratory tests may not be billed with the AY modifier and no separate payment shall be made when an ESRD facility or laboratory furnishes ESRD-related laboratory tests to an ESRD beneficiary. We discuss laboratory tests furnished under the PPS in our CY 2011 and CY 2012 ESRD PPS final rules (75 FR 49053 through 49056 and 76 FR 70249 through 70250, respectively). Furthermore, the Lipid Profile laboratory test is appropriately included in the ESRD PPS payment bundle when Lipid abnormalities result from, or are related to the beneficiary's ESRD. For example, some forms of dialysis, particularly peritoneal dialysis, are associated with increased cholesterol and triglyceride levels, and a Lipid Profile laboratory test to assess these levels would be included in the bundled payment. If, however, the Lipid Profile laboratory test is furnished for reasons other than for the treatment of ESRD, the laboratory services may be billed with the AY modifier and are eligible for separate payment. With regard to the comment requesting guidance for blood draws and laboratory collections, we refer the commenter to Change Request 7617, Transmittal 150, entitled, ''Implementation of Changes in End Stage Renal Disease Payment for Calendar Year 2012'' issued on November 16, 2011.

Comment: One commenter requested that CMS consider the implementation of pediatric co-morbidities to the pediatric case mix adjustments, while another commenter requested consideration of a case-mix adjustment for race. One association called for CMS to establish a new technology adjuster in a non-budget-neutral manner, stating that new technologies have the potential to lead to better diagnosis, treatment, and patient outcomes.

Response: We thank the commenters for their suggestions, but note that we did not propose to implement these adjusters in the CY 2013 ESRD PPS proposed rule. We refer the commenters to the CY 2011 ESRD PPS final rule (75 FR 49128 through 49134; 75 FR 49108 and 49115; 75 FR 49174), in which we explained the methodology used to develop the ESRD PPS for the pediatric population, discussed the reasons for not including a patient-level case mix adjuster for race, and responded to comments suggesting that we provide separate payment for new and innovative drugs and technologies.

Comment: Some commenters requested that the cost reports be amended to reflect the actual cost of care. Some of the recommendations included that the cost report should provide flexibility to allow for innovation, eliminate the limitation on medical director fees, recognize the cost of supporting the ESRD networks, and allow immediate recognition on cost reports of ''new or innovative items/services,''

Response: We thank the commenters for their suggestions. We plan to analyze the cost reports to determine if there are any changes required and will consider the suggestions provided.

We received a number of other comments on a variety of topics that we believe are outside the scope of the proposed rule. The commenters requested that ESRD beneficiaries be able to maintain disability benefits while employed; expressed concern about the ''corporate practice of medicine'' by dialysis facilities; noted that securing the necessary documentation for acute co-morbidities is problematic and urged CMS to furnish co-morbidity claims data from the CMS database; advocated for inclusion of their product in the ESRD PPS payment; and disputed over payment changes to its product under Part D. We appreciate the comments; however, because these comments were not in response to any proposals or discussions in the proposed rule, they are beyond the scope of this final rule. We refer the commenters to the CY 2011 ESRD PPS final rule, where we believe that we addressed many of these issues (75 FR 49030).

III. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for Payment Year (PY) 2015

A. Background

For over 30 years, monitoring the quality of care provided to end-stage renal disease (ESRD) patients by dialysis providers or facilities (hereinafter referred to collectively as ''facility'' or ''facilities'') has been an important component of the Medicare ESRD payment system. The ESRD quality incentive program (QIP) is the most recent step in fostering improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by CMS. The ESRD QIP is authorized by section 153(c) of MIPPA, which added section 1881(h) to the Act. CMS established the ESRD QIP for PY 2012, the initial year of the program in which ESRD payment reductions based on quality performance are being made to dialysis facilities, in two rules published in the **Federal Register** on August 12, 2010 and January 5, 2011 (75 FR 49030 and 76 FR 628, respectively). On November 10, 2011, CMS published a final rule in the **Federal Register** outlining the PY 2013 and PY 2014 ESRD QIP (76 FR 70228).

Section 1881(h) of the Act requires the Secretary to establish an ESRD QIP, which we have implemented by (i) selecting measures; (ii) establishing the performance standards that apply to the individual measures; (iii) specifying a performance period with respect to a year; (iv) developing a methodology for assessing the total performance of each facility based on the performance standards with respect to the measures for a performance period; and (v) applying an appropriate payment reduction to facilities that do not meet or exceed the established Total Performance Score. In this final rule, we describe each of these elements, as applicable, and our final policies for their application to PY 2015 and future payment years of the ESRD QIP.

B. Summary of the Proposed Provisions and Responses to Comments on the ESRD QIP for PY 2015

A proposed rule, entitled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment System, Quality Incentive Program, and Bad Debt Reductions for All Medicare Providers'' (77 FR 40952), hereinafter referred to as the CY 2013 ESRD PPS proposed rule, appeared in the **Federal Register** on July 11, 2012, with a comment period that ended on August 31, 2012. In that proposed rule, we made proposals for the ESRD QIP, including introducing and expanding measures, refining the scoring methodology, modifying the program's public reporting requirements, establishing how the ESRD QIP payment reduction applies to facilities whose ownership has changed, and initiating a data validation pilot program. We received approximately 55 public comments on these proposals from many interested parties including dialysis facilities, organizations representing dialysis facilities, nephrologists, nurses, dietitians, home health advocacy groups, pharmaceutical manufacturers, patients, advocacy groups, and the Medicare Payment Advisory Commission (MedPAC). In this section of the final rule, we provide a summary of each proposed requirement, a summary of the public comments received on these requirements, our responses to these comments, and the final policies that we will adopt for the program.

C. Considerations in Updating and Expanding Quality Measures Under the ESRD QIP for PY 2015 and Subsequent PYs

1. Value-Based Purchasing (VBP) Overview

Throughout the past decade, Medicare has been transitioning from a program that pays for healthcare based solely on the number of services furnished to a beneficiary to a program that ties payments to providers and suppliers to the quality of care of the services they deliver. By paying for the quality of care, rather than merely the quantity of care, we believe we are strengthening the healthcare system while also advancing the National Quality Strategy and the three part aim which promote (i) better care for the individual thereby (ii) advancing the health of the entire population while also (iii) reducing costs. CMS specifies the domains and specific measures of quality for our VBP programs and we are working to link the aims of the National Quality Strategy with our payment policies on a national scale.

There are currently six domains of measurement for our VBP programs, based on the six priorities of the National Quality Strategy: (i) Care coordination; (ii) population/community health; (iii) efficiency and cost reduction; (iv) safety; (v) patient- and caregiver-centered experience and outcomes; and (vi) clinical care. Together these domains not only encourage better care at the facility level, but also encourage different care settings to interface to comprehensively improve healthcare overall. Although currently none of the VBP programs measure quality across all of the six domains, we are working to ensure that each program considers measures supporting the six national priorities where feasible. Furthermore, we are working in partnership with facilities, beneficiaries, the National Quality Forum (NQF), the Measures Application Partnership, sister agencies in the Department of Health and Human Services (HHS), and other stakeholders to develop new measures where gaps exist, refine measures requiring adjustment, and remove measures when appropriate. We are also working with stakeholders to ensure that the ESRD QIP serves the needs of our beneficiaries and also advances the goals of the National Quality Strategy.

We believe that the development of an ESRD QIP that is successful in promoting the delivery of high quality healthcare services in dialysis facilities is paramount. We seek to adopt measures for the ESRD QIP that promote high-quality, safer, and more efficient care. In addition to the priorities of the National Quality Strategy, our measure development and selection activities for the ESRD QIP take into account other national priorities, such as those established by the National Priorities Partnership (*http://www.qualityforum.org/npp/*), HHS Strategic Plan (*http://www.hhs.gov/secretary/about/priorities/priorities.html*), the National Strategy for Quality Improvement in Healthcare (*http://www.healthcare.gov/center/reports/quality03212011a.html*), and the HHS National Action Plan to Prevent Healthcare Associated Infections (HAIs) (*http://www.hhs.gov/ash/initiatives/hai/esrd.html*). To the extent practicable, we have sought to adopt measures that have been endorsed by a national consensus organization, recommended by multi-stakeholder organizations, and developed with the input of facilities, purchasers/payers, beneficiaries, and other stakeholders.

2. Brief Overview of Proposals

For PY 2014, we adopted measures for the ESRD QIP that fall under three of the six VBP measure priority domains based on the National Quality Strategy:

- Safety: National Healthcare Safety Network (NHSN) Dialysis Event reporting;
- Patient- and caregiver-centered experience: In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey reporting; and
- Clinical quality of care: (i) Hemoglobin Greater Than 12 g/dL; (ii) Hemodialysis Adequacy (Urea Reduction Ratio (URR)); (iii) Vascular

Access Type; (iv) and Mineral Metabolism reporting (76 FR 70228).

For PY 2014, we also proposed to change the requirements for the Mineral Metabolism reporting measure.

For PY 2015, we proposed to add new measures in the clinical quality of care domain and to expand the scope of the NHSN Dialysis Event reporting measure (safety domain) and the Mineral Metabolism reporting measure (clinical quality of care domain). We believe that the PY 2015 ESRD QIP should not only promote the health of ESRD patients, but also uphold the goals of the National Quality Strategy (NQS). To that end, we proposed to include 11 measures in the PY 2015 ESRD QIP. We also proposed to include these measures and measure topics in subsequent payment years. The proposed measures would evaluate facilities on the following topics that fall under the NQS clinical quality of care measure domain:

- For purposes of evaluating anemia management:
  - Hemoglobin Greater Than 12 g/dL, a clinical measure.
  - Anemia Management, a reporting measure.*
- To evaluate dialysis adequacy:
  - A clinical Kt/V measure for adult hemodialysis patients.*
  - A clinical Kt/V measure for adult peritoneal dialysis patients.*
  - A clinical Kt/V measure for pediatric hemodialysis patients.*
- To determine whether patients are treated using the most beneficial type of vascular access:
  - An arteriovenous fistula measure.
  - A catheter measure.
- To address effective bone mineral metabolism management:
  - Hypercalcemia, a clinical measure.*
  - Mineral Metabolism, a reporting measure (expansion proposed).

Additionally, we proposed to expand a previously adopted reporting measure addressing safety:

- NHSN Dialysis Event reporting measure.

We also proposed to continue using a previously adopted reporting measure assessing patient- and caregiver-centered experience:

- ICH CAHPS survey reporting measure.

*Indicates that the measure is new to the ESRD QIP.

Although we did not propose to adopt measures that address care coordination, population/community health, or efficiency and cost of care, we solicited comments in the proposed rule on potential measures that would fall into each of these areas. We discussed the following measures that are under consideration for possible adoption in subsequent payment years: a 30-Day Hospital Readmission measure to address care coordination; an access to care measure to address population/community health; and an efficiency measure. We also discussed the Standardized Hospitalization Ratio Admissions (SHR) measure and the Standardized Mortality Ratio (SMR) measure that we are considering for program adoption in future years. We welcomed, and continue to welcome, further comments on these and other potential measures for future payment years.

3. Measures Application Partnership Review

In addition to the considerations discussed above, in selecting measures for the PY 2015 ESRD QIP, we considered input from the multi-stakeholder group, the Measures Application Partnership (*http://www.qualityforum.org.map/*). Section 1890A(a)(1) of the Act, as added by section 3014(b) of the Affordable Care Act, requires the entity with a contract under section 1890(a) of the Act, currently NQF, to convene multi-stakeholder groups to provide input to the Secretary on the selection of quality and efficiency measures for use in certain programs. Section 1890A(a)(2) of the Act requires the Secretary, not later than December 1 of each year, to make available to the public a list of quality and efficiency measures that are under consideration for use in certain programs. Section 1890A(a)(3) of the Act requires the entity with a contract under section 1890(a) of the Act to transmit the input of the multi-stakeholder groups to the Secretary not later than February 1 of each year, beginning in 2012. Section 1890A(a)(4) of the Act requires the Secretary to take into consideration the input of the multi-stakeholder groups in selecting quality and efficiency measures. The Measures Application Partnership is the public-private partnership comprised of multi-stakeholder groups convened by NQF for the primary purpose of providing input on measures as required by sections 1890A(a)(1) and (3) of the Act. The Measures Application Partnership's input on the quality and efficiency measures under consideration for adoption in CY 2012 was transmitted to the Secretary on February 1, 2012 and is available at (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69885*). As required by section 1890A(a)(4) of the Act, we considered these recommendations in selecting quality and efficiency measures for the ESRD QIP.

Four proposed measures for the PY 2015 ESRD QIP (that is, three for dialysis adequacy and one for hypercalcemia) were made publicly available in accordance with section 1890A(a)(2) of the Act and were reviewed by the Measures Application Partnership. The Measures Application Partnership gave support to two of the proposed measures, NQF #1454: Proportion of patients with hypercalcemia and NQF #1423: Minimum spKt/V for Pediatric Hemodialysis Patients. The Measures Application Partnership supported the direction of a proposed composite measure comprised of two NQF-endorsed measures, NQF #0249: Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy—HD Adequacy—Minimum Delivered Hemodialysis Dose and NQF #0318: Peritoneal Dialysis Adequacy Clinical Performance Measure III—Delivered Dose of Peritoneal Dialysis Above Minimum. The Measures Application Partnership recommended that the composite measure comprised of the two NQF dialysis adequacy measures be tested to ensure feasibility. We took these comments into consideration when we proposed measures for the PY 2015 ESRD QIP.

4. PY 2014 Mineral Metabolism Measure

In the CY 2012 ESRD PPS final rule, we adopted the Mineral Metabolism reporting measure for the PY 2014 ESRD QIP which requires each facility to attest that it monitored serum calcium and serum phosphorus at least once a month for each Medicare ESRD patient (76 FR 70271). We have since realized, however, that it may be difficult for some facilities to make this attestation if, for example, a patient is seen at the beginning of the month, his or her blood is not drawn, and then he or she is hospitalized or transient for the remainder of the month. While it is our intention to encourage facilities to put systems and processes into place to ensure at least monthly serum calcium and phosphorus monitoring, we believe it is reasonable to give consideration to situations where the monthly blood draw does not happen within the dialysis facility given these scenarios. Therefore, for PY 2014, we proposed to change the Mineral Metabolism reporting requirement.

We considered proposing to require facilities to report the required information for less than 100 percent of their patients. There are circumstances, however, that are beyond a facility's control wherein it may not be able to

draw a sample for this patient. Therefore, for purposes of scoring the measure, we proposed to modify the PY 2014 measure to require that, in order for a facility to receive 10 points on the PY 2014 Mineral Metabolism measure, it must attest that it monitored on a monthly basis the serum calcium and serum phosphorus levels for every Medicare ESRD patient provided that: (i) The patient is alive for the entirety of the applicable month; (ii) if the patient is treated in-center, that patient was treated at that facility at least twice during the claim month; and (iii) if the patient receives dialysis at home, a facility must report this information regardless of the number of treatments, provided that a claim is submitted for that patient. We also proposed that if a patient is hospitalized or transient during a claim month, the facility could monitor the serum calcium and serum phosphorus readings for that patient for the month if a patient has labs drawn by another provider/facility, those labs are evaluated by an accredited laboratory (a laboratory that is accredited by, for example, Joint Commission, College of American Pathologists, AAB (American Association of Bioanalysts), or State or Federal agency), and the dialysis facility reviews the serum calcium and serum phosphorus readings. We stated our belief that these proposals will provide more flexibility for facilities and will also prevent facilities from drawing blood, even when not necessary, each time a patient visits for fear that he or she will fail to come to the facility again during that month. We requested comment on this proposal.

We also requested comment on our consideration to lower the attestation to monthly monitoring of 98 percent of Medicare ESRD patients. We chose 98 percent in order to encourage improvement, and to ensure that we do not undermine the current level of high-reporting (based on the CROWNWeb pilot data). We recognize that 100 percent might not be appropriate due to some individual cases that may not fit specified criteria.

Additionally, for purposes of clarification, we noted that the PY 2014 attestations for both the Mineral Metabolism and ICH CAHPS measures will become available in CROWNWeb in December 2012. As noted in the CY 2012 ESRD PPS final rule, these attestations must be made before January 31, 2013 (76 FR 70269, 70271).

We received the following comments on these proposals:

Comment: Many commenters were appreciative of our willingness to revisit our requirements for the PY 2014 Mineral Metabolism attestation. Some commenters suggested that we modify the exclusion to include the following patients: (i) Beneficiaries who are regularly treated at the facility and who fit into one of these categories: (a) Beneficiaries who die within the applicable month; (b) beneficiaries that receive fewer than 7 treatments in a month; and (c) beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented, good faith effort to have them participate in such a visit during the applicable month; (ii) transient dialysis patients; (iii) pediatric patients (unless the measure is specific to this population); and (iv) kidney transplant recipients with a functioning graft. Commenters stated that these exclusions are consistent with our own measures, CROWNWeb, and the URR reporting specifications; additionally, these exclusions seek to hold facilities accountable only for those beneficiaries to whom they regularly give care and for whose care they can affect. One commenter believed that home dialysis patients should only be included if they attend their monthly visit. One commenter requested that we use NQF inclusion criteria for purposes of defining the exclusions of the Mineral Metabolism reporting measure.

Response: Upon further review, we agree with commenters who believe that the exclusions should be modified. We recognize that treating a patient twice may not provide enough time to effectuate quality patient care. We agree with the commenters who suggested that an in-center hemodialysis patient should be excluded if treated by a facility fewer than seven times during the month, regardless of whether the patient is officially admitted to that facility. With seven treatments, we believe that a facility should have had adequate opportunities to draw blood necessary to measure serum calcium and phosphorus levels. We also believe that the threshold of seven will discourage unnecessary testing of in-center hemodialysis patients by facilities because they will know that, since in-center patients are typically treated three times per week, a patient must have been treated by the facility for at least two weeks to be included; thus, the facility need not feel pressure to draw blood for every in-center patient during the first few visits of the month. Based on these considerations, we will not finalize our proposal to exclude only in-center patients who have been treated fewer than two times by the facility during the claim month. Instead, we will exclude any patient who is treated by the facility fewer than seven times during the reporting month.

We do not believe that it is necessary to specifically exclude transient patients from this measure because, as noted, any patient that is treated by the facility at least seven times during the applicable reporting month is present at the facility for enough time that the facility should be held accountable for that patient. Likewise, for the same reasons mentioned above, we do not believe we need to separately exclude patients who are deceased at the end of the reporting month. Provided that the patient is treated by the facility at least seven times during that month, the facility should be able to draw blood necessary to monitor serum calcium and serum phosphorus levels even if the patient is deceased at the end of the month.

We continue to believe that facilities should be required to attest that they monitored the serum calcium and phosphorus levels of home dialysis patients irrespective of whether those patients attend a monthly appointment. We believe that it is incumbent upon a facility to make home dialysis patients aware that they must attend monthly appointments to be properly treated. In addition, since the mechanisms that cause cardiovascular and bone disease do not differ between home and in-center hemodialysis patients, we believe that the inclusion of home dialysis patients in the Mineral Metabolism reporting measure is appropriate. Therefore we will finalize our proposal that we will include any home hemodialysis patient for which a facility submits a claim with respect to the reporting month in this measure.

We also believe it is important to include transplant patients until they are officially discharged from a facility; regular monitoring can help ensure that a transplant remains effective and that the facility is continuing to provide the best care possible.

We believe it is important to monitor serum calcium and serum phosphorus levels in adult and pediatric patients alike because improper bone mineral metabolism management can lead to serious, negative outcomes, including death, in both populations. Although we are aware that specific target values for calcium and phosphorus have not been set for the pediatric population, we still believe that this measure will lead to better observation of mineral metabolism in these patients if one or both of these values are unusually high or low. Additionally, we believe that the inclusion of pediatric patients in this measure is consistent with current guidelines on the frequency of mineral

metabolism testing as reported in KDIGO guidelines chapter 3 ''Diagnosis of CKD–MBD: biochemical abnormalities.'' Thus, we believe that this measure is appropriate for both adult and pediatric patients.

Finally, we do not believe that we must use NQF inclusion criteria for this measure. Although we seek to align our measures and our selection criteria with NQF as much as possible, as we stated in the CY 2011 ESRD PPS Final Rule, we believe it is appropriate, at this time to employ a measure that has not been NQF-endorsed (76 FR 70271 through 72).

For the reasons stated above, we are finalizing that to earn 10 points on the Mineral Metabolism reporting measure, facilities must attest in CROWNWeb that they have monitored the serum calcium and serum phosphorus levels on a monthly basis for (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim.

Comment: Several commenters encouraged us to not adopt a percentage reporting threshold because it does not distinguish between beneficiaries legitimately excluded and those that were merely missed. Other commenters requested that we use both exclusions and a threshold, recognizing that there are some circumstances preventing blood draws that facilities cannot control; one commenter suggested a threshold of 90 percent or an allowance of two patients to ensure that small facilities are not disproportionally affected. Another commenter recommended that we use a threshold of 95 percent. Another commenter stated that requiring 98 percent reporting may make it difficult for patients to travel because dialysis facilities may encourage them otherwise to ensure compliance with the measure.

Response: We agree with the commenters who argued that, even with exclusions, there are circumstances in which facilities cannot attest to monitoring the serum calcium and serum phosphorus levels for every patient at least once per month. For example, a facility may wait until later to draw blood from a patient because it believes that patient will be treated by the facility for the entirety of the month, but learns that the patient has been hospitalized unexpectedly for all or part of the applicable month. Therefore, we believe that we should not require an attestation of 100 percent monitoring. Based on data from the CROWNWeb pilot, we believe that facilities report serum calcium and serum phosphorus levels for approximately 96 percent of their patients. Therefore, we will finalize that facilities must attest to monitoring calcium and phosphorus on a monthly basis for at least 96 percent, in total, of (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim.[1]

We are concerned that small facilities may be disproportionately impacted by this 96 percent reporting threshold because, for example, a facility with 10 patients could miss monitoring for only one patient and fail to meet the threshold. We have previously stated that, to disincentivize cherry picking, we seek to ensure that one patient does not skew a facility's score. We do, however, seek to ensure the highest quality of care regardless of the facility size. Taking these two competing interests into consideration, we believe that it is appropriate to allow facilities that treat less than 11 Medicare patients during the performance period to attest that they have met the requirements for this measure if they monitored the serum calcium and serum phosphorus levels on a monthly basis for at least all but one of its (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. We believe 11 is the appropriate cut-off because, as we explain below, a case minimum of 11 allows us to include as many facilities as possible while also taking into account privacy and reliability. We believe that one is the appropriate number because, as noted above, although we seek to ensure the highest quality of care regardless of facility size, we also seek to mitigate cherry-picking by ensuring that one patient does not skew a facility's score.

Comment: Many commenters noted that it is impractical for facilities to obtain labs from other providers because other providers are not required to measure these data, do not share data with dialysis facilities, and, even if facilities could obtain these data, they could not be sure that the labs were consistent or reported under the same standards.

Response: We recognize that it may be difficult for facilities to coordinate with hospitals and other care providers in order to obtain lab values. Accordingly, we are not mandating facilities to do so. In the proposed rule (77 FR 40969), we stated that facilities may obtain lab values from other providers. This proposal was specifically designed to afford facilities more flexibility in acquiring serum calcium and phosphorus values. Facilities are highly encouraged to coordinate with other providers, but this measure does not mandate them to do so. We believe that the commenters' concerns about inconsistent lab data are mitigated by the requirement that the lab must be accredited. Facilities can use these values for the purpose of monitoring the serum calcium and phosphorus levels of their patients; additionally, collecting these data may encourage providers to engage one another about the patient's conditions and care.

Comment: Several commenters asked for clarification on the following points: (1) Are only Medicare patients included in the denominator, (2) are Medicare Railroad and Medicare Advantage (MA) patients included in the denominator, (3) could CMS give an example of an accurate application of the exclusions and/or threshold, (4) if CMS institutes a threshold, would it be rounded, (5) if a patient is excluded from the measure for attestation purposes, must his or her values still be reported in CROWNWeb, and (6) how does CMS plan on counting the number of treatments for home patients.

Response: We will address these questions in turn.

First, a facility treating at least 11 Medicare patients during the performance period is required to monitor serum calcium and serum phosphorus on a monthly basis for all (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. These patients include Medicare Advantage and Medicare Railroad beneficiaries.

As an example of the application of the exclusions and threshold, assume the following: (i) A facility treats 30 Medicare patients in month X; (ii) patient A is an in-center hemodialysis patient who was treated by the facility seven times during the first two weeks of month X, but the facility failed to obtain a blood draw during this period, and the patient is in the hospital for the next two weeks of month X but the facility monitors the patient's serum phosphorus and calcium by obtaining these values from the hospital; (iii) patient B and C are both in-center hemodialysis patients who were treated by the facility at least seven times during month X, but the facility fails to monitor the serum calcium and serum phosphorus of these patients during

[1] We note that the reporting requirements are somewhat different for CROWNWeb. All patients must be reported for CROWNWeb purposes, even if those patients would not be included in the measure for purposes of the ESRD QIP.

month X; (iv) patient D was visiting the facility and was treated by the facility only 4 times during month X; and (v) the facility monitors the serum calcium and serum phosphorus on a monthly basis for every other (i) in-center Medicare patient who had been treated at least seven times by the facility during month X; and (ii) home hemodialysis Medicare patient for whom the facility submitted a claim during month X. The facility is considered to have monitored the serum calcium and serum phosphorus during month X for every patient except B and C because patient D was only treated four times during the month and the facility obtained the values for patient A from another provider. The facility's monitoring rate for month X is 27/29, or 93.1 percent (rounded to 93 percent). A facility with 30 patients must attest that it monitored on a monthly basis the serum calcium and serum phosphorus for all (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. Therefore, this facility could not attest that it successfully monitored the serum calcium and serum phosphorus in total for at least 96 percent of its (i) in-center Medicare patients who had been treated at least 7 times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submitted a claim.[2] For purposes of this measure, facilities may round up to a whole percentage point when calculating whether they met the 96 percent threshold.

Finally, for the reasons discussed above, facilities will be required to monitor the serum calcium and serum phosphorus at least once per month for every home hemodialysis patient for whom it submits a claim regardless of the number of treatments during that month.

Comment: Many commenters requested that we revisit various aspects of the PY 2014 ESRD QIP.

Response: The PY 2014 ESRD QIP was finalized on November 1, 2011 (76 FR 70228). Although we requested comment regarding the PY 2014 Mineral Metabolism reporting measure in the proposed rule, we did not propose to reconsider any other elements of the PY 2014 program. Therefore, we consider these comments to be outside the scope of the proposed rule. We refer readers to the 2012 ESRD PPS final rule for more information on the finalized PY 2014 ESRD QIP (76 FR 70228).

For the reasons stated above, we finalize that a facility treating at least 11 Medicare patients during the performance period can attest to meeting the requirements of the PY 2014 Mineral Metabolism reporting measure if it monitors on a monthly basis the serum calcium and serum phosphorus for at least 96 percent in total of all (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. We also finalize that a facility treating fewer than 11 Medicare patients during the performance period can attest to meeting the requirements of the PY 2014 Mineral Metabolism reporting measure if it monitors on a monthly basis the serum calcium and serum phosphorus levels for at least all but one of its (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim.

D. Proposed Measures for the PY 2015 ESRD QIP and Subsequent PYs of the ESRD QIP

Similar to our other quality reporting and pay for performance programs, we proposed that once a quality measure is selected and finalized for the ESRD QIP through rulemaking, the measure would continue to remain part of the program for all future years, unless we remove or replace it through rulemaking or notification (if the measure raises potential safety concerns). We believe that this will streamline the rulemaking process, provide continuity of quality measurement, and allow ESRD facilities to plan both quality reporting and quality improvement activities. In general, we anticipate considering quality measures for removal or replacement if: (1) Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made; (2) performance or improvement on a measure does not result in better or the intended patient outcomes; (3) a measure no longer aligns with current clinical guidelines or practice; (4) a more broadly applicable (across settings, populations, or conditions) measure for the topic becomes available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available; (6) a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or (7) collection or public reporting of a measure leads to negative unintended consequences. If there is reason to believe that a measure raises potential safety concerns, we proposed that we would take immediate action to remove the measure from the ESRD QIP and not wait for the annual rulemaking cycle. We proposed that such measures would be promptly removed from the measure set, and we would confirm the removal in the next ESRD QIP rulemaking cycle. ESRD facilities and the public would be immediately notified of our decision to remove a measure that raises potential safety concerns through the usual ESRD program communication channels, including memos, email notification, and web postings.

Many of the quality measures used in different Medicare and Medicaid reporting programs are endorsed by NQF. As part of its regular maintenance process for endorsed performance measures, the NQF requires measure stewards to submit annual measure maintenance updates and undergo maintenance of endorsement review every 3 years. Under the measure maintenance process, the measure steward (owner/developer) is responsible for updating and maintaining the currency and relevance of the measure and confirming specification changes to NQF on an annual basis. NQF solicits information from measure stewards for annual reviews in order to review measures for continued endorsement in a specific 3-year cycle. Non-NQF-endorsed measures may also go through similar maintenance by their measure stewards; such maintenance includes reviewing and updating measures.

Through the measure maintenance process, measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measures. Examples could be changes to exclusions to the patient population, changes to definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes to measures that result in what are considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

We proposed that if a measure that we have adopted for the ESRD QIP is updated in a manner that we consider to not substantially change the nature of the measure, we would use a

[2] Note that, for ease, we provided an example for only one month. However, to make the attestation, a facility must monitor for the duration of the performance period the serum calcium and serum phosphorus levels on a monthly basis for all (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim.

subregulatory process to incorporate those updates to the measure specifications that apply to the program. Specifically, we would revise our previously adopted measure specifications to clearly identify the updates made by the NQF or other measure steward and either post the updates directly on the CMS Web site or provide links to where the updates can be found. We would also provide sufficient lead time for facilities to implement the changes where changes to the data collection systems would be necessary.

We proposed to continue to use the rulemaking process to adopt changes to a measure that we consider to substantially change the nature of the measure. We stated our belief that this proposal adequately balances our need to incorporate updates to ESRD QIP 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 this proposal and on our proposal that once a quality measure is adopted, it is retained for use in the subsequent ESRD QIP payment years unless we remove or replace it as discussed above.

The comments we received on these proposals and our responses are set forth below.

Comment: Commenters requested clarification regarding the removal or replacement criteria for measures, specifically the criteria listed in (2) and (5) and the process for removal or replacement. Commenters suggested that CMS provide illustrative scenarios and consider convening an emergency technical expert panel (TEP) to identify and analyze removal or replacement issues. Commenters also encouraged us to add two criteria for removal or replacement: (i) Negative unintended consequences to the Medicare ESRD system as a whole; and (ii) if data for a measure cannot be collected reliably and accurately or if collecting the data places an undue burden on facilities. One commenter asked that CMS confirm that we will use rulemaking to retire or remove measures from the ESRD QIP. Finally, the commenters stated that some of the measures proposed meet the replacement and removal criteria and suggested that CMS implement only new measures that meet the proposed criteria.

Response: We thank those commenters who provided suggestions regarding the criteria and process for measure replacement or removal from the ESRD QIP. We concur with those commenters who argue in favor of implementing measures that meet the proposed criteria. We do not believe that an emergency technical expert panel (TEP) is an appropriate part of the removal process, as we typically convene TEPs in order to obtain expert stakeholder input as part of the measure development process. These TEPs are convened as needed during the measure maintenance cycle and can provide any necessary comment regarding the clinical appropriateness of implemented measures. Emergency TEPs would also be difficult and expensive to employ quickly, such as in response to public comments in support of measure removal. We will consider the inclusion of additional removal criteria such as those suggested by commenters through future rulemaking, but will finalize the proposed criteria to remain consistent with similar criteria implemented for other quality reporting and pay-for-performance programs, such as the Hospital Inpatient Quality Reporting Program and Hospital Outpatient Quality Reporting Program. The second criterion we proposed, the availability of alternative measures with a stronger relationship to patient outcomes, is intended to allow us to implement new measures in the ESRD QIP that have a stronger association with relevant health outcomes. Such measures may better assess the quality of care provided by dialysis facilities and in such cases, we believe it would be appropriate to reflect this in the ESRD QIP. Our use of the fifth criterion is consistent with this principal, and would be applied in those circumstances where we believe existing measures are not as temporally proximal to health outcomes of interest as are newly available measures. We believe that in such cases, it would be appropriate to remove these measures, rather than simply increase the volume of quality measures for which dialysis facilities are responsible under the ESRD QIP.

Except for measures that raise potential safety concerns, any decisions to remove or replace measures under the ESRD QIP will be made through the rulemaking process. Each year, we will assess whether any measures should be removed or replaced under the ESRD QIP, and we will make appropriate proposals during the rulemaking cycle. Stakeholders will then have the opportunity to provide feedback regarding the proposed removal or replacement of these measures, and the rationale behind our proposals. Any measure removal will then be finalized as part of the ESRD PPS final rule.

We take the suggestion that we implement only new measures that meet the proposed criteria to mean that we should implement only measures that do not meet the proposed removal criteria. We recognize the potential value in taking these criteria into consideration for measure implementation, and believe we do so to the extent practicable. However, we believe that we must take into consideration additional criteria, such as statutory requirements governing the ESRD QIP and emergent public health and safety issues, when determining what measures to propose and finalize for the program. In some cases, it is possible that these issues will take precedence over the criteria proposed for measure removal.

Comment: Several commenters urged us to adopt measure specifications and data definitions that are clear, modifying this information through rulemaking alone. Commenters argued that it is only appropriate to use sub-regulatory processes to aid facilities in interpreting the specifications and definitions, and suggested that we develop a regular and transparent process for collecting and responding to these questions, ideally on a quarterly basis with a schedule set forth in rules.

Response: We thank those commenters who provided feedback to our proposal to update NQF-endorsed measures using a subregulatory process. We concur that measure specifications and data definitions should be clear. However, we believe that using a subregulatory process to make certain types of updates to measures is appropriate. 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 non-substantive updates made by the NQF to the measure specifications we have adopted for the ESRD QIP so that these measures remain up-to-date and clinically relevant. 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, we are finalizing a policy under which we will use a subregulatory process to make non-substantive updates to NQF-endorsed measures used for the ESRD QIP. With respect to what constitutes substantive versus non-substantive changes, we expect to make this determination on a case-by-case basis. Examples of non-substantive changes 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 used in the Hospital IQR Program). We believe that non-substantive changes may include updates to NQF-endorsed measures based upon changes to guidelines upon which the measures are based.

We will continue to use rulemaking to adopt substantive updates made by the NQF to the endorsed measures we have adopted for the ESRD QIP. 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 the 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 non-substantive would apply to all ESRD QIP measures. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process.

We aim to be as transparent as possible in implementing the ESRD QIP. Occasionally, questions arise related to measures that have been adopted. We plan to publish these questions and answers on a publicly available Web site. We will consider standardizing a timeline for submission of and answers to these questions as the program evolves.

For the reasons discussed above, we are finalizing our proposal regarding continued use of measures in the ESRD QIP unless we remove or replace them. We are also adopting a policy under which we will use a subregulatory process to make non-substantive updates to measures, and will use the rulemaking process to make substantive updates to measures.

1. PY 2014 Measures Continuing for PY 2015 and Subsequent PYs

We previously finalized six measures including one measure with two measure sub-components (see Table 2 below) for the PY 2014 ESRD QIP (76 FR 70228). We proposed to continue to use five of these measures for the PY 2015 ESRD QIP; however, we also proposed to augment two (NHSN Dialysis Event reporting and Mineral Metabolism reporting) of these five measures used in PY 2014 to continue to promote improvement in the PY 2015 ESRD QIP. We proposed to remove the PY 2014 URR Dialysis Adequacy measure. In addition, we proposed to add three new measures of dialysis adequacy, an anemia management reporting measure, and a hypercalcemia clinical measure (Table 3).

TABLE 2—MEASURES ADOPTED FOR THE PY 2014 ESRD QIP

NQF No.	Measure title	
N/A	Percent of Patients with Hemoglobin Greater Than 12 g/dL*	
N/A	URR Hemodialysis Adequacy	
N/A for composite measure	Vascular Access Type	Hemodialysis Vascular Access-Maximizing Placement of Arterial Venous Fistula (AVF)* (NQF#0257). Hemodialysis Vascular Access-Minimizing use of Catheters as Chronic Dialysis Access* (NQF#0256).
N/A[1]	NHSN Dialysis Event Reporting*+ Enroll and report 3 months of dialysis event data.	
N/A[2]		In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Reporting* Facilities are required to attest that they administered the ICH CAHPS survey via a third party during the performance period.
N/A[3]		Mineral Metabolism Reporting Facilities are required to attest that they have monitored each of their Medicare patient's phosphorus and calcium levels monthly throughout the performance period.*+

[1] We note that an NQF-endorsed bloodstream infection measure (NQF#1460) exists, and data for this measure is collected as part of dialysis event reporting in NHSN. It is our intention to use this measure in future years of the ESRD QIP. We believe that a reporting measure is a necessary step in reaching our goal to use NQF#1460.

[2] We note that a related measure utilizing the results of this survey has been NQF-endorsed (#0258), and it is our intention to use this measure in future years of the ESRD QIP. We believe that a reporting measure is a necessary step in reaching our goal to use NQF#0258.

[3] We note that the NQF has previously endorsed phosphorus and calcium monitoring measures (#0261 and #0255) upon which this measure is based. NQF has since withdrawn its endorsement of the calcium measure.

* Indicates a measure we are proposing for PY 2015 and future years of the ESRD QIP.

+ Indicates a measure we are proposing to augment for PY 2015 and future years of the ESRD QIP.

TABLE 3—NEW MEASURES PROPOSED FOR THE ESRD QIP PY 2015 AND FUTURE YEARS OF THE PROGRAM

NQF No.	Measure title
N/A	Anemia Management Reporting.
0249	Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy—HD Adequacy—Minimum Delivered Hemodialysis Dose.
0318	Peritoneal Dialysis Adequacy Clinical Performance Measure III—Delivered Dose of Peritoneal Dialysis Above Minimum.
1423	Minimum spKt/V for Pediatric Hemodialysis Patients.
1454	Proportion of Patients with Hypercalcemia.

We proposed to continue using two measures and one measure topic adopted in PY 2014 for the PY 2015 ESRD QIP and subsequent payment years of the program. For the reasons stated in the CY 2012 ESRD PPS final rule (76 FR 70262, 70264 through 65, 70269), we proposed to continue using: (i) The Hemoglobin Greater than 12 g/dL measure; (ii) the Vascular Access Type measure topic comprised of two measures, (a) the Hemodialysis Vascular Access-Maximizing Placement of AVF (NQF #0257) measure, and (b) the Hemodialysis Vascular Access-Minimizing use of Catheters as Chronic Dialysis Access (NQF #0256) measure; and (iii) the ICH CAHPS survey reporting measure. The technical specifications for these measures can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/Anemia Management-HGB-2015-NPRM.pdf; http://www.dialysisreports.org/pdf/esrd/public-measures/VascularAccess-Catheter-2015-NPRM.pdf; http://www.dialysisreports.org/pdf/esrd/public-measures/VascularAccess-Fistula-2015-NPRM.pdf;* and *http://www.dialysis reports.org/pdf/esrd/public-measures/ICHCAHPS-2015-NPRM.pdf.* We requested comment on the proposed continuation of these measures.

The comments we received on these proposals and our responses are set forth below. We will separately discuss each of the measures and the comments received on these measures.

a. Hemoglobin Greater Than 12 g/dL

Comment: Many commenters strongly supported the continuation of this measure, specifically because proper anemia management can prevent patients from developing serious, life threatening conditions. Other commenters, however, asked that we consider removing the measure or reducing its weight since high hemoglobin and ESA overuse no longer pose a realistic concern because of the economic incentives of the ESRD PPS payment bundle and the new clinical evidence and FDA-approved label for ESAs (*http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm).* One commenter noted that the TREAT study and its own research indicate that large ESA doses, rather than high hemoglobin levels, result in adverse effects. Finally, one commenter believes that the Hemoglobin Greater Than 12 g/dL measure leads to confusion because physicians begin increasing ESA dosage only after hemoglobin levels have fallen far below 12 g/dL, resulting in an increase in patients with low hemoglobin levels. The same commenter noted that it is difficult to incentivize clinics to provide proper ESA dosage with the ESRD PPS payment bundle and the Hemoglobin Greater than 12 g/dL measure combined. Finally, one commenter urged us to individualize anemia management measures.

Response: We appreciate feedback relating to the use of the Hemoglobin Greater Than 12 g/dL measure in the ESRD QIP. We recognize that changes in the incentive structure for ESA therapy may have consequences for ESA utilization. We feel, however, that because of the negative clinical outcomes that can result from high hemoglobin levels in the ESRD population, this measure is still important in ensuring that facilities provide quality care.

We also appreciate the need to consider dosage and clinical practice when ascertaining the potential adverse effects of ESA therapy. We have begun to develop additional anemia management measures that account for ESA dose. These measures are focused on utilization of ESAs and transfusion avoidance to further incentivize proper care. We intend to propose to adopt one or more of these measures for the ESRD QIP in future rulemaking.

Finally, we agree that it is important to individualize care for each beneficiary. We believe that the Hemoglobin Greater than 12 g/dL measure both allows facilities discretion to properly manage hemoglobin levels in each patient and prevents adverse patient outcomes associated with hemoglobin levels that are too high. However, we recognize that greater individualization may be possible and are currently working to develop additional anemia management measures that will enhance this aspect of the ESRD QIP.

Comment: Several commenters supported the measure, generally, but asked us to make refinements. One commenter suggested that we measure hemoglobin on a three or 6-month rolling basis rather than monthly because monthly measurement does not provide a comprehensive assessment of the care patients are receiving; studies show that although hemoglobin levels can fluctuate greatly within short periods of time, the mean hemoglobin level can remain in the measure target range. Another commenter stated that, as the measure is currently conceived, facilities cannot act on its results. Because it takes time for hemoglobin levels to change, one commenter recommended excluding patients who have been on ESA therapy for one month or less and patients whose ESA therapy was promptly discontinued once the facility became aware that their hemoglobin levels were over 12 g/dL. Finally, one commenter noted that hemoglobin levels at high altitude facilities are more likely to be greater than 12 g/dL.

Response: We thank the commenters who made suggestions regarding the refinement of the Hemoglobin Greater Than 12 g/dL measure. Addressing the concern commenters raised with the high degree of variability in hemoglobin from month to month, the measure rate is calculated using the average hemoglobin of a patient over 4–12 months. For example, if a patient is treated for 4 months, then we use the average of the 4-month period to calculate the measure rate. If a patient is treated for 5 months, we use the average from that 5-month period and so on. Relevant to concerns raised about the exclusion of patients who have just begun ESA therapy, the measure currently excludes new patients (less than 90 days since ESRD onset), and excludes claims for which there is no evidence of ESA use. We believe these exclusions address the commenters' concerns. Regarding the comment that hemoglobin levels at high altitude facilities are more likely to reach the measure threshold, we do not currently employ risk adjustment for the measure for this or other environmental factors that could conceivably have similar impacts. However, we plan to conduct monitoring and surveillance of our quality measures for issues such as geographical variation.

Comment: One commenter argued that using patients' yearly averages for measures fails to test the actionability of the measures because it is difficult to identify areas of improvement until the end of the year. Instead, the commenter suggests ''per-facility averaging,''—averaging of end-of-month hemoglobin results for each facility's patients, each month, then averaging up to 12 of those facility monthly averages, which this commenter argued allows facilities to know their year-to-date numerators and denominators, fostering ongoing quality incentive and process improvement.

Response: We appreciate the commenter's suggestion regarding per-facility averaging and all feedback to improve the usefulness of our quality measures to facilities. However, we believe that averaging hemoglobin over multiple patients in a facility would be inconsistent with medical guidance, which deals with patient specific situations. We believe that facilities should strive to provide the best care to each patient treated by the facility.

Comment: One commenter requested confirmation that patients who are not

on ESA therapy are not included in the Hemoglobin Greater than 12 g/dL measure.

Response: The measure rate is calculated using claims that include a hemoglobin level and ESA dosing information.

Comment: Several commenters requested that we include a measure in the ESRD QIP that establishes a floor for hemoglobin, specifically noting that, because of the bundle, there may be a perceived financial incentive to underutilize ESAs. They argued that studies have shown that as hemoglobin drops below 10, mortality and hospitalization increase, and that hemoglobin levels affect a patient's quality of life (both empirically and anecdotally). Some commenters stated that we should reinstate the Hemoglobin Greater than 10 g/dL measure that we used in the PY 2012 ESRD QIP, arguing that the measure is reliable and is consistent with the FDA-approved labeling which recognizes the importance of transfusion avoidance and recommends that initiation of ESA therapy be considered when the hemoglobin level falls below 10 g/dL. One commenter argued that patients should be allowed to make decisions about their quality of life and safety, even if that means keeping the hemoglobin level higher than recommended. Other commenters noted that patients with hemoglobin less than 10 g/dL are increasing, as are the rate of transfusions, and increased transfusions can decrease the chances of a successful transplant; in turn, failed transfusions can increase the cost of care since patients with transplants cost less than those on dialysis. One commenter stated that we should specifically consider reinstituting a hemoglobin floor if the United States Renal Data Service information shows that transfusion rates have risen significantly. Other commenters suggested that even if we do not adopt a measure for low hemoglobin, we report hemoglobin levels, transfusion rates, and ESA dosage on DFC and include the Hemoglobin Less than 10 g/dL measure on DFC. Finally, other commenters urged us to continue to monitor and support metrics such as transfusions, quality of life, reactivity to antibodies preventing transfusions, and underutilization of ESAs.

Response: We thank the commenters for bringing to us their concerns about the ESRD PPS payment bundle potentially increasing the risk for underutilization of ESA therapy. As noted in the CY 2012 ESRD PPS final rule (76 FR 70257), we could not at the time identify a specific hemoglobin lower bound level that has been proven safe for all patients treated with ESAs, and the state of evidence supporting such a lower bound remains weak. For these reasons, we believe that the rationale for removing the Hemoglobin Less Than 10 g/dL measure from the ESRD QIP measure set remains valid. However, we recognize that the potential for ESA underutilization is an important issue. As noted in the CY 2012 ESRD PPS final rule (76 FR 70257), we will continue to monitor the Medicare ESRD population for evidence of underutilization of ESAs, a rise in blood transfusions, and the replacement of ESA therapy with transfusions. Although we are no longer including the Hemoglobin Less than 10 g/dL measure in the ESRD QIP (and will no longer be publicly reporting it on DFC beginning January 2013), the results will be available via a downloadable file for facilities to provide for continued monitoring of the measure. Finally, we continue to work with stakeholders through a consensus-based measure development process to produce measures capable of addressing ESA underutilization and blood transfusions, while remaining consistent with the existing relevant guidelines and evidence base.

We also appreciate comments encouraging us to move toward implementing quality of life and other patient-centered measures that address anemia management. These measurement domains are important to us and we plan to develop appropriate measures to be implemented in the ESRD QIP during future rulemaking.

For the reasons stated above, we will continue to use the Hemoglobin Greater than 12 g/dL measure for PY 2015 and future years of the ESRD QIP. The technical specifications for this finalized measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/AnemiaManagement-HGB-2015-FR.pdf*

b. Vascular Access Type (VAT) Measure Topic

Comment: Many commenters strongly supported our continued inclusion of the VAT measure topic in the PY 2015 ESRD QIP. Many commenters, however, also expressed concern that the composite measure over-emphasizes fistulae, underemphasizes grafts, and, therefore, promotes inappropriate care in some cases. Commenters noted that fistulae are not suitable for some patients, fistulae take time to mature, and grafts are sometimes the most clinically appropriate. Several commenters asked us to decrease the emphasis on fistulae by developing a graft measure and, in the meantime, weight the catheter measure at ⅔ of the VAT measure topic and the fistula measure at ⅓ of the VAT measure topic. Other commenters urged us to take a ''fistula first, catheter last'' approach that would award some points for patients with grafts. Commenters were also concerned that the fistula standards are too stringent and could cause unintended consequences such as ''cherry-picking'' patients who are not eligible for a fistula. Commenters suggested that we exclude or allow doctors to exclude certain patients from the measure's denominator providing for more individualized care, noting that studies show that facilities are unlikely to ''game'' such an exception.

Response: As discussed in the CY 2011 ESRD PPS Final Rule, we continue to believe that the VAT measure topic and its respective weights incentivize the best care for ESRD beneficiaries (76 FR 70265, 70275). Catheters are undesirable due to their high rate of complications, such as infections, and we discourage their use through the catheter measure. We believe that the preferred type of vascular access is an AV fistula due to lower rates of complications, which we promote through the fistula measure. Although grafts do decrease the risk of infections and complications when compared to catheters, grafts do not decrease these risks as much as fistulae. We, therefore, do not believe that grafts are either beneficial enough to be specifically rewarded or harmful enough to be specifically penalized. Furthermore, we do not believe it is in the best interest of patients to weight the fistula measure more than the catheter measure because our primary goal is to promote fistula use; we believe that both measures are equally important in promoting the best clinical practices with respect to VAT.

We recognize that the catheter measure could incentivize ''cherry-picking'' of patients, leading to access to care issues for patients with catheters. We are actively monitoring access to care and other potential issues associated with ''cherry-picking,'' and it is our intent to engage the community as we monitor these issues.

Comment: One commenter encouraged us to promote fistulae in pediatric patients as well as adults.

Response: We thank the commenter who encouraged the promotion of fistulae use in pediatric patients. The NQF-endorsed fistula measure excluded pediatric patients. Children on chronic dialysis have a fundamentally different psychosocial profile than adults. Fistula use, with its attendant frequent painful needle sticks are less commonly used in

children than adults. In addition, there are technical issues that make fistula creation more difficult in children. We will continue to investigate whether there are measures in existence or that could be developed for the purpose of appropriately addressing vascular access among pediatric patients and may propose to adopt one or more of these measures in future rulemaking.

For the reasons listed above, we will continue to use the VAT measure topic for PY 2015 and future years of the ESRD QIP. The technical specifications for the finalized measures in this measure topic can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/VascularAccess-Catheter-2015-FR.pdf* and *http://www.dialysisreports.org/pdf/esrd/public-measures/VascularAccess-Fistula-2015-FR.pdf*.

c. In-center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS)

Comment: Many commenters supported the measure in its entirety. Many commenters supported monitoring patients' experiences, but believe the ICH CAHPS survey, with 57 questions, is too burdensome and lengthy for beneficiaries to complete. These commenters requested that we minimize this burden and suggested that the ICH CAHPS survey be parsed into three parts, with each patient receiving one of these parts and a group of core questions. Commenters also suggested that CMS allow facilities to give patients the survey and allow patients to return surveys via a ''drop-box'' at the facility or by mail to the third-party administrator; commenters believe this approach will improve the response rate as patients are less likely to ignore the survey and one commenter noted that, without such an approach, the experiences of homeless patients will not be recorded.

Response: As we noted in the 2012 ESRD PPS Final Rule, we continue to believe that assessing the experiences of patients is vital to quality care (76 FR 70269 through 70). Patient surveys can, and should, draw a facility's attention to issues that can only be raised by those receiving care. Although commenters may consider the survey to be burdensome to patients, the CAHPS tool went through extensive testing during development including focus groups and one-on-one patient sessions which assessed this burden and created specifications accordingly. Furthermore, we believe that concerns about patient burden can be at least partially mitigated without decreasing the number of questions on the survey or how the survey is administered. For example, as the specifications indicate,[3] patients may take a break during the administration of the survey or take the survey in multiple sittings if they feel that the number of questions is too great to answer at one time. Finally, we do not believe that facilities should be permitted to give patients the survey at the facility and allow patients to submit these surveys via a ''drop box'' or any other method. We believe that patients are much more likely to truthfully respond to the surveys if they are perceived to be in no way connected to the facility; providing the surveys at the facility and allowing patients to return them by any means may lead to the patient to believe that his or her answers can be traced to him or her, and this thought may bias the surveys. Thus, we believe that this survey as it is currently specified is the best method available at this time to measure patient experience.

We thank commenters for bringing to our attention the hardships homeless patients may face in accessing the survey. Although we believe that the survey most accurately represents patients' experiences of care at this time, we will continue to evaluate how we can accurately capture all patient populations, including the homeless.

Comment: One commenter suggested that CMS define a threshold for patients at which a facility would not need to administer the survey.

Response: We recognize that there are many small dialysis facilities for which hiring a third-party administrator to fulfill the ICH CAHPS survey requirements is impractical or prohibitively costly. Therefore, beginning PY 2015, we will exempt any facilities that have treated (whether that patient was visiting the facility or otherwise) 10 patients during the performance period or fewer that are qualified to take the survey. Patients are qualified to take the survey if they are adult, in-center hemodialysis patients. We believe that 11 patients (regardless of the number of times these patients were treated) is an appropriate threshold for applying the measure because it is consistent with the policy that we are finalizing for all measures in which we recognize that facilities with 10 or fewer patients in the denominator of a measure should be exempt from that measure. Although we are not requiring facilities to submit actual ICH CAHPS data at this time, we are considering collecting it in the future. We also intend to use the information collected from reporting measures for purposes of scoring clinical measures based on the same data in subsequent payment years and want to adopt a minimum reporting threshold that we can apply to all measures. For these reasons, we are finalizing that facilities must attest to administering the ICH CAHPS survey if they treat during the performance period at least 11 adult, in-center hemodialysis patients. We also finalize that we will consider a facility to have met the 11 patient threshold unless it affirmatively attests in CROWNWeb that it treated 10 or fewer in-center, adult hemodialysis patients during the performance period. If a facility does not affirmatively attest to having treated 10 or fewer in-center, adult hemodialysis patients during the performance period, we will score it on this measure. Additionally, we are applying this policy to the NHSN Dialysis Event reporting measure, discussed below, because we intend to use the data from that measure to adopt a clinical measure in subsequent payment years. Unlike the ICH CAHPS measure, the NHSN measure applies to both adult and pediatric in-center hemodialysis patients. Therefore, we finalize that a facility must treat at least 11 in-center hemodialysis patients (whether adult or pediatric) during the performance period to be scored on the NHSN Dialysis Event reporting measure. To be considered a facility which has treated 10 or fewer in-center hemodialysis patients (whether adult or pediatric) during the performance period, the facility must make an attestation in CROWNWeb to this effect. If a facility does not make this attestation, we will score it on this measure.

Comment: One commenter expressed concern that patients often do not answer the surveys honestly for fear of retaliation and the validity of the survey should be questioned.

Response: We recognize that patients may feel pressure to answer questions in the survey favorably. We believe, however, this concern is mitigated because under the measure specifications, a third-party must administer the survey. These third-party administrators are not associated with facilities and do not report patient-specific data to the facilities. Therefore, the facility would have no knowledge of patient's answers.

Comment: Several commenters expressed concern about CROWNWeb's ability to provide an adequate reporting system for this measure.

Response: CROWNWeb was launched nationally in June of 2012, and we recognize that some facilities may still be familiarizing themselves with the

[3] *See https://www.cahps.ahrq.gov/content/products/ICH/PROD_ICH_Intro.asp?p=1022&s=222.*

new system. As discussed, facilities are not required to report ICH CAHPS data to CROWNWeb or any other system; they are only required to make an attestation that they administered the surveys according to the specifications. The attestations for the ICH CAHPS measure for PY 2015 are not due until the end of January 2014. We have no reason to believe that the attestation function will not be ready by the end of January 2013, the PY 2014 deadline. We believe that by this time, facilities' transition period should have ended, and facilities will be able to successfully submit their attestations. Therefore, because the attestations should be ready in CROWNWeb by January 2013 for the PY 2014 ESRD QIP, they should also be available in CROWNWeb for the PY 2015 program.

Comment: Many commenters noted that the ICH CAHPS measure's third-party administration requirement imposes significant costs on facilities and that facilities should be allowed to include these costs in their cost reports.

Response: Facilities may report allowable operating expenses in their Medicare cost reports. We believe that it is consistent with this payment policy for facilities to include the ICH CAHPS costs on their cost reports because they are allowable operating expenses.

Comment: Several commenters urged us to adopt the ICH CAHPS measure as an outcome measure rather than a reporting measure. One commenter believes that, if we cannot implement the measure as an outcome measure for PY 2015, we should do the following in order to facilitate our adoption of an ICH CAHPS outcome measure as soon as possible: (i) Develop a standardized protocol and quality assurance guidelines for survey administration that are more detailed than the AHRQ requirements; (ii) contract with an experienced organization that can provide oversight for the ICH CAHPS program; and (iii) approve survey vendors. Another commenter argued that the survey should be limited to questions about the facility rather than the physician.

Response: Currently, we are not able to include the ICH CAHPS survey as an outcome measure because we do not possess data from which we can set performance standards. We believe that it is important to adopt an outcome-based measure as soon as possible, and we are diligently working to ensure that it is a part of the program as soon as possible. To that end, we will be working to set up a survey vendor approval program; we believe that the specifications are appropriately detailed, but we will continue to assess whether they should be refined before we propose to adopt this survey as an outcome-based measure. Regarding the survey questions, the majority of the survey is limited to questions about the facility. Only seven of the 58 core questions are about the patients' nephrologists. There are 22 questions about the staff at the facility (not including the doctor), three about the center, and nine about treatment; the remaining questions capture demographic information. The continuous care received by dialysis patients makes them keenly aware of their primary doctors' involvement. To the extent that the questions are about the physician, we believe that they are appropriate because they are targeted at the nephrologist who is most involved in the patient's dialysis care.

Comment: Commenters requested that we develop new measures of patient's experiences. One commenter argued that a measure should be developed that evaluates a patient's experience during each dialysis session because each experience can vary, and further argued that this type of evaluation would allow facilities to better assess why patients do not stay for entire treatments or miss treatments. Many commenters requested that we develop a CAHPS measure for home hemodialysis and peritoneal dialysis patients. Commenters also suggested that we make the responses to the surveys public.

Response: We remain dedicated to developing and adopting measures of patient experiences of care in the ESRD QIP, specifically those patients who are treated at home. At this time we cannot operationally make the responses to the ICH CAHPS survey public because, as noted above, we do not possess the data; however, we will consider making these surveys public in future years if facilities are required to submit their ICH CAHPS data to CMS.

For the reasons discussed above, we are finalizing the ICH CAHPS reporting measure for use in the PY 2015 ESRD QIP and future years of the program. We are also finalizing that the measure applies to facilities that treat a minimum of 11 in-center, adult hemodialysis patients during the performance period. We will consider a facility to have met the 11 in-center, adult hemodialysis patient threshold unless it affirmatively attests in CROWNWeb to having treated 10 or fewer adult, in-center hemodialysis patients during the performance period. If a facility does not make the attestation, we will score it accordingly. The technical specifications for this finalized measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/ICHCAHPS-2015-FR.pdf.*

2. Expansion of Two PY 2014 Measures for PY 2015 and Subsequent PYs

As stated earlier, we believe it is important to continue using measures from one payment year to the next payment year of the program to encourage continued improvements in patient care. Therefore, we proposed to expand the requirements under two reporting measures that we adopted for the PY 2014 ESRD QIP. These proposed expanded requirements would apply to the measures for PY 2015 and subsequent payment years of the ESRD QIP.

a. Expanded National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure

Hospital Acquired Infections (HAIs) are a leading cause of preventable mortality and morbidity across different settings in the healthcare sector, including dialysis facilities. In a national effort to reduce HAIs outcome, HHS agencies, including CMS and the Centers for Disease Control and Prevention (CDC) are working together to encourage facilities to report to the NHSN as a way to track and facilitate action intended to reduce HAIs. The NHSN is currently a secure, internet-based surveillance system that integrates patient and healthcare personnel safety surveillance systems managed by the Division of Healthcare Quality Promotion at the CDC. NHSN has been operational since 2006 and tracks data from acute care hospitals, long-term care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and long term care facilities. We believe that reporting dialysis events to the NHSN by all facilities supports national goals for patient safety, particularly goals for the reduction of HAIs.

For the reasons stated above, we proposed to retain the NHSN Dialysis Event reporting measure that we adopted for the PY 2014 ESRD QIP (76 FR 70268 through 70269), but with an expanded reporting period. For PY 2014, ESRD facilities were required to: (i) Enroll in the NHSN and complete any training required by the CDC related to reporting dialysis events via the NHSN system; and (ii) submit three or more consecutive months of dialysis event data to the NHSN. For the PY 2015 ESRD QIP and future payment years, we proposed to retain the NHSN measure and expand the reporting period to a full 12 months of dialysis event data. Although we expect most

facilities to have enrolled and trained in the NHSN dialysis event system by the end of CY 2012, we proposed that facilities that have not done so by January 1, 2013 or facilities that receive a CMS certification number (CCN) during 2013 must enroll and complete this training before reporting the data in order to fulfill the requirements of this reporting measure. The information reported to NHSN would be provided by the CDC to CMS for use in the ESRD QIP.

As discussed in more detail below, we proposed that the performance period for the PY 2015 ESRD QIP would be CY 2013. We proposed that facilities must report dialysis event data monthly to the NHSN for this measure. We also proposed that facilities be granted a ''grace period'' of one month to report these data. For further information regarding the NHSN's dialysis event reporting protocols, please see *http://www.cdc.gov/nhsn/psc_da_de.html.* This link provides general information and links to more detailed, specialized information.

We note that this proposed measure only applies to facilities treating patients in-center. For purposes of the NHSN Dialysis Event reporting measure, we determine whether a facility treats patients in-center by referencing the facility's information in CMS data sources (that is, SIMS and CROWNWeb). Facilities report the types of patients that they serve in these data sources. If a facility lists in-center services, we proposed that the facility would be required to comply with the NHSN dialysis event reporting measure.

Section 1881(h)(2)(B)(i) of the Act requires that, unless the exception set forth in section 1881(h)(2)(B)(ii) of the Act applies, the measures specified for the ESRD QIP under section 1881(h)(2)(A)(iii) of the Act must have been endorsed by the entity with a contract under section 1890(a) of the Act (which is currently NQF). Under the exception set forth in 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

An NQF-endorsed bloodstream infection measure (NQF#1460) exists and is collected by the CDC as part of dialysis event reporting in NHSN. This measure assesses the number of hemodialysis patients with positive blood cultures. This measure differs from the dialysis event reporting measure that we adopted for the PY 2014 ESRD QIP and proposed to expand beginning with the PY 2015 program because it evaluates the number of hemodialysis outpatients with positive blood cultures over a specified time period. By contrast, the NHSN Dialysis Event reporting measure that we proposed assesses facilities based on whether they enroll and report dialysis event data to the NHSN, not based on what the data reported are. We intend to propose to adopt NQF #1460 once facilities have reported enough data to enable us to compute performance standards, achievement thresholds, improvement thresholds, and benchmarks for the measure.

For the reasons stated in the CY 2012 ESRD PPS final rule (76 FR 70268 through 69), we proposed to retain the measure and expand the reporting period for PY 2015 and future payment years of the program. We requested comment on this proposal, and noted that the technical specifications for this measure are located at *http://www.dialysisreports.org/pdf/esrd/public-measures/NHSNDialysisReporting-2015-NPRM.pdf.*

The comments we received on these proposals and our responses are set forth below.

Comment: Many commenters supported the expansion of the NHSN Dialysis Event reporting measure, stating that monitoring the number of patients with access-related infections for an entire year will help the community better understand ways to reduce infection rates. Some commenters expressed concern with certain aspects of the measure. Several commenters expressed their concern about the burden of this measure, specifically highlighting the burden of manual data-entry and the staff hours demanded for this entry and oversight; one commenter noted that NQF criteria related to feasibility favor electronic collection and data collected during the course of care. Commenters argued further that manual data entry affects reliability, further affecting the baseline calculations for future measures. Many commenters suggested a batch download system. Some commenters noted that the CDC intends to make a Clinical Document Architecture (CDA) system available for batch entries, but expressed concern that the CDC CDA system will be available for individual facilities only (rather than for an entire corporation); others stated that they did not believe the CDA system will be ready for data entry by the end of CY 2012. Commenters also stated that the NHSN system is yet another Web site to which ESRD facilities must report, reducing time staff can spend caring for patients. Finally, some commenters support the expansion of the measure, but only if the required monthly reporting is at the facility rather than the patient level.

Response: We do not believe that this measure is unnecessarily burdensome. Monitoring vascular access infections following uniform definitions and utilizing the comparative rate data to evaluate and improve performance is part of providing good patient care. Although enrollment and training can be time-consuming, approximately 90 percent of all hemodialysis centers have already enrolled in NHSN. Furthermore, we believe that any burden a facility may face is outweighed by the importance of this measure since infections can often lead to serious complications, including death. Further to help decrease the burden, the CDC began allowing facilities to report to NHSN through imported CDA files on September 14, 2012. Using this function, any individual with Administrative Rights for a facility will be able to import that facility's specific CDA files that meet NHSN's formatting requirements. This includes large dialysis organizations that have given Administrative Rights to a single person for purposes of the entire (or some portion of) the organization. However, at this time each facility's files must be submitted separately. Because we are aware that large dialysis organizations (as well as many other dialysis companies) have given Administrative Rights to a single representative of the organization, we recognize that they will eventually be able to submit CDA data for a number of individual facilities, from a single central location, all through a single batch submission process. This batch data submission process is expected to be available in August 2013. Finally, the monthly reporting required by the NHSN is at the facility level. Facility-level review of the data in NHSN is expected, whether the data are reported by facility staff or by a corporate representative. We believe that facilities have a direct role in preventing infections by collecting the NHSN Dialysis Event data, actively assessing their data, and regularly feeding back this information to clinical staff to improve practices.

Comment: One commenter argued that the NHSN Dialysis Event reporting measure will not improve care because the system is not efficient and is not correlated to CROWNWeb. Many commenters urged us to synchronize NHSN and CROWNWeb data

requirements. Commenters also requested that CMS continue to use the same reporting schedule for PY 2015 as it will for PY 2014, allowing facilities to report quarterly with all data being required by March 31, 2014. Commenters noted that quarterly reporting is important because this timeframe will allow facilities ample time to submit data correctly, stating that some infections take more than a month to identify and capture. One commenter recommended that we modify the requirements of this provision to allow a facility to report a full 12 months of data by January 31, 2014. Other commenters urged us to ensure that the NHSN Dialysis Event reporting measure allows the NHSN system to remain a surveillance system.

Response: We disagree with the comment that the NHSN Dialysis Event reporting measure will not improve care. Requiring facilities to report through the NHSN will allow us to monitor and better understand the causes of infections. Additionally, as we stated in the proposed rule (77 FR 40971 through 72), we intend to use the information gathered by this reporting measure to adopt a clinical measure in future years; this measure will encourage facilities to decrease the circumstances which lead to infections. Although we intend to use data from the NHSN to adopt a clinical measure, we will work with the CDC to ensure that the ESRD QIP does not unnecessarily limit the surveillance purposes of the NHSN system.

Commenters are correct in that the NHSN Dialysis Event reporting measure data is not correlated to CROWNWeb. We recognize that CROWNWeb and the NHSN are two distinct systems which require reporting. At this time, we do not require infection reporting in CROWNWeb. We believe that it is more beneficial for both facilities and CMS to require infection reporting through the NHSN. The NHSN is a well-established secure, internet-based surveillance system that integrates patient and healthcare personnel safety surveillance systems managed by the Division of Healthcare Quality Promotion at the CDC; it is used by many other types of providers to report infections. We believe that NHSN's history and wide-spread surveillance make it the best mode of reporting dialysis events at this time.

We do not agree with commenters' suggestions to extend the reporting timeline for the PY 2015 NHSN Dialysis Event reporting measure. The NHSN system recommends monthly reporting, and we believe it is important to adhere to the NHSN requirements as much as possible. However, to maximize data completeness and accuracy, facilities will be allowed to add to and modify the reported data until the performance period reporting deadline. Data for the entire performance period must be reported by April 15, 2014. We chose April 15, 2014 because this date allows facilities a full quarter after the performance period to review their data for completeness and accuracy. After consulting with the CDC, we believe that such a timeframe will maximize the reliability of the data and allow facilities to report any infections that developed during the performance period but that are identified after the performance period has ended.

Comment: One commenter is concerned with the proposed expansion of this measure if NHSN data is not validated or audited for completeness. This commenter expressed specific concern that there could be surveillance bias in interpreting submitted data.

Response: We recognize that bias exists because some facilities may be more likely to identify and report dialysis events than others. Varying degrees of completeness of the data could lead to inaccurate comparisons between facilities. The CDC and CMS are beginning to formulate a strategy to validate data for purposes of the ESRD QIP; we are committed to rigorous validation to identify inaccuracies and ensure reliability of the data.

Comment: One commenter suggested that CDC standardize and clarify data definitions to ensure ''apples-to-apples'' comparisons and allow corporate oversight of data entered into the system for verification and reliability purposes. Another commenter stated that it does not support the adoption of a future NHSN Dialysis Event clinical measure because facility policies and procedures and physician practices vary widely with respect to the circumstances under which blood cultures are obtained and results are reported; this commenter requested that reporting be standardized before the measure is adopted.

Response: The CDC develops protocols, definitions, and criteria for the purposes of standardizing reporting, and expects that all NHSN users strictly adhere to the protocol guidance for data that are reported into NHSN. The dialysis event surveillance reporting protocol is available on CDC's NHSN Web site and includes data definitions (*http://www.cdc.gov/nhsn/PDFs/pscManual/8pscDialysisEventcurrent.pdf*). Users may contact the NHSN help desk (*NHSN@cdc.gov*) for clarifications to these data definitions. We will continue to work with the CDC to monitor these concerns while we consider adopting a measure based on NHSN data for future years of the program.

Comment: One commenter requested clarification regarding whether facilities are required to report infections occurring in the dialysis unit only, exempting the facilities for infections that result from care in other environments.

Response: The measure specifications, which are available at (*http://www.cdc.gov/nhsn/PDFs/pscManual/8pscDialysisEventcurrent.pdf*), provide that positive blood cultures occurring within one calendar day after a hospital admission must also be reported. For further clarification on reportable event definitions and considerations surrounding attribution, please contact the NHSN help desk (*NHSN@cdc.gov*).

Comment: One commenter asked us to confirm that, as long as the census data is reported every month, the facility may attest to having met the requirements for the NHSN measure.

Response: For the reasons discussed above, we finalize that a facility may attest for purposes of being exempt from reporting for the NHSN dialysis event measure if it treats fewer than 11 in-center hemodialysis patients during the performance period. If a facility treats 11 or more in-center hemodialysis patients, we will score the facility based on whether it reported data to the NHSN.

Comment: One commenter urged us to develop a measure which targets the cause of the infections. Another commenter suggested that CMS consider adding NHSN dialysis specific indicators, perhaps in stages, such as local access site infection, access-related bloodstream infection, and vascular access infection to the NHSN surveillance data.

Response: We thank commenters for these suggestions. We acknowledge that preventing and monitoring infections is crucial to patient care. We will continue to work with the dialysis community to include robust infection measures in the ESRD QIP.

Comment: Many commenters support our proposed transition of the NHSN Dialysis Event reporting measure to a clinical measure using the NQF-endorsed measure #1460. Some commenters urged us to adopt the clinical measure in PY 2015. Other commenters, however, suggested that we allow sufficient time to ensure that NHSN data can be reported without additional burden to providers. One commenter suggested that, once the measure is adopted as a clinical measure, we interpret the rate of positive blood cultures against the

facility's rate of empiric antibiotic treatment, since some facilities treat empirically rather than through taking blood cultures.

Response: We thank commenters for supporting our proposal to adopt the NQF-endorsed infection measure for future years of the program. We are unable to adopt the NQF-endorsed clinical measure for PY 2015 because we have not yet gathered data on which we can base performance standards. For purposes of the ESRD QIP, facilities began reporting to the NHSN during 2012; to receive full points on the measure for PY 2014, facilities need only to report three months of data. We do not believe it is appropriate to base performance standards on three months of data for purposes of an infection measure because infections can vary by season. We believe that using a 12-month period for setting these standards will prove more accurate. Because we are requiring 12 months of data for the PY 2015 ESRD QIP, we believe we can use this information to adopt standards for a clinical measure in future years. Additionally, we agree with the commenters who believe that it may be necessary for facilities to become more familiar with the NHSN system before we adopt a clinical measure.

We thank the commenter who suggested that we interpret the rate of positive blood cultures against the facility's rate of empiric antibiotic treatments to account for facilities that might treat patients empirically for infection without drawing cultures. The NHSN collects information on IV antimicrobial starts, in part, for this reason. Providers are expected to adhere to standards of clinical practice, which include obtaining blood cultures prior to antibiotic administration for suspected bloodstream infections.

Comment: One commenter stated its support for the adoption of an MRSA standardized infection rate clinical measure.

Response: We thank the commenter for providing this suggestion and will take it into consideration in future measure development and rulemaking.

For the reasons stated above, we finalize the NHSN Dialysis Event reporting measure as proposed except for the following; a facility must treat at least 11 in-center hemodialysis patients (both adult and pediatric) during the performance period to be scored on the NHSN Dialysis Event reporting measure, as noted above. To be considered a facility which has treated 10 or fewer in-center hemodialysis patients during the performance period, the facility must make an attestation in CROWNWeb to this effect. If a facility does not make this attestation, we will score it accordingly. Additionally, we recommend that facilities report monthly to the NHSN. Data for the entire performance period must be reported by April 15, 2014. The technical specifications for this finalized measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/NHSNDialysisReporting-2015-FR.pdf.*

b. Expanded Mineral Metabolism Reporting Measure

Undertreatment of bone mineral metabolism disease can cause severe consequences for ESRD patients. For PY 2014, it was not yet feasible for us to adopt a clinical measure evaluating facilities based on their patients' bone mineral metabolism rates because facilities did not report serum phosphorus and serum calcium values during the baseline and performance periods that we finalized with respect to that year. Instead, for PY 2014, we finalized a measure assessing whether facilities routinely monitored the serum calcium and serum phosphorus levels in their patients. For PY 2015, we proposed to expand this measure by requiring facilities to report a serum calcium and serum phosphorus level for each qualifying patient each month according to the requirements in CROWNWeb. Facilities would be required to enter these values into CROWNWeb on a monthly basis. Facilities would be granted a ''grace period'' of one month to enter the data. For example, we would require a facility to report serum calcium and serum phosphorus data for January 2013 on or before February 28, 2013. The final month of data from the performance period would be reported on or before January 31, 2014.

We do not intend for this measure to encourage unnecessary testing or unduly burden a facility. Consequently, for purposes of scoring the measure, we considered proposing to require facilities to report the required information for less than 100 percent of their patients. Specifically, we considered lowering the threshold to reporting 98 percent of patients for a month in order to receive credit for that month. We chose 98 percent in order to encourage improvement, and to ensure that we do not undermine the current level of high-reporting (based on the CROWNWeb pilot data). We recognize that 100 percent might not be appropriate due to some individual cases that may not fit specified criteria. We ultimately proposed that a facility should be required to take and report these values for every patient at least once per month so that each beneficiary receives the highest standard of care. We noted, however, that there are circumstances beyond a facility's control wherein it may not be able to draw a sample for this patient. Therefore, we did not propose that the facility itself must draw the serum phosphorus and serum calcium levels. If, for example, a patient is hospitalized or transient during a claim month, we proposed that the facility may report the serum calcium and serum phosphorus readings for the patient for a month if a patient has labs drawn by another provider/facility and those labs are evaluated by an accredited laboratory (a laboratory that is accredited by, for example, the Joint Commission, the College of American Pathologists, the AAB (American Association of Bioanalysts), or State or Federal agency), and the dialysis facility obtains the serum calcium and serum phosphorus readings. Additionally, we proposed to only consider a patient qualified for this measure (i) if the patient is alive at the end of the month; (ii) if the patient is treated in-center, that patient was treated at that facility at least twice during the claim month; and (iii) if the patient receives dialysis at home, a claim is submitted for that patient. We stated our belief that that these proposals will provide more flexibility for facilities and will also discourage facilities from drawing blood, even when not necessary, for fear that the patient will fail to come to the facility again during that month. We requested comment on these proposals. We also requested comment on whether facilities should only have to report data for 98 percent of their patients.

Section 1881(h)(2)(B)(i) of the Act requires that, unless the exception set forth in section 1881(h)(2)(B)(ii) applies, the measures specified for the ESRD QIP under section 1881(h)(2)(A)(iii) of the Act must have been endorsed by the entity with a contract under section 1890(a) of the Act (which is currently NQF). Under the exception set forth in 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed so long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

An NQF-endorsed measure assessing hypercalcemia exists (NQF #1454) and we proposed to adopt this measure for the PY 2015 ESRD QIP and subsequent

payment years, as further discussed below. The NQF-endorsed hypercalcemia measure, however, does not score facilities based only on whether or not that facility reported serum calcium values. The Mineral Metabolism reporting measure, unlike the Hypercalcemia measure, would assess only whether facilities report serum calcium and serum phosphorus values. It would not score facilities based on the actual values that they report. We stated our belief that it is important to continue to encourage reporting independent of a measure that scores based on the actual values reported because we need such values to monitor aspects of bone mineral metabolism, for example phosphorus management, independent of hypercalcemia; we noted that this information will allow us to develop comprehensive bone mineral metabolism measures for use in future years of the ESRD QIP.

In the CY 2012 ESRD PPS final rule, we discussed the basis for the Mineral Metabolism reporting measure (76 FR 70270 through 71). We stated that ''the NQF has previously endorsed phosphorus and calcium monitoring measures (NQF #0261 and NQF #0255) and, in 2008, we adopted serum calcium and serum phosphorus monitoring as Clinical Performance Measures (*http://www.dialysisreports.org/ESRDMeasures.aspx).''* The NQF measures referenced above call for monitoring these serum calcium and serum phosphorus values, but they do not require actual reporting of these values, as is the intent of the Mineral Metabolism reporting measure.

For these reasons, we proposed to expand the Mineral Metabolism reporting measure for PY 2015 and subsequent payment years under 1881(h)(2)(B)(ii) of the Act. The technical specifications for this measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/MineralMetabolism-Reporting-2015-NPRM.pdf.* We further noted that requiring the reporting of serum calcium and serum phosphorus levels for the PY 2015 ESRD QIP will allow us to develop mineral metabolism measures based on clinical data in the future. We requested comment on these proposals to expand the Mineral Metabolism reporting measure.

The comments we received on these proposals and our responses are set forth below.

Comment: Many commenters generally supported this measure, but requested that we make modifications to our proposed exclusions. These commenters suggested that we exclude, for all of the reporting measures, the following patients: (i) Beneficiaries who are regularly treated at the facility and who fit into one of these categories: (a) Beneficiaries who die within the applicable month; (b) beneficiaries that receive fewer than 7 treatments in a month; and (c) beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented, good faith effort to have them participate in such a visit during the applicable month; (ii) transient dialysis patients; (iii) pediatric patients (unless the measure is specific to this population); and (iv) kidney transplant recipients with a functioning graft. Commenters stated that these exclusions are consistent with our own measures reported on DFC. Additionally, commenters stated that these exclusions seek to hold facilities accountable only for those beneficiaries to whom they regularly give care and for whose care they can affect. Another commenter, however, stated that we should not implement other commenters' suggestions that we exclude beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented, good faith effort to have them participate in such a visit during the applicable month; this commenter stated that it is the responsibility of the facilities to educate patients on the importance of making and keeping appointments. Additionally the commenter argued that ''good faith'' is too vague; commenter requested that, if we did adopt this exclusion, we clearly define a ''good faith effort.''

Response: Upon further review, we agree with commenters who believe that the exclusions should be modified. We recognize that treating a patient twice may not provide enough time to effectuate quality patient care. We agree with the commenters who suggested that an in-center hemodialysis patient should be excluded if treated by a facility fewer than seven times during the month, regardless of whether the patient is officially admitted to that facility. With seven treatments, we believe that a facility should have had adequate opportunities to draw blood necessary to report serum calcium and phosphorus levels. We also believe that the threshold of seven will discourage unnecessary testing of in-center hemodialysis patients by facilities because they will know that, since in-center patients are typically treated three times per week, a patient must have been treated by the facility for at least two weeks to be included; thus, the facility need not feel pressure to draw blood for every patient for the first few visits of the month. Based on these considerations, we will not finalize our proposal to exclude only in-center patients who have been treated fewer than two times by the facility during the claim month. Instead, we will exclude any in-center patient who is treated by the facility fewer than seven times during the reporting month.

We do not believe that it is necessary to specifically exclude transient patients from this measure because, as noted, any patient that is treated by the facility at least seven times during the applicable reporting month is present at the facility for enough time that the facility should be held accountable for that patient. Likewise, for the same reasons mentioned above, we do not believe we need to separately exclude patients who are deceased at the end of the reporting month. Provided that the patient is treated by the facility at least seven times during that month, the facility should be able to draw blood necessary to report serum calcium and serum phosphorus levels even if that patient is deceased at the end of the month.

We continue to believe that facilities should be required to report the serum calcium and phosphorus levels of home dialysis patients irrespective of whether those patients attend a monthly appointment. We believe that it is incumbent upon a facility to make home dialysis patients aware that they must attend monthly appointments to be properly treated. In addition, since the mechanisms that cause cardiovascular and bone disease do not differ between home and in-center hemodialysis patients, we believe that the inclusion of home dialysis patients in the Mineral Metabolism reporting measure is appropriate. Therefore we will finalize our proposal that we will include any home hemodialysis patient for which a facility submits a claim with respect to the reporting month in this measure.

We also believe it is important to include transplant patients until they are officially discharged from a facility; regular monitoring can help ensure that a transplant remains effective and that the facility is continuing to provide the best care possible.

We believe it is important to monitor serum calcium and serum phosphorus levels in adult and pediatric patients alike because improper bone mineral metabolism management can lead to serious, negative outcomes, including death, in both populations. Although we are aware that specific target values for calcium and phosphorus have not been set for the pediatric population, we still believe that this measure will lead to

better observation of mineral metabolism in these patients if one or both of these values are unusually high or low. Additionally, we believe that the inclusion of pediatric patients in this measure is consistent with current guidelines on the frequency of mineral metabolism testing as reported in KDIGO guidelines chapter 3 ''Diagnosis of CKD–MBD: biochemical abnormalities.'' Thus, we believe that this measure is appropriate for both adult and pediatric patients.

For the reasons stated above, we finalize that facilities must report in CROWNWeb the serum calcium and serum phosphorus levels on a monthly basis for (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim.

Comment: Several commenters encouraged us to not adopt a percentage reporting threshold because it would not distinguish between beneficiaries legitimately excluded and those that were merely missed. Other commenters requested that we use both exclusions and a threshold; one commenter suggested a threshold of 90 percent or an allowance of two patients to ensure that small facilities are not disproportionally affected. Another commenter stated that requiring 98 percent reporting may make it difficult for patients to travel because dialysis facilities may encourage them otherwise to ensure compliance with the measure. One commenter requested that we provide guidance regarding the standardization of blood-draws so that data can be reliable before we implement a reporting threshold.

Response: We agree with the commenters who argued that, even with exclusions, there are circumstances in which facilities cannot report the serum calcium and serum phosphorus levels for every patient at least once per month. For example, a facility may wait to draw blood from a patient because it believes that the patient will be treated for the entirety of the month, but learns that the patient has been hospitalized unexpectedly for all or part of the applicable month. Therefore, we believe that we should not require an attestation of 100 percent monitoring. Based on data from the CROWNWeb pilot, we believe that facilities are generally able to report serum calcium and serum phosphorus for approximately 96 percent of their patients. As commenters have argued, the information in CROWNWeb, however, was voluntarily reported which may mean that the data is biased toward facilities that value reporting; additionally, the data from the CROWNWeb pilot was mainly supplied by LDOs that may be more likely to have more resources and corporate policies that require reporting compliance. Furthermore, such a high percentage requirement may disadvantage small facilities. For example, if a facility has 10 patients, failure to report for one patient will drop that facility's reporting rate to below 90 percent.

Taking all of these issues into consideration, we finalize a normative reporting threshold for this measure; facilities will be required to report at the rate of the 50th percentile of all facilities in 2013 for each month of the performance period in order to gain 10 points on the measure. However, if the 50th percentile of all facilities in 2013 is greater than 97 percent, facilities will only be required to report monthly for 97 percent, in total, of their (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. This floor ensures that facilities are not penalized as long as they improve by one percent above the reporting rates in the CROWNWeb pilot; that is, facilities know that, provided they reach 97 percent for each month of the performance period, they will meet the requirements of the measure. We believe that it is important to adopt a reporting rate of 97 percent in PY 2015 to ensure continued improvement. We believe that this methodology fairly balances the concerns that the reporting in CROWNWeb is skewed with our desire to encourage continued improvement in the community.

We are concerned that small facilities may be disproportionately impacted by the reporting threshold because, for example, a facility with 10 patients could fail to report for only one patient and, therefore, fail to meet the threshold. As we have stated, we intend to use the information collected from reporting measures for purposes of scoring clinical measures based on the same data in subsequent payment years. Therefore, we will not require a facility to report this measure if it treats fewer than 11 (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. If a facility does not treat at least 11 of these patients during the performance period, it will be required to attest to this fact via CROWNWeb. If a facility does not make the attestation, we will score it accordingly.

Comment: Some commenters did not support including this measure in PY 2015. One commenter argued that it is inappropriate to adopt this measure because it is not-NQF endorsed, nor. One commenter stated that it is inappropriate to adopt this measure under the exception set forth in the statute for measures which are not NQF-endorsed; this commenter stated that the NQF process ensures that measures have gone through a rigorous evaluation process, including reliability and validity. Some commenters argued that this measure should be deferred because we have not articulated the intent of the data collection or explained the measure for which we intend to ultimately use these data. Several commenters do not support this measure because facilities already collect these data so the measure is unlikely to improve care, and they requested that we adopt a measure based on outcomes. One commenter does not support adoption of this measure because, it contends, Kidney Disease: Improving Global Outcomes (KDIGO) has not indicated that serum calcium and serum phosphorus must be reported on a monthly basis. Further, the commenter argues that although it is customary to measure serum calcium and phosphorus monthly, there is no evidence that it indicates quality care.

Response: KDIGO recommends monthly measurements (see Table 13 on internet document titled ''Kidney Disease Improving Global Outcomes Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD–MBD)'' at *http://www.kdigo.org/guidelines/mbd/guide3.html#chap31*)). KDIGO also emphasizes the importance of following trends versus single measurements, thus supporting relatively frequent measurements (for example, monthly). There is evidence that calcium and phosphorus levels may be associated with clinical outcomes. Monthly measurements will serve to identify elevated levels of serum calcium and phosphorus and trigger therapeutic interventions, thus contributing to high quality care. Because of these important considerations, and for the reasons stated above, we believe that it is important to adopt this measure even though it is not NQF-endorsed. We disagree that it is inappropriate to adopt a measure not endorsed by NQF under the exception set forth in the statute. We believe the exception language was intended for such a circumstance where an endorsed measure is not available for implementation to address key issues described in the statute, such as mineral

metabolism. We will continue to work toward the development and implementation of appropriate, NQF-endorsed measures to support the ESRD QIP.

Comment: Many commenters noted that it is impractical for facilities to obtain lab values from other providers because other providers are not required to measure these data, do not share data with dialysis facilities, and, even if facilities could obtain these data, they could not be sure that the lab values were consistent or reported under the same standards. Finally, these commenters stated that CROWNWeb does not permit facilities to submit data obtained from other providers if the lab result is outside the admission or discharge date.

Response: We recognize that it may be difficult for facilities to coordinate with hospitals and other care providers in order to obtain lab values. Therefore, we are not mandating facilities to do so. In the CY 2013 ESRD PPS proposed rule (77 FR 40969), we stated that facilities may obtain lab values from other providers. This proposal was specifically designed to afford facilities more flexibility in acquiring and reporting serum calcium and serum phosphorus values. As discussed previously in this preamble, facilities are highly encouraged to coordinate with other providers, but the ESRD QIP does not mandate them to do so. We believe that the commenters' concerns about inconsistent lab data are mitigated by the requirement that the lab must be accredited. Finally, the commenter is right in that CROWNWeb does not allow facilities to submit data obtained from other providers if the lab result is outside the admission or discharge date. As long as the patient is treated at least seven times by the facility during the applicable reporting month, however, the facility will be required to report the patient's serum phosphorus and calcium levels regardless of whether the patient also has blood drawn elsewhere (for example, as a result of a hospitalization) during the month.

Comment: Many commenters encouraged us to monitor, in addition to phosphorus and calcium, serum levels of parathyroid hormone (PTH), arguing that proper bone mineral management must take all three factors into account. Commenters also encouraged us to adopt measures in all of these areas.

Response: We thank those commenters who advocated the monitoring of PTH. We recognize the important role played by parathyroid hormone in mineral metabolism in the ESRD population, and will pursue avenues by which we may monitor serum levels of parathyroid hormone in the future.

As explained above, we are modifying our proposed exclusions and finalizing that any facility must report serum calcium and serum phosphorus levels for all (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim least once per month via CROWNWeb at the lesser of the 50th percentile of facilities in 2013 or 97 percent per month to receive 10 points on the measure. We also finalize that we will only apply this measure to facilities with at least 11 (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. Facilities who treat less than 11 of these patients during the performance period must attest to this fact in CROWNWeb. If they do not make this attestation, we will score them accordingly. The technical specifications for this finalized measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/MineralMetabolism-Reporting-2015–FR.pdf.*

3. New Measures for PY 2015 and Subsequent PYs of the ESRD QIP

As the program evolves, we believe it is important to continue to evaluate and expand the measures selected for the ESRD QIP. Therefore, for the PY 2015 ESRD QIP and subsequent payment years, we proposed to adopt five new measures. The proposed new measures include: Three measures of dialysis adequacy (together comprising one dialysis adequacy measure topic); one measure of hypercalcemia; and one reporting measure related to hemoglobin and ESA dosages for all patients.

a. Kt/V Dialysis Adequacy Measure Topic

Section 1881(h)(2)(A)(i) states that the ESRD QIP must evaluate facilities based on measures of ''dialysis adequacy.'' For PYs 2012 through 2014, the ESRD QIP included a hemodialysis adequacy measure evaluating the number of patients with a URR of at least 65 percent. For the PY 2015 ESRD QIP, and future payment years, we proposed to remove the URR Hemodialysis Adequacy measure. In its place, we proposed to adopt three measures of dialysis adequacy (together comprising one dialysis adequacy measure topic) based on Kt/V (K = clearance, t = dialysis time, and V = volume of distribution) for the PY 2015 ESRD QIP and future payment years of the program. Kt/V is a widely accepted measure of dialysis adequacy in the ESRD community because it takes into account the amount of urea removed with excess fluid. Further, while the URR Hemodialysis Adequacy measure only applies to in-center hemodialysis patients, we stated that the proposed Kt/V measures will allow us to evaluate dialysis adequacy in adult hemodialysis (HD) patients (in-center and home hemodialysis (HHD)) receiving three treatments weekly, adult peritoneal dialysis (PD) patients, and pediatric HD patients receiving three to four treatments weekly. We proposed to adopt the following NQF-endorsed Kt/V measures of dialysis adequacy, each one applicable to a different patient population:

(i) NQF #0249: Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy—HD Adequacy—Minimum Delivered Hemodialysis Dose;

(ii) NQF #0318: Peritoneal Dialysis Adequacy Clinical Performance Measure III—Delivered Dose of Peritoneal Dialysis Above Minimum; and

(iii) NQF #1423: Minimum spKt/V for Pediatric Hemodialysis Patients. The proposed measures assess whether Medicare dialysis patients (PD, HD, and pediatric hemodialysis) meet the modality specific Kt/V threshold. Performance on the measures is expressed as a proportion of patient-months meeting the measure threshold. The technical specifications for these measures can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/PediatricHemodialysis Adequacy-ktv-2015-NPRM.pdf; http://www.dialysisreports.org/pdf/esrd/public-measures/PeritonealDialysis Adequacy-ktv-2015-NPRM.pdf;* and *http://www.dialysisreports.org/pdf/esrd/public-measures/Hemodialysis Adequacy-ktv-2015-NPRM.pdf.*

We requested comment on these proposals. The comments we received on these proposals and our responses are set forth below.

i. Adult Hemodialysis Adequacy

Comment: The majority of commenters strongly supported the adoption of this measure and the removal of URR as a measure of dialysis adequacy, stating that the measure is more accurate and used more widely by the dialysis community. Other commenters, however, stated that URR is a more appropriate measure of dialysis adequacy because Kt/V is dependent upon many factors, including mid-week sampling, accurate urine collection, and dialysis

prescriptions, whereas URR needs only pre- and post-blood draws. One commenter did not support a Kt/V measure because it only promotes ''adequacy'' rather than optimal health, urea is not associated with toxicity, it does not take into account ultrafiltration, and it is only a point in time measurement. Some commenters supported the adoption of Kt/V as a measure of dialysis adequacy for hemodialysis patients, but requested that we delay implementation until PY 2016 so that we can ensure the data we are using to calculate achievement thresholds, benchmarks, and performance standards were calculated using consistent methodology. One commenter suggested that we include Kt/V in PY 2015, but calculate rates for performance standards, benchmarks, and thresholds based on data from January 1, 2012–June 30, 2012 since these dates would include only data that were calculated using the NQF-endorsed formulae. Finally, one commenter stated that we should request raw data from facilities and calculate Kt/V to ensure consistency.

Response: We thank those commenters who supported the implementation of these measures. We note that the published literature suggests there is insufficient evidence to support the superiority of alternative measures of small solute clearance over spKt/V. The KDOQI Clinical Practice Guideline for Methods for Measuring and Expressing Hemodialysis Dose (CPG 2) also state that ''the delivered Kt/V determined by single-pool urea kinetic modeling continues to be preferred as the most precise and accurate measure of dialysis'' (page 12, KDOQI 2006 Update). Furthermore, the minimum delivered hemodialysis dose for both adult and pediatric patients, spKt/V>=1.2, was endorsed by NQF in 2007. Regarding concerns about the use of consistent methodology in the calculation of performance standards, beginning in January 2012, the measure specifications for adult and pediatric hemodialysis Kt/V state that single-pool Kt/V be measured using Daugirdas II or Urea Kinetic Modeling. We anticipate that these specifications will provide valid and consistent spKt/V values.

We thank the commenter for the suggestion of utilizing data from January 1, 2012–June 30, 2012 to set achievement thresholds, benchmarks, and performance standards. We believe, however, that whenever possible, these values should be based on a full year of data since these data, although not necessarily calculated using the same NQF-endorsed methodology, represent any changes that may occur as a result of seasonality. Additionally, utilizing this timeframe will enable us to post the numerical values of the performance standards as soon as they are available in December 2012 or January 2013.

We thank the commenter for the suggestion of collecting raw data rather than calculated spKt/V values. At this time, we are not operationally able to request these elements on claims. We will consider this suggestion in future years of the program.

Comment: Several commenters supported the measure but requested that we refine it to specify that the calculated spKt/V include estimates of residual renal function (RRF) to avoid incentivizing improper, longer dialysis sessions for these patients; one commenter recommended that, consistent with KDOQI guidance, RRF be included in spKt/V only if the urine collection used to measure it was within the previous 90 days. Commenters also requested that we exclude patients dialyzing four or more times per week or overnight and include patients with Kt/V less than 2.5 since many patients achieve these values.

Response: Consistent with the 2006 KDOQI Clinical Guidelines for hemodialysis adequacy, we do not find published, medical evidence to support the inclusion of RRF in defining the minimum target spKt/V. Additionally, effective January 2012, the Medicare claims processing instructions specifically state that the reported spKt/V should not include RRF. We currently exclude patients dialyzing four or more times per week from the adult HD measure because this exclusion was NQF-endorsed.

According to the measure specifications, overnight dialysis patients are included in the HD spKt/V measure unless they are dialyzing less than two or greater than four times per week, or if they are in the first 90 days of ESRD treatment. We do not currently have the ability to identify patients who are receiving thrice weekly in-center nocturnal hemodialysis and do not have a measure specific to this population. We are currently working with stakeholders to develop adequacy measures to address frequent, home, and nocturnal hemodialysis patients for future years of the ESRD QIP.

Finally, patients with spKt/V less than 0.5 or greater than 2.5 are excluded from the Kt/V adult hemodialysis dialysis adequacy measure. Patients with HD spKt/V values greater than 2.5 are excluded from the measure calculation as these values are considered implausible for most hemodialysis patients.

Comment: Commenter stated that spKt/V does not reflect patients on short daily, frequent, and nocturnal dialysis and should be updated accordingly. Another commenter requested that we develop a spKt/V measure for home dialyzers.

Response: We are currently working with stakeholders to develop adequacy measures to address other members of the ESRD population (i.e. frequent, home, and nocturnal hemodialysis patients) for future years of the ESRD QIP.

Comment: One commenter requested that we specify that the lab draw for this measure should be done mid-week to better reflect patients' actual conditions.

Response: Under the measure specifications for the Kt/V adult hemodialysis adequacy measure, facilities are required to report the last spKt/V measurement of the month. The NQF-endorsed measures for minimum dialysis adequacy for both pediatric and adult patients do not adjust for the day of the week; a minimum target value of spKt/V greater than or equal to 1.2 should be achieved regardless of when this is measured. We appreciate your suggestion and will take it under consideration during our ongoing measure maintenance.

Comment: One commenter stated that ''dialysis adequacy'' is a misnomer because it does not provide a full picture of dialysis adequacy. Instead, the commenter suggests it be called a measure of ''urea removal,'' encouraging stakeholders to develop measures that are more comprehensive of dialysis adequacy. Another commenter asked us to recognize that ''adequacy'' is not synonymous with optimal levels.

Response: ''Dialysis adequacy'' is used in the ESRD QIP to represent the quantification of urea removal by dialysis, one widely accepted measurement of adequacy of this treatment. We recognize there are other aspects of dialysis adequacy, and we are currently working with stakeholders to develop additional measures for future years of the ESRD QIP. Additionally, we emphasize that these minimum spKt/V target levels may not be optimal levels for all patients. Therefore we encourage clinicians to consider targeting higher spKt/V targets on an individual patient basis as clinically indicated.

ii. Peritoneal Dialysis Adequacy

Comment: Many commenters supported the adoption of this measure and asked us to finalize the measure along with the formula and methodology for its calculation. One commenter explicitly asked us to finalize a methodology for obtaining

dialysate, blood, and urine sampling. Other commenters, however, did not support the measure, stating that we have not yet specified a consistent reporting methodology. These commenters suggested that we finalize this measure as a reporting measure only for PY 2015, define a methodology for calculating the values in the final rule, and use data from CY 2013 for purposes of adopting this measure as a clinical measure in future years. One commenter stated that we should request raw data from facilities and calculate Kt/V to ensure consistency. Finally, some commenters stated that they did not support the measure.

Response: We thank the commenters who supported the adoption of this measure. There is more than one method that may be used by facilities to calculate PD Kt/V. Methods for reporting PD Kt/V on Medicare claims were specified prior to the start of data collection in July 2010 and are based on measure specifications endorsed by the National Quality Forum in 2007. Measurement of peritoneal dialysis Kt/V is based on timed (24 hour) dialysate collection to measure urea clearance (k). Time (t) is specified in the definition (week or per week). The only component of Kt/V measurement in peritoneal dialysis that is formula-based is the estimation of total body water (V). V is estimated from either of two formulae (Watson or Hume) predictive equations that are based on patient anthropometric and demographic information. We will consider the standardization of estimating total body water as part of our annual ongoing measure maintenance process, but we note that we believe it is appropriate to adopt this measure without this standardization because the Watson and Hume formulae yield substantially similar results. Moreover, NQF approved the measure with the specification to use the Watson or Hume formula to estimate ''V.'' We choose to collect reported Kt/V, rather than the data elements for Kt/V, due to the limitations of collecting data on Medicare claims and to minimize burden on facilities.

Comment: One commenter supported the use of Kt/V as a measure of dialysis adequacy for peritoneal dialysis patients, but suggested that we refine it in the final rule. This commenter stated that we need to: (i) Clarify in the technical measure specifications that a patient is only included in the measure population if he/she has been on peritoneal dialysis for 90 days or more so that a patient transferring from hemodialysis to peritoneal dialysis will not be immediately counted in the measure; and (ii) exclude patients in the first month they are eligible to be included in the denominator if no Kt/V measurement is taken until the fourth month since the measure specifies Kt/V need only be measured once every 4 months. One commenter noted that a monthly measurement period for the measure is problematic because Kt/V is assessed throughout the month in home training clinics; this commenter suggested that there be a 30-day window from the time of the adequacy measure to adjust the prescription and repeat the adequacy measure.

Response: We thank commenters for their feedback regarding the exclusion criteria for Kt/V for adult peritoneal ESRD patients. To the first point, patients are excluded from this measure if they are in the first 90 days of treatment for ESRD. If a patient changes from hemodialysis to peritoneal dialysis during a month, the patient would be included in both the HD and PD Kt/V measure calculations. The 2006 KDOQI Clinical Practice Guidelines for peritoneal dialysis adequacy (Guideline 2.1.2) state ''the total solute clearance (residual kidney and peritoneal, in terms of Kt/V) should be measured within the first month after initiating dialysis therapy and at least once every 4 months thereafter.'' While this measure is consistent with the guideline, we acknowledge that a patient may be included in the PD Kt/V measure calculation in the same month their modality changed to PD. However, after switching from hemodialysis to peritoneal dialysis, peritoneal dialysis clearance typically is not measured right away or even in the same month as the PD catheter insertion, as the peritoneal membrane is in a state of flux and its membrane transport characteristics are unstable for a few weeks. In several clinical scenarios it may not be appropriate to measure PD Kt/V within the first several weeks after initiation of peritoneal dialysis. Therefore, we believe that the PD unit personnel will not have measured PD adequacy in the 30 days following the transition from HD to PD. With regard to the comment on excluding patients from the denominator for the first month if no measurement is taken until the fourth month, we use the data reported in conjunction with Medicare dialysis facility claims value code D5: Result of last Kt/V reading and occurrence code 51: Date of last Kt/V reading. The claims reporting instructions indicate that for PD patients this should be within the last 4 months of the claim date of service. All monthly claims with valid PD Kt/V values will be used in the calculation. In response to the monthly measurement period comment, for PD patients, facilities are only required to report Kt/V once every 4 months.

Comment: One commenter urged us to develop a pediatric peritoneal dialysis adequacy measure in collaboration with stakeholders.

Response: We are currently working with stakeholders to develop a pediatric peritoneal dialysis adequacy measure as part of a consensus-based measure development process, and we will consider implementing such a measure through future rulemaking.

iii. Pediatric In-Center Hemodialysis Adequacy

Comment: Several commenters supported the adoption of a Kt/V hemodialysis adequacy measure for pediatric patients even if we do not adopt the adult Kt/V measures. Other commenters, however, argued that we should not finalize the pediatric in-center hemodialysis adequacy measure because (i) the measure does not exclude RRF patients; and (ii) the measure applies to 4 times per week hemodialysis. These commenters believe that adoption of the proposed measure would, in effect, raise the pediatric dialysis dose above the adult dialysis dose in a substantial number of children who either have a significant RRF or are treated with dialysis four days a week; they caution that we should avoid incentivizing improper, longer dialysis sessions for these patients. Some commenters urged us to harmonize the adult and pediatric spKt/V hemodialysis adequacy measures, specifically regarding the required number of dialysis sessions for inclusion in the measure and the inclusion of RRF. Another commenter stated that we should consider changing the measure so that it is based on weekly dose. Other commenters stated, generally, that spKt/V is not appropriate for pediatric patients and encouraged us to work with stakeholders to develop a suitable pediatric dialysis measure.

Response: We thank the commenters who supported the implementation of the spKt/V hemodialysis adequacy measure for pediatric patients and those who provided feedback for its implementation. The measure methodology was developed through a consensus-based process incorporating the input of a Technical Expert Panel and was endorsed by NQF in 2011. The pediatric hemodialysis adequacy measure differs from the corresponding adult adequacy measure in that the measure applies to patients receiving four dialysis treatments a week.

Analysis of 2007 claims data suggest that in 5.6 percent of patient-weeks, dialysis sessions occurred four times per week for pediatric patients. Given that this is a significant proportion, the TEP concluded that these patients should be included in this measure. As seen in Table 4 below, there were three or four dialysis sessions in approximately 88 percent of patient-weeks. Based on these results, the TEP concluded that by defining the denominator as hemodialysis patients receiving dialysis three or four times weekly, the measure will be applicable to most pediatric hemodialysis patients.

TABLE 4—DIALYSIS SESSIONS PER PATIENT WEEK AMONG ALL HD PEDIATRIC PATIENTS < 20 YEARS OLD

Sessions per week	Number of patient-weeks	Percent
1	211	2.6
2	614	7.5
3	6712	82.2
4	533	6.5
5	60	0.7
6	36	0.4
7	3	0.04

N=312 patients with first Medicare dialysis claim on or before January 1, 2007.

With regard to the incorporation of RRF in the calculation of adequacy, the TEP did not agree that RRF should be added to the measure description for several reasons: (i) Published studies evaluating dialysis adequacy in the pediatric population do not include residual renal function; (ii) RRF changes continuously with age in the pediatric population; and (iii) RRF is difficult to measure among pediatric patients. Neither the NQF-endorsed measure specifications nor the KDOQI guidelines support measuring spKt/V in pediatric patients based on a weekly dose. Furthermore there is no evidence to support a minimum target value for a weekly Kt/V dose. We will continue to consider other measurements of dialysis adequacy for the pediatric population; at this time, we believe that this measure is the most suitable.

For the reasons stated above, we are adopting the Kt/V measure topic as proposed. The technical specifications for each of the finalized measures in this measure topic can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/HemodialysisAdequacy-ktv-2015–FR.pdf* (adult hemodialysis), *http://www.dialysisreports.org/pdf/esrd/public-measures/PeritonealDialysisAdequacy-ktv-2015–FR.pdf* (adult peritoneal dialysis), and *http://www.dialysisreports.org/pdf/esrd/public-measures/PediatricHemodialysisAdequacy-ktv-2015–FR.pdf* (pediatric in-center hemodialysis).

b. Hypercalcemia

Section 1881(h)(2)(A)(iii) of the Act states that the measures specified for the ESRD QIP shall include other measures as the Secretary specifies, including, to the extent feasible, measures of bone mineral metabolism. Abnormalities of bone mineral metabolism are exceedingly common and contribute significantly to morbidity and mortality in patients with advanced Chronic Kidney Disease (CKD). Numerous studies have associated disorders of mineral metabolism with morbidity, including fractures, cardiovascular disease, and mortality. Therefore, we believe it is necessary to adopt a clinical measure that encourages proper bone mineral metabolism management.

One indicator of bone mineral metabolism management is ensuring normal calcium levels in the blood. Therefore, we proposed to use the NQF-endorsed measure, NQF #1454: Proportion of patients with hypercalcemia, to evaluate ESRD facilities for the PY 2015 and future payment years of the ESRD QIP. This measure assesses the number of patients with uncorrected serum calcium greater than 10.2 mg/dL for a 3-month rolling average. ''Uncorrected'' means not corrected for serum albumin concentration. Performance on this measure is expressed as a proportion of patient-months for which the 3-month rolling average exceeds the measure threshold. Because the NQF-endorsed measure calls for a 3-month rolling average, we also proposed that the first measure rate for this measure would be calculated using the first 3 months of data collected during the proposed performance period (that is, there would be no measure rate for the first 2 months of the performance period; we would calculate the first measure rate for the performance period using the first 3 months of data and would then calculate a rate each successive month, dropping the oldest month and adding the newest month). Because we proposed to adopt this measure not only for PY 2015, but also subsequent payment years, we also proposed that, beginning with the PY 2016 program, we would measure hypercalcemia beginning in January of the applicable performance period. This would allow us to have a 3-month rolling average for all months in the performance period. We proposed that the 3-month rolling average rate for January would be calculated using the rates from November and December of the previous year as well as January of that year. Likewise, we proposed that the rate for February would be calculated using the rates from December, January and February to calculate the 3-month rolling average, and so on. Technical specifications for this measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/MineralMetabolism-Hypercalcemia-2015–NPRM.pdf.*

The comments we received on these proposals and our responses are set forth below.

Comment: Several commenters supported this measure, noting that it is consistent with KDIGO guidelines and is especially necessary given that we will include oral-only drugs in the bundle beginning in PY 2014; some commenters specifically argued that that there is sufficient validity and reliability of the data collected in CROWNWeb to establish an appropriate clinical measure for PY 2015, and noted that this measure is in keeping with Congress' intent to include a measure of bone mineral metabolism in the ESRD QIP. Other commenters, however, stated their belief that, despite its NQF-endorsement, the measure is not aligned with clinical standards, is contrary to KDIGO guidelines, and does not advance the aims of the National Quality Strategy. Additionally, several commenters, both those supporting and opposing the measure, argued that it is inappropriate to use CROWNWeb data to define performance standards, achievement thresholds, and benchmarks because the data underrepresents small- and mid-sized dialysis organizations, does not account for the differences in reporting which may exist when data are voluntarily reported (and data were voluntarily reported in the CROWNWeb pilot), was submitted with the understanding that it was test data and would not be used by CMS programs, and because it suffers from serious data collection problems, a lack of definitions, and a lack of reporting requirements in CROWNWeb. Many commenters suggested that we adopt this measure as a reporting measure only for PY 2015. Several other commenters believe that the proposed hypercalcemia measure is only appropriate if we include similar clinical measures for serum phosphorus, parathyroid hormone (PTH), and other mineral metrics because a hypercalcemia measure alone represents a piecemeal approach to bone and mineral metabolism that will not be sufficient to ensure quality care for ESRD patients and may even incentivize

inappropriate care. Finally, commenters recommended that CMS monitor secondary parathyroid hormone and not include oral-only drugs in the bundle until such measures and monitoring are in place.

Response: Commenters rightly state that the performance standards, achievement thresholds, and benchmarks for the proposed Hypercalcemia measure were not calculated using data from all facilities. Because it is possible that these calculations could contain a systemic bias, and we have no effective means of addressing that bias in the ESRD QIP as this time, we will not finalize a clinical measure for hypercalcemia, as discussed above, until valid data from all facilities are accessible for the purpose of establishing performance standards, achievement thresholds, and benchmarks. We are not finalizing a clinical Hypercalcemia measure at this time. We do, however, continue to believe that hypercalcemia is an important indicator of bone mineral metabolism, and we intend to use this measure in subsequent payment years.

Comment: One commenter stated that, generally, we should not use data from CROWNWeb for the ESRD QIP until the validity of CROWNWeb data is confirmed. Commenters also urged us to find solutions for the CROWNWeb issues which the community has been experiencing in order to ensure that, as measures increasingly rely on CROWNWeb data, there is no question as to the data's validity.

Response: We thank the commenters who expressed concern regarding the use of CROWNWeb data for the ESRD QIP. Given the potential risk to validity of ESRD QIP clinical measures calculated using CROWNWeb data, we will not finalize the proposed clinical measure for hypercalcemia that depends on those data, as noted above.

Comment: One commenter urged us to exclude patients who have hypercalcemia for reasons other than ESRD treatment (for example, medication and malignancy) from the Hypercalcemia measure. The commenter requests confirmation that the Hypercalcemia measure includes all patients rather than just Medicare patients, and is concerned with CMS' move to include the total facility population in the measure collection process. One commenter seeks clarification regarding whether a lower or higher rate is desirable for the Hypercalcemia measure.

Response: We thank the commenters for raising these issues with the Hypercalcemia measure, and we will incorporate them in discussions during future rulemaking, when the Hypercalcemia measure is considered as a measure for the ESRD QIP in future payment years.

For the reasons discussed above, we will not finalize the Hypercalcemia measure for use in the PY 2015 ESRD QIP or subsequent years until indicated otherwise in rulemaking.

c. Anemia Management Reporting Measure

Section 1881(h)(2)(A)(i) requires ''measures on anemia management that reflect the labeling approved by the Food and Drug Administration (FDA) for such management.'' Although the current FDA-approved label for ESAs only specifically addresses hemoglobin levels greater than 11 g/dL, previous FDA-approved labels suggested patients on ESAs maintain a hemoglobin level of 10–12 g/dL. As we noted in the CY 2012 ESRD PPS final rule, upon further research, the FDA determined that there is no evidence suggesting a lower target level at which hemoglobin does not cause increased risks of death, serious adverse cardiovascular reactions, and stroke and, therefore, changed its approved label on June 24, 2011 (76 FR 70257).

As a result of the changes in the FDA approved-label and the implementation of the ESRD QIP, we are monitoring trends and indicators of anemia management for the Medicare ESRD population. We have found that the average monthly blood transfusion rate increased from 2.7 percent in 2010 to 3.2 percent in 2011. We are working through our ESRD QIP monitoring and evaluation program to further assess the effect of the ESRD PPS. We believe that it is important that we continue monitoring hemoglobin levels in patients to ensure that anemia is properly treated, and we, therefore, proposed to adopt a measure for PY 2015, and future payment years, which requires facilities to report ESA dosage (if applicable) and hemoglobin and/or hematocrit levels for patients on at least one monthly claim. In addition to this measure, proposed below, we plan to continue to monitor the rate of transfusions and may consider the adoption of relevant quality measures through future rulemaking if necessary.

Since January 1, 2012, facilities have been required to report hemoglobin or hematocrit[4] levels for each patient on every claim (CR 7640). Beginning April 1, 2012, if a hemoglobin or hematocrit value is not included in the claim, the claim is returned to the facility (CR 7593). If a hemoglobin or hematocrit value is not available for a patient, a facility can enter a default value of 99.99 on the claim and the claim will not be returned, provided the facility is not billing for an ESA. The default value is not acceptable when the claim includes an ESA, in such a case, the claim will be returned to the facility.

We stated in the proposed rule that we are concerned that our current policy of paying claims that include a default hemoglobin or hematocrit value of 99.99 could lead to the under-reporting of patients' hemoglobin or hematocrit levels and ESA dosage by facilities; we are specifically concerned that we will not receive complete and accurate hemoglobin/hematocrit readings for those patients not receiving ESAs because a default value of 99.99 can be reported on claims, and these claims will be paid, if no ESA is administered to the patient. Additionally, we believe that facilities might choose to strategically not report certain patients' hemoglobin or hematocrit levels on certain claims—those where the patient's hemoglobin levels are greater than 12 g/dL—in order to make the performance rate of their Hemoglobin Greater Than 12 g/dL measure seem better and reduce the likelihood of a payment reduction under the ESRD QIP.

Because it is possible that facilities could under-report hemoglobin or hematocrit levels, we proposed to adopt an Anemia Management reporting measure for the PY 2015 ESRD QIP, and future payment years of the program. For this measure, we proposed to require facilities to report a hemoglobin or hematocrit value and, as applicable, an ESA dosage for all Medicare patients at least once per month via claims. We proposed to consider claims with 99.99 values as not meeting the requirements of this measure (that is, claims reporting 99.99 will be counted as if the hemoglobin or hematocrit value were left blank).

We stated that we do not intend for this proposed measure to encourage unnecessary testing or unduly burden a facility. Consequently, for purposes of scoring the measure, we considered proposing to require facilities to report the required information for less than 100 percent of their patients. Specifically, we considered lowering the threshold to reporting 98 percent of patients for a month in order to receive credit for that month. We ultimately proposed that a facility should be required to take and report these values for every patient at least once per month so that each beneficiary receives the

[4] Hematocrit values are used to calculate hemoglobin levels by taking the hematocrit value and dividing by three.

highest standard of care. We realize, however, that there are circumstances beyond a facility's control wherein it may not be able to draw a sample for this patient. Therefore, we did not propose that the facility itself must draw blood for each patient. If, for example, a patient is hospitalized or transient during a claim month, the facility may report the hemoglobin/hematocrit readings and ESA dosage (if applicable) for the patient for a month if a patient has labs drawn by another provider/facility and those labs are evaluated by an accredited laboratory (a laboratories that is accredited by, for example, the Joint Commission, the College of American Pathologists, the AAB (American Association of Bioanalysts), or State or Federal agency), and the dialysis facility obtains the hemoglobin/hematocrit readings and ESA dosage. Additionally, we proposed to only consider a patient qualified for this measure (i) if the patient is alive at the end of the month; (ii) if the patient is treated in-center, that patient was treated at that facility at least twice during the claim month; and (iii) if the patient receives dialysis at home, a claim is submitted for that patient. We believe that these proposals will provide more flexibility for facilities and will also discourage facilities from drawing blood, even when not necessary for fear that the patient will fail to come to the facility again during that month. We requested comment on this proposal. We also requested comment on whether facilities should only have to report data for 98 percent of their patients.

The proposed Anemia Management reporting measure was not included in the list of measures under consideration in accordance with section 1890A(a)(2) of the Act because we had not yet fully assessed the impact of the new FDA-approved ESA labeling on the ESRD population. We have since received and analyzed more, but still incomplete, anemia management data; we believe it is necessary to require facilities to provide complete data so that we may fully understand the effect of the changes to ESA labeling and other factors. The proposed Anemia Management reporting measure will play a critical role in patient safety. As noted above, our monitoring activities indicate that there has been a slight but noticeable increase in transfusions since the adoption of the ESRD PPS. Additionally, a United States Renal Data System analysis presented in May 2012 found an increase in blood transfusion rates among ESRD patients concurrent with the implementation of the ESRD PPS. Although the association of changes in transfusion rates with the ESRD PPS, FDA labeling changes, and other factors are not yet known, we believe proactive facility engagement in regular monitoring of patient hemoglobin or hematocrit levels regardless of ESA use is critical to maintaining safe care, protecting the safety of beneficiaries, and monitoring the program effectively. We further believe that the data collected from the proposed measure are necessary for measure development in a clinical area of critical significance to patient safety—anemia and transfusion. A delay in proposing to adopt this reporting measure may prevent us from creating clinical measures for use in future years of the program and pose a risk to patients. Finally, we noted that section 1881(h) of the Act specifically highlights the importance of anemia management measures, and we do not believe it would be in the best interest of the program to wait an additional year to propose this measure.

For the reasons stated above, we proposed to adopt an Anemia Management reporting measure for the PY 2015 ESRD QIP and subsequent payment years. We provided the technical specifications for this measure, at *http://www.dialysisreports.org/pdf/esrd/public-measures/AnemiaManagement-Reporting-2015–NPRM.pdf.* We requested public comment on these proposals.

The comments we received on these proposals and our responses are set forth below.

Comment: Some commenters supported the measure, stating that they believe this measure will allow us to closely monitor the underutilization of ESAs and the increase in transfusions. Commenters also stated that they believe that this measure will assist in explaining and monitoring timely ESA discontinuation and studying the potential effect of altitude on patients. Many commenters supported this measure, but requested that we make modifications to our proposed exclusions. These commenters suggested that we exclude, for all of the reporting measures, the following patients: (i) Beneficiaries who are regularly treated at the facility and who fit into one of these categories: (a) beneficiaries who die within the applicable month; (b) beneficiaries that receive fewer than 7 treatments in a month; and (c) beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented, good faith effort to have them participate in such a visit during the applicable month; (ii) transient dialysis patients; (iii) pediatric patients (unless the measure is specific to this population); and (iv) kidney transplant recipients with a functioning graft. Commenters stated that these exclusions would be consistent with our own measures reported on DFC; commenters also stated that these exclusions seek to hold facilities accountable only for those beneficiaries to whom they regularly give care and for whose care they can affect. Another commenter, however, stated that we should not implement other commenters' suggestions that we exclude beneficiaries receiving home dialysis therapy who miss their in-center appointments when there is a documented, good faith effort to have them participate in such a visit during the applicable month; this commenter stated that it is the responsibility of the facilities to educate patients on the importance of making and keeping appointments. Additionally this commenter argued that ''good faith'' is too vague; commenter requested that, if we did adopt this exclusion, we clearly define a ''good faith effort.'' Another commenter stated that peritoneal dialysis patients do not need to be seen at a facility once per month and the measure should be accordingly revised.

Response: Consistent with the Mineral Metabolism reporting measure, we agree with commenters who believe that the exclusions should be modified. We recognize that treating a patient twice may not provide enough time to effectuate quality patient care. We agree with the commenters who suggested that an in-center hemodialysis patient should be excluded if treated by a facility fewer than seven times during the month, regardless of whether the patient is officially admitted to that facility. With seven treatments, we believe that a facility should have had adequate opportunities to draw blood necessary to report hemoglobin/hematocrit. We also believe that the threshold of seven will discourage unnecessary testing of in-center hemodialysis patients by facilities because they will know that, since in-center patients are typically treated three times per week, a patient must have been treated by the facility for at least two weeks to be included; thus, the facility need not feel pressure to draw blood for every patient during the first few visits of the month. Based on these considerations, we will not finalize our proposal to only exclude in-center patients who have been treated fewer than two times by the facility during the claim month. Instead, we will exclude any patient who is treated by the facility

fewer than seven times during the reporting month.

We do not believe that it is necessary to specifically exclude transient patients from this measure because, as noted, any patient that is treated by the facility at least seven times during the applicable reporting month is present at the facility for enough time that the facility should be able to measure that patient's hemoglobin/hematocrit. Likewise, for the same reasons, we do not believe we need to separately exclude patients who are deceased at the end of the reporting month. Provided that the patient was treated by the facility at least seven times during that month, the facility should be able to draw blood necessary to obtain hemoglobin/hematocrit values even if the patient is deceased at the end of the month.

Additionally, we do not agree that facilities should not be held accountable for drawing blood from home dialysis patients who fail to attend a monthly appointment. We believe that it is incumbent upon a facility to make home dialysis patients aware that they must attend monthly appointments to be properly treated. Therefore, we will finalize our proposal that we will include any home hemodialysis patient for which a facility submits a claim with respect to the reporting month in this measure.

Finally, we believe it is important to include transplant patients until they are officially discharged from a facility; regular monitoring can help ensure that a transplant remains effective and the facility is continuing to provide the best care possible.

For the reasons stated above, we will modify our proposals for the exclusions for this measure and finalize that, for the PY 2015 ESRD QIP, facilities must report hemoglobin/hematocrit at least once per month via claims for (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. If the facility administers an ESA to these patients, it must also report the HCPCS code and corresponding unit for that patient. We will interpret an empty HCPCS field to mean that no ESA was administered.

Comment: Several commenters encouraged us to not adopt a percentage reporting threshold because it does not distinguish between beneficiaries legitimately excluded and those that were merely missed. Other commenters requested that we use both exclusions and a threshold; one commenter suggested a threshold of 90 percent or an allowance of two patients to ensure that small facilities are not disproportionally affected. Another commenter stated that requiring 98 percent reporting may make it difficult for patients to travel because dialysis facilities may encourage them otherwise in order to ensure compliance with the measure. One commenter requested that we provide guidance regarding the standardization of blood-draws so that data can be reliable before we implement a reporting threshold.

Response: We agree with the commenters who argued that, even with exclusions, there are circumstances in which facilities cannot report the hemoglobin/hematocrit and ESA dosage, as applicable, for every patient at least once per month. It is possible that these exclusions alone may hold a facility responsible for a patient who was technically treated by the facility but who did not receive actual treatment from the facility during the applicable month. For example, a facility may wait to draw blood from a patient because it believes that the patient will be treated there for the entirety of the month, but learns that the patient has been hospitalized unexpectedly for all or part of the applicable month. Therefore, we believe that we should not require facilities to report for 100 percent of their patients. Based on data from CROWNWeb, we believe that facilities report hemoglobin/hematocrit and ESA dosage for approximately 99 percent of their patients on a monthly basis. We believe it is appropriate to assume that a similar percentage was reported via claims. Although, as commenters have argued with regard to the Mineral Metabolism reporting and the Hypercalcemia measures, this information in CROWNWeb was voluntarily reported which may mean that the data is biased toward facilities that value reporting; additionally, the data from the CROWNWeb pilot was mainly supplied by LDOs that may be more likely to have more resources and corporate policies that require reporting compliance.

Taking all of these issues into consideration, we finalize a normative reporting threshold for this measure; facilities will be required to report at the lesser of the 50th percentile of all facilities in 2013 or 99 percent, in total, of their (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. This floor ensures that facilities are not penalized as long as they report at a high rate that is consistent with CROWNWeb data; that is, facilities know that, provided they reach 99 percent for each month of the performance period, they will meet the requirements of the measure. We believe that this methodology fairly balances the concerns that the reporting in CROWNWeb is skewed with our desire to encourage continued excellence in the community.

We are concerned that small facilities may be disproportionately impacted by the reporting threshold because, for example, a facility with 10 patients could fail to report for only one patient and, therefore, fail to meet the threshold. As we discuss below, we believe that 11 cases is an appropriate minimum for purposes of scoring clinical measures. As we have stated, we intend to use the information collected from reporting measures for purposes of scoring clinical measures based on the same data in subsequent payment years. Therefore, we will not require a facility to report this measure if it treats less than 11 (i) in-center Medicare patients who have been treated at least seven times by the facility; or (ii) home hemodialysis Medicare patients for whom the facility submits a claim. If a facility does not treat at least 11 of these patients during the performance period, it will be required to attest to this fact via CROWNWeb. If a facility does not make the attestation, we will score it accordingly.

Comment: Several commenters do not support this measure because facilities already collect these data so the measure is unlikely to improve care. Some of these commenters asked us to require facilities to report this information separate from the ESRD QIP on at least one monthly claim to ensure anemia is properly treated.

Response: As we noted in the proposed rule (77 FR 40974), we believe that this measure will discourage underreporting of ESAs and hemoglobin. Currently, facilities may report a value of 99.99 as default hemoglobin for claims that do not include an ESA. Since the bundle includes ESAs, it may not be financially beneficial for a facility to report an ESA, especially if a patient's hemoglobin is greater than 12—negatively affecting its Hemoglobin Greater than 12 g/dL measure score. Additionally, we are concerned that the 99.99 value will be overutilized and will not allow us to properly monitor hemoglobin levels across the ESRD population. If we are able to closely and accurately monitor ESA dosage and hemoglobin, we believe we will be able to improve care by using this information to monitor the effects of the bundle and the ESRD QIP on beneficiaries; we also believe we may

utilize these data in the future to develop an anemia management clinical measure.

Comment: Many commenters noted that it is impractical for facilities to obtain lab values from other providers because other providers are not required to measure these data, do not share data with dialysis facilities, and, even if facilities could obtain these data, they could not be sure that the labs were consistent or reported under the same standards. Additionally, one commenter argued that hemoglobin levels from other facilities will be of little use without further information regarding why the patient was at that facility. One commenter agreed that hemoglobin/hematocrit values can be supplied by another provider provided the labs are evaluated by an accredited facility.

Response: We recognize that it may be difficult for facilities to coordinate with hospitals and other providers in order to obtain lab values. We, however, are not mandating facilities to do so. In the proposed rule (77 FR 40974), we stated that facilities may obtain lab values from other providers. This proposal was specifically designed to afford facilities more flexibility in acquiring and reporting hemoglobin and hematocrit values, as well as ESA dosage. Facilities are highly encouraged to coordinate with other providers, but this measure does not mandate them to do so. We believe that the commenters' concerns about inconsistent lab data are mitigated by the requirement that the lab must be accredited. Further, we do not believe that data from another provider will be of little use. We can use these values to monitor hemoglobin and hematocrit levels of ESRD patients, as well as ESA dosage; additionally, collecting these data may encourage providers to engage one another about the patient's conditions and care.

Comment: One commenter noted that hemoglobin values on claims are from the prior month; therefore the 99.99 is used for the claim in the first month of a patient's dialysis or if a patient had a transplant. The commenter requested clarification on what it should report in these circumstances. Other commenters argued that 99.99 should be available without penalty to facilities because in some instances, it is appropriate. One commenter supported disincentivizing 99.99 reporting in order to stop facilities from not reporting patients with high hemoglobin.

Response: The commenter is correct in that the Erythropoietin Monitoring Policy (2006) [5] requests that the hemoglobin/hematocrit reading reported on claims be defined as ''the most recent reading taken before the start of this billing period. For patients beginning dialysis, use the most recent value prior to the onset of treatment.'' We recognize that, for some patients, specifically those new to dialysis, this hemoglobin/hematocrit values may not be available. Therefore, we will not require a facility to report a hemoglobin/hematocrit value for a patient if that patient has been on dialysis for less than one month (including when dialysis is resumed after a transplant); facilities may report the default value without being penalized in this circumstance. We remind facilities that if an ESA is reported on a claim, the facility must also report a hemoglobin/hematocrit level, regardless of whether that patient is new to dialysis (CR 7460).

Comment: One commenter asked us to include Omontys, an ESA new to the market, in this measure. Other commenters generally requested that we monitor new ESAs and their effects on hemoglobin levels.

Response: We intend to monitor ESA dosage for all ESAs used by dialysis facilities. Using HCPCS codes, a facility must indicate which ESA it administered, including Omontys.

Comment: One commenter noted that it supports the reporting of hemoglobin, but not hematocrit because the data set should be standardized to require only hemoglobin reporting.

Response: Facilities can report either hemoglobin or hematocrit on claims. Either will count for the purpose of this measure. (For the Hemoglobin Greater than 12 g/dL measure, hematocrit values are changed to hemoglobin by dividing by 3). As of 2011, only 14 percent of facilities reported hemoglobin, while 70 percent reported hematocrit. We believe that requiring 70 percent of all facilities to alter their reporting method would generate undue burden on the dialysis facility community, for relatively little gain, as we have an established method for incorporating both hemoglobin and hematocrit into the measure calculation.

Comment: Some commenters asked us to state the purposes of the anemia management reporting measure with more specificity. Some commenters requested that we clarify how we intend to report and make publicly available hemoglobin/hematocrit levels and ESA dosages. Commenters asked us to clarify the plans for the use of the information and how we will account for patient weight in our analyses.

Response: We believe that the anemia management reporting measure emphasizes the importance of anemia management for the ESRD population and will support efforts to establish more meaningful, evidence-based clinical measures of anemia management in the future. We intend to publicly report the anemia management reporting measure rates in the same manner that we use to publicly report other measure rates under the ESRD QIP but will not score facilities based on those rates. Facilities will be able to preview the reporting data to be publicly reported before we post it on DFC. At present, the Anemia Management reporting measure does not take patient weight into account, but we will consider whether this type of adjustment is appropriate for future years of the ESRD QIP. We would also like to clarify that we will use HCPCS codes that indicate ESA administration and their corresponding units for assessing whether an ESA was administered. We will interpret an empty HCPCS field to mean that no ESA was administered.

Comment: One commenter supports this measure but suggests that the data be captured in CROWNWeb since hemoglobin levels are only reported on claims with ESA doses.

Response: The commenter is correct that CROWNWeb only requires a hemoglobin/hematocrit if an ESA is entered.

Since January 1, 2012, however, facilities have been required to report hemoglobin/hematocrit on claims regardless of whether an ESA dose was administered (CR 7460). Facilities are expected to report the anemia management reporting measure on their claims.

Comment: One commenter supports the measure but only for patients with hemoglobin less than 10 g/dL. It is more likely, the commenter argues, that one will identify a patient with a low hemoglobin (even if that patient is not on ESAs) if a new reporting measure is instituted. The commenter believes that reporting hemoglobin for patients not on ESAs who have a hemoglobin greater than 12 g/dL is not necessary because these patients are not at risk for the complications that arise from targeting high hemoglobin levels using ESAs.

Response: It is our intention to use the data we collect from this reporting measure to develop an anemia management clinical measure and monitor anemia management trends. In order to better understand the ESRD population as a whole and collect a

[5] *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM4135.pdf.*

robust data set, we believe it is important to collect hemoglobin/hematocrit levels for patients regardless of their values or if an ESA was administered. Using this information, we can, among other things, assess trends across the entire population and use these data for measure development and monitoring purposes.

As explained above, we are modifying our proposed exclusions and finalizing that a facility must report hemoglobin/hematocrit and ESA dosage (via HCPCS codes and their units) for the lesser of the 50th percentile of facilities in 2013 or 99 percent, in total, of its (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. We will interpret an empty HCPCS field to mean that no ESA was administered. We also finalize that we will only apply this measure to facilities with at least 11 (i) in-center Medicare patients who have been treated at least seven times by the facility; and (ii) home hemodialysis Medicare patients for whom the facility submits a claim. Facilities who treat less than 11 of these patients during the performance period must attest to this fact in CROWNWeb. If they do not make this attestation, we will score them accordingly. Additionally, we will not penalize facilities for using the default 99.99 value for a patient in his/her first month of treatment at that facility. The technical specifications for this finalized measure can be found at *http://www.dialysisreports.org/pdf/esrd/public-measures/AnemiaManagement-Reporting-2015-FR.pdf.*

4. Measures Under Consideration for Future PYs of the ESRD QIP

In addition to the PY 2015 ESRD QIP, we noted in the proposed rule that we are considering measures for future payment years of the program. We are specifically considering whether we should propose in future rulemaking to adopt the following two measures,

- NQF #1463: Standardized Hospitalization Ratio for Admissions (SHR) and
- NQF #0369: Dialysis Facility Risk-adjusted Standardized Mortality Ratio (SMR).

We stated that we intend to adopt these measures for future payment years of the ESRD QIP, possibly beginning with the PY 2018 program. We notified facilities of our intent and solicited comments on incorporating these measures into future payment years of the ESRD QIP.

a. Standardized Hospitalization Ratio (SHR)

Hospitalizations are an important indicator of patient quality of life and morbidity. The SHR is an NQF-endorsed (#1463), risk-adjusted measure of hospitalization for dialysis patients. The measure is claims-based and describes, as a ratio, the number of ESRD Medicare patient actual admissions versus expected hospitalizations adjusted for the facility's Medicare patient case mix. Please refer to the NQF Web site (*www.qualityforum.org*) to obtain more detail about this measure.

b. Standardized Mortality Ratio (SMR)

The SMR measure is an NQF-endorsed (#0396) critical patient-centered, outcome measure of overall patient care furnished by facilities. We believe that the SMR measure would encourage appropriate overall patient care by facilities and incentivize facilities to examine the holistic health of the patient rather than treating the patient based on an individual measure-by-measure basis. The SMR measure describes, as a ratio, the number of ESRD Medicare patient actual deaths versus expected deaths adjusted for the facility's Medicare patient case mix. Please refer to the NQF Web site (*www.qualityforum.org*) to obtain more detail about this measure.

c. Public Reporting of SHR and SMR Measures

Although the SHR and SMR measures may not be adopted for the ESRD QIP until a future payment year, we intend to publicly report these measure ratios to the public via Dialysis Facility Compare (DFC) to encourage facilities to improve their care. Section 4558(b) of the Balanced Budget Act of 1997 (Pub. L. 105–33) (BBA) directs the Secretary to develop, not later than January 1, 1999, and implement, not later than January 1, 2000, a method to measure data reflective of the quality of renal dialysis services provided under the Medicare program. Under this authority, we began reporting the SMR measure on DFC in January, 2001 as a survival measure and used three categories to rate facility performance: ''as expected,'' ''worse than expected,'' and ''better than expected.'' The SMR measure that we are considering adopting for the ESRD QIP was developed in 1999 and facilities are required to submit these data via form 2746. The SHR measure that we are considering adopting for the ESRD QIP was developed in 1995, presented to a Technical Expert Panel after modifications to risk adjustment and statistical modeling in 2007, and received NQF-endorsement in 2011. The data needed to calculate the SHR measure have been regularly reported to DFR since 1995 and have been used by facilities for quality improvement activities. We plan to add the SHR data to the DFC effective January 2013; additionally we will report the actual SMR rates/ratio on the DFC beginning January 2013.

We originally proposed to adopt the SHR measure for the PY 2014 ESRD QIP, but did not finalize the proposal, in part, because commenters voiced concerns regarding the accuracy of the co-morbidity data used in the calculation of the measures. Details on public comments and why we did not adopt the SHR measure are articulated in the CY 2012 ESRD PPS final rule (76 FR 70267). Since that time, we have identified that the claim form UB 92 with the type of bill (TOB) field 72x allows a facility to input up to 17 co-morbid conditions per claim submission. We acknowledge that patient co-morbidities can change with time and since the capability already exists on the UB 92 TOB, we believe the best means for facilities to update patient co-morbidities is through the ESRD 72x claims form. Details on this form can be found in the Medicare Claims Processing Manual, Chapter 8—Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims (*https://www.cms.gov/manuals/downloads/clm104c08.pdf*).

In addition, because the NQF-endorsed SHR and SMR measures are risk-adjusted for ESRD patients that reside in nursing homes, in order to calculate the measure rates on DFC, we will utilize data from the Minimum Data Set (MDS) to identify those individuals in nursing homes. We would use these data not only for reporting the measure rates on DFC at present, but also for calculating the measures if we adopted them for use in future years of the ESRD QIP. The Omnibus Budget Reconciliation Act (OBRA) of 1987 requires that all Medicare and Medicaid certified nursing homes complete MDS assessments on all of their patients.

We requested comment regarding the feasibility of adopting these measures for future payment years of the ESRD QIP.

The comments we received on these proposals and our responses are set forth below.

Comment: Although most commenters agreed that measures for hospitalization are important for quality reporting purposes, many commenters strongly opposed that the SHR measure be included in the ESRD QIP in subsequent payment years. These

commenters argued that the SHR measure is a measure over which facilities have little control because patients often follow the advice of their primary care physician or visit a hospital without consulting the facility to receive treatments that could be furnished in the outpatient setting. Commenters expressed concern that the measure could lead to cherry-picking, disincentivize appropriate hospitalization, and is not transparent enough for facilities to make improvements in this area because of they are confused about the risk-adjustment methodology. Other commenters stated that the measure needs further refinement and validation, specifically regarding risk adjustment for frail patients such as those in nursing homes, cultural factors, socioeconomic factors, and health factors specific to the ESRD population. Commenters asked that these adjusters be made public. One commenter believes that this measure would create a bias for facilities on the basis of location. Some commenters suggested that, instead of implementing this measure, CMS consider a coordinated care model. Other commenters requested that we adopt a pilot for this measure wherein only aggregate data is reported until the measure can be further assessed and validated. Several commenters suggested that we implement an SHR measure focused on admissions that could have been prevented by interventions from dialysis facilities; one commenter suggested that the SHR measure be modified to calculate a ''risk-adjusted standardized hospitalization ratio for dialysis access-related infections and fluid overload,'' since these are elements facilities can control.

Response: We thank commenters for these opinions. We will take these comments into consideration as we further assess the appropriateness of adopting the SHR measure for the ESRD QIP.

Comment: Many commenters strongly supported the consideration of SHR for future years of the ESRD QIP. One commenter requested that we implement the measure as soon as possible. Commenters also supported reporting measure rates on DFC beginning in CY 2013. One commenter supports the addition of SHR data to DFC as long as a caveat is included explaining that dialysis facilities can influence but do not control hospitalization rates. This commenter also requested that the ''expected,'' ''better than expected,'' and ''less than expected'' categories remain on DFC. One commenter argued that there is not enough data on SHR to report rates on DFC.

Response: We thank the commenters who supported the future consideration of the SHR for implementation. We intend to begin public reporting of the SHR on DFC as of January 2013 to indicate the relative performance of facilities. We believe that dialysis facilities own partial responsibility for the rate at which their patients are hospitalized, in particular when that rate is substantially higher than at other peer facilities and may not be explained by variation in the illness of patients. We do acknowledge that care provided by dialysis facilities is not the sole determinant of the hospitalization of ESRD patients and this measure would not support the assertion that they are. The SHR is only shown for patients with at least 5 patient years at risk, which corresponds to approximately 10 expected hospitalizations. The confidence interval for the SHR will also be reported on DFC to show the uncertainty in the value due to random variation, which will help to address the issue of limited data for the SHR. We appreciate these suggestions and will take them into consideration as we further assess the appropriateness of adopting the SHR measure for the ESRD QIP.

Comment: Some commenters strongly support using the 72x claims as indicators of risk factors for facilities and patients. One commenter suggested that this information could be used in creating an access to care measure/adjustment in the future. Other commenters, however, believe that reporting comorbidities on the 72x claim could be a huge administrative burden for facilities, including time associated with validating that the data they submit on these claims is valid.

Response: We recognize that reporting co-morbidities on 72x claims could be burdensome to some facilities. We believe, however, that this information is valuable, specifically in the context of future measure development. We will continue to assess the best means available for risk-adjustment for both the SHR and SMR measures, taking both the benefits of the information and the burden to facilities into account, should we propose to adopt these measures in future rulemaking.

Comment: One commenter argued that SHR is not a measure whereby facilities can make meaningful improvement because the measure's rates cannot be calculated in real-time; the commenter asked that claims be made available to the facility in a timely manner if the measure is adopted so that they can become aware of hospitalizations and other co-morbidities and calculate their SHR in real-time.

Response: We will consider this suggestion if we decide to propose to adopt the SHR measure for the ESRD QIP in future rulemaking.

Comment: One commenter noted that the SHR measure should be at least a two to three year measure as 1 year of data is not sufficient for an accurate assessment.

Response: We recognize that the NQF-specifications call for a measurement period that is longer than 1 year, and we continue to assess how to implement such an extended measure period effectively in the ESRD QIP if we propose to adopt the SHR measure in future rulemaking.

Comment: Many commenters opposed the use of SMR in future years for reasons similar to that of SHR. Commenters expressed concern that the measure could lead to cherry-picking and is not transparent enough for facilities to make improvements in this area because of they are confused about the risk-adjustment methodology. Other commenters stated that the measure needs further refinement and validation, specifically regarding risk adjustment for frail patients such as those in nursing homes, cultural factors, socioeconomic factors, and health factors specific to the ESRD population. Commenters asked that these adjusters be made public. One commenter believes that this measure would create a bias for facilities on the basis of location. Another commenter argued that the measure should only account for catheter/dialysis complications and should not include ''sudden deaths.'' One commenter stated that literature suggests that the measure is invalid in small facilities and only valid in large facilities when averaged over several years. Some commenters suggested that, instead of implementing this measure, CMS consider a coordinated care model. Other commenters requested that we adopt a pilot for this measure wherein only aggregate data is reported until the measures can be further assessed and validated.

Response: We thank the commenters who shared concerns and provided suggestions regarding the future consideration of the SMR for implementation in the ESRD QIP. We will continue to consider these suggestions as we decide whether to propose to adopt the SMR measure. In the DFR, we limit reporting to facilities with at least 3 expected events for the time period. Similarly, we only calculated SHR based on at least 5 patient years at risk, which corresponds

to approximately 10 expected hospitalizations. We incorporated these limitations on the measures to account for potentially imprecise estimates resulting from small facility size.

Comment: One commenter stated that the SMR measure should not be adopted until CMS can articulate how it fits into the ESRD QIP's strategic vision.

Response: While we recognize that the ESRD population is at high risk for mortality by definition, we believe that mortality rates are susceptible to the quality of care provided by dialysis facilities. We believe the SMR may help distinguish the quality of care offered by dialysis facilities as determined by mortality, a key health care outcome used to assess quality of care in other settings, such as hospitals. We believe the SMR may also fill an important gap in the ESRD QIP by assessing the outcome of all ESRD care provided at the dialysis facilities, rather than individual processes of care. For these reasons, we will continue to consider the inclusion of the SMR in future rulemaking cycles.

Comment: Many commenters strongly supported the consideration of SMR for future program years, noting that death is the most important measurement of negative outcomes. One commenter requested that we implement the measure as soon as possible. One commenter suggested that the measure specifically focus on patients within their first 90–120 days of dialysis since these patients are generally more likely to die. Commenters also supported reporting measure rates on DFC beginning in CY 2013.

Response: We thank commenters for their support of this measure. At this time, we do not believe it should be included in the PY 2015 ESRD QIP due to the concerns voiced by other commenters. We will consider the measure's assessment of patients in their first months of dialysis for future rulemaking. Finally, we will begin reporting the SMR measure rates on DFC in 2013 and are attempting to address potential shortcomings pointed out by commenters that we described in the CY 2012 ESRD PPS final rule (76 FR 70267) prior to proposing the measure for ESRD QIP.

Comment: One commenter argued that SMR is not a measure whereby facilities can make meaningful improvement because the measure's rates cannot be calculated in real-time; the commenter asked that claims be made available to the facility in a timely manner if the measure is adopted so that they can become aware of hospitalizations and other co-morbidities and may calculate their SMR in real-time.

Response: We will consider this suggestion if we decide to propose to adopt the SMR measure for the ESRD QIP in future rulemaking.

Comment: One commenter noted that the SMR measure should be at least a two to three year measure as 1 year is not sufficient for an accurate assessment.

Response: We recognize that the NQF-specifications call for a measurement period that is longer than 1 year, and we continue to assess how to implement this measurement period effectively in the ESRD QIP if we decide to propose to adopt the SMR measure.

Comment: One commenter requested clarification regarding whether the facility's rates would be compared to current or past national averages when assessing the number of expected deaths.

Response: The SMR measure estimates the relative death rate ratio for a facility, as compared to the national death rate. The relative death rate ratio and the national results are all determined during the same (current) time period.

In response to comments, we will continue to consider the SMR and SHR measures for future years of the program. We will, as proposed, begin displaying the rates/ratios for these measures on DFC beginning in early 2013.

5. Other Potential Future Measures Under Development

As part of our effort to continuously improve the ESRD QIP, we are working on developing additional, robust measures that provide valid assessments of the quality of care furnished to ESRD patients by ESRD facilities. Some areas of measure development are discussed below. In addition, we are considering the feasibility of developing quality measures in other areas such as kidney transplantation, quality of life, health information technology for quality improvement at the point of care and the electronic exchange of information for care coordination, and transfusions. We requested comment on these potential areas of future measurement and welcomed suggestions on other topics for measure development.

The comments we received on these proposals and our responses are set forth below.

Comment: We received suggestions for many future measures. These included: (i) A CAHPS/experience of care measure for home dialysis and pre-dialysis patients; (ii) a measure assessing catheter access site infections; (iii) a measure for adequate serum albumin; (iv) a measure promoting immunizations; (v) measures assessing iron management; (vi) patient fluid management measures; (vii) measures incentivizing home hemodialysis; (viii) an NHSN measure for home patients that includes peritonitis; (ix) measures that specifically monitor nursing sensitive indicators; (x) a measure that tracks which modalities a facility offers; (xi) a measure that tracks whether a facility exceeds the average percentage of patients between 18 and 54 who are employed; (xii) a measure that tracks whether facilities have shifts after 5:00 p.m.; (xiii) an emergency department use measure; (xiv) a measure on transplantations/referrals; (xv) a measure on dialysis adequacy for frequent dialyzers; (xvi) measures on phosphorus and PTH; (xvii) a composite measure which takes into account the interdependability of calcium, phosphorus, and parathyroid hormone in bone mineral metabolism; (xviii) measures assessing quality of life; and (xix) palliative care measures.

Response: We thank the commenters for your comments regarding measure implementation. We will take these suggestions into consideration during future measure development and rulemaking.

Comment: Some commenters specifically requested that we broaden the use of pediatric measures in the ESRD QIP. These commenters recommended that we (i) develop (a) a dialysis adequacy measure for peritoneal pediatric patients and (b) a CAHPS/experience of care measure for pediatric patients; and (ii) consider the following NQF-endorsed measures: (a) Measure 1418: Frequency of Adequacy Measurement for Pediatric Hemodialysis Patients; (b) Measure 1421: Method of Adequacy Measurement for Pediatric Hemodialysis Patients; (c) Measure 1425: Measurement of nPCR for Pediatric Hemodialysis Patients; (d) Measure 1433: Use of Iron Therapy for Pediatric Patients; and (e) 1424: Monthly hemoglobin measurement for Pediatric Patients.

Response: We thank the commenters for suggesting additional measures relevant to the pediatric portion of the ESRD population for future consideration in the ESRD QIP. We recognize the importance of assessing the quality of care furnished to pediatric ESRD patients. To this end, we are adopting in this final rule a measure of pediatric hemodialysis adequacy for PY 2015. We will consider whether it is appropriate to propose to adopt

additional pediatric measures for the ESRD QIP.

Comment: Some commenters specifically discouraged us from considering certain measures for future ESRD QIP adoption. These included (i) a quality of life measure, because no research shows that facilities can improve this aspect of patient life and patients often refuse to take surveys; and (ii) measures on electronic information exchange because it is unclear what these measures would entail or how they could be carried-out.

Response: We appreciate the comments and will take them into consideration during future measure development.

Comment: Many commenters supported a measure on transfusions if this measure assessed transfusions that are within the control of ESRD facilities. One commenter suggested that, before the measure is adopted, we wait to see the results of studies looking at when transfusions are and are not within a facility's control. One commenter requested clarification regarding where CMS accesses transfusion data, whether the information shows the underlying reason for the transfusion, and the timeframe for CMS' access and analysis of the data.

Response: We appreciate the comments and will take them into consideration during future measure development.

Comment: Commenters also discussed the general principles CMS should embrace in future years of the program. Commenters encouraged us to work with the kidney care community to adopt a strategic vision for the ESRD QIP, specifically the criteria and process for the adoption of measures and domains. One commenter requested that CMS and other stakeholders agree on the timeline and process for future measure development. Commenters also urged us to provide the criteria used to select measures, recommending the NQF selection criteria, and engage the Measures Application Partnership in identifying measures to include in the program and their weighting. In selecting measures, commenters stated that every measure should (i) have a verified entity responsible to maintain and update it at least once every three years; and (ii) be fully and clearly specified and tested for reliability and validity. Commenters also recommended that we phase measures into the program, requiring reporting of the measure outside of the ESRD QIP for at least 1year, and once a measure is added, we score facilities based on the lesser of the facility's performance or the national performance rate, at least for the first year. One commenter stated that all future measures should be NQF-endorsed before they are adopted. Another commenter noted that NQF-endorsement does not mean a measure is appropriate for the ESRD QIP.

Response: We remain dedicated to a transparent, consensus-based measure development process that offers multiple opportunities for input from stakeholders. The measure development process that we currently use includes using Technical Expert Panels and public comment periods, seeking NQF endorsement, providing measures to the Measures Application Partnership for feedback, and the rulemaking process in which we respond to stakeholder comments. We encourage continued engagement by the kidney care community in this process, both in prioritizing additional measures, supporting ongoing measure development, and providing feedback for currently implemented measures.

At present, we analyze all clinical measures for validity and reliability, and NQF endorsement is a key consideration we take into account when deciding whether to propose to adopt clinical measures. Where endorsed measures are not available to address key issues relevant to the ESRD population, we intend to consider unendorsed measures until such endorsed measures are available. We agree that clinical measures should be fully specified at the time they are proposed.

We believe that, generally, it is helpful to both the ESRD QIP community and CMS to phase-in measures as the commenter suggests. We do not entirely understand the comment stating that we should score facilities based on the lesser of the facility's performance or the national performance rate. We take this to mean that we should use a scoring methodology similar to PY 2012 and PY 2013 for new measures. At this time, we believe the objectives of the program are best served by scoring facilities using the achievement and improvement scoring methodology for the reasons discussed below.

Comment: Some commenters support additional measures but requested that they be implemented no sooner than PY 2018 since CROWNWeb has just launched and data collection would likely be through CROWNWeb.

Response: We recognize that CROWNWeb is a new data collection system and plan to take that into consideration while developing and implementing ESRD QIP measures in the future.

Comment: In designing future years of the ESRD QIP, commenters urged us to focus on the most important measures because adding measures could dilute each measure's weight in the calculation of the Total Performance Score.

Response: We acknowledge the commenter's concern and note that we will seek to balance appropriateness of the measures, importance of the measures, and parsimony as we consider what measures to implement through future rulemaking.

Comment: Some commenters made broad suggestions about measure adoption in the future, suggesting that we use a phased approach for measure implementation whereby the measures would be reported outside of the ESRD QIP for 1 year prior to adoption of the measure in the ESRD QIP; commenters argued that this reporting period will allow us to set a proper baseline for clinical measures.

Response: We thank commenters for their suggestions. In general, we seek to collect at least 1 year of data through claims or CROWNWeb before adopting a measure for the ESRD QIP. However, we make this assessment on a case-by-case basis because of the importance of timely implementation of some measures (for example, measures that directly affect patient safety). We will continue to consider these issues as the ESRD QIP evolves.

Comment: One commenter encouraged us to improve the program by maintaining a reasonable number of measures in order to reduce administrative costs and publicly reporting quality measures on DFC.

Response: As the ESRD QIP evolves from year-to-year, we seek to continuously evaluate the effectiveness of the measure set, burden to providers, and clarity for beneficiaries.

a. Thirty-Day Hospital Readmissions

One of the major areas our VBP programs seek to promote is care coordination. Care coordination measures assess caregivers not only on the care directly under their control, but also on their success in coordinating care with other providers and suppliers. Hospital readmission is often the outcome of uncoordinated care. Care coordination measures encourage primary caregivers, ESRD facilities, physicians, and hospitals to work together to improve the quality of care. A 30-day hospital readmissions measure is a primary example of care coordination. This measure is currently under development for the ESRD QIP, and we requested comment regarding our use of such a measure in future payment years.

The comments we received on this topic and our responses are set forth below.

Comment: Commenters made many suggestions with regard to a 30-Day Readmissions measure. Some commenters did not support the adoption of this measure for the ESRD QIP, arguing that facilities cannot always control hospitalization, and suggested that facilities would be better suited to use this type of measure in a coordinated care setting. One commenter encouraged us to adopt this measure in place of an SHR measure because a 30-Day Readmission measure is more likely to increase care coordination and less likely to encourage cherry-picking. One commenter suggested that a 30-Day Readmission measure include a grace period of 10–14 days for which the facility would not be held responsible, preventing facilities from being penalized if the patient received low-quality care in the hospital, and limiting the possibility that facilities could turn away patients who have recently been hospitalized. This commenter also pointed out that the hospital 30-Day Readmissions measure does not include ESRD patients and argued that hospitals should be held responsible for readmissions during the grace period the commenter suggests. One commenter requested that the community be able to review the findings of the Hospitalization TEP that CMS held in May 2012 before this type of measure is adopted.

Response: We appreciate the comments regarding our consideration of a 30-day readmission measure and will take them into consideration in future rulemaking. We note that it is our policy to make publicly available the results of measure development TEPs through *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TechnicalExpertPanels.html.*

b. Efficiency

One of the main goals of our VBP programs is not only to enhance quality of care but also improve efficiency in providing that care. At present, we are not aware of an efficiency measure that is appropriate for the ESRD population. We noted, however, that we were interested in receiving comments regarding this concept.

The comments we received on this topic and our responses are set forth below.

Comment: We received many comments regarding our proposal of developing and adopting an efficiency measure in future years. Several commenters noted that an efficiency measure is not necessary because of the bundled payment. Many commenters asked that, if such a measure is developed, it be case-mix adjusted for nursing home residents, homeless patients, and drug and alcohol abuse to discourage cherry-picking. One commenter cautioned us to explore the unintended consequences which may result from this measure, and another commenter requested that we engage in more studies defining ''efficiency'' before we adopt a measure.

Response: We thank our commenters for their input regarding the consideration of an efficiency measure for implementation in the ESRD QIP. We will take these suggestions into account as we develop measures for future years of the ESRD QIP.

c. Population/Community Health

We are aware that unintended consequences, specifically those involving access to care, may result from the ESRD QIP. To address these concerns, we are currently monitoring access to care and exploring the development of new measures or adjustments to existing measures that would mitigate the unintended consequences and/or incentivize facilities caring for patients who may, generally, contribute to lower facility measure rates. We requested comment on developing such a measure or adjustments to measures, specifically with regard to access to care issues.

The comments we received on this topic and our responses are set forth below.

Comment: Many commenters provided feedback on a possible access to care measure. Some commenters encouraged the development of such measures. Many of these commenters suggested that, instead of creating a measure to assess access to care, we develop comorbidity adjustments for quality measures that would ease facilities' concerns about treating these patients. Commenters who serve aging patients with multiple comorbidities believe there needs to be further consideration for facilities caring for these types of patient populations. Other commenters noted that present and future measures should exclude homeless patients, nursing home patients, and patients with comorbidities of drug/alcohol abuse and mental health issues to protect access to care for these patients. Several commenters believe that care coordination is important but is not practical due to data timing issues and knowledge of staff; these commenters suggested that CMS fund additional staff and technology prior to implementing care coordination measures. One commenter suggested that we analyze the following factors when assessing access to care: (i) Miles traveled to facility; (ii) time required to commute to facility; and (iii) method of transportation/responsible party.

Response: We thank the commenters for expressing interest in addressing the issue of access to care. We are sensitive to the particular role access to care can play for ESRD patients, and the limitations encountered in collecting relevant data. Clinical measures assessing mortality and hospitalization in the ESRD population were proposed in the PY 2014 ESRD QIP, and we have incorporated risk adjustment for comorbidities in the specifications for these measures, but it is not clear to us how effectively this risk-adjustment can address problems with access. Factors such as distance traveled are not captured by claims data. We believe that exclusion of the suggested groups (homeless, nursing home patients, etc.) from quality measures may protect access for these groups, but would fail to adequately address issues for quality of care in those patients who are most at risk for poor health outcomes. We are also concerned that such exclusions may excuse facilities from taking steps toward more effective coordination of care. We respectfully disagree that care coordination is not practical. Rather, we believe it is a vital element of care for a population that is by definition at particular risk for transitions into and out of care settings such as acute care hospitals. It is particularly important for those patients who reside in long-term care facilities such as nursing homes, or who must seek care for chronic conditions related to mental health issues or drug/alcohol abuse to receive care that is coordinated since these individuals often receive extensive care from various types of providers.

6. Scoring Background and General Considerations for the PY 2015 ESRD QIP

Section 1881(h)(3)(A)(i) of the Act requires the Secretary to develop a methodology for assessing the total performance of each facility based on the performance standards established with respect to the measures selected for the performance period. For the PY 2014 ESRD QIP, we adopted a performance scoring methodology that assessed facilities on both their achievement and improvement on clinical measures. We stated that we believe that this scoring methodology will more accurately reflect a facility's performance on the measures because it

will enable us to differentiate between facilities that simply meet the performance standards, those that exceed the performance standards by varying amounts, and those that fall short of the performance standards. We also stated that we believe that the PY 2014 methodology appropriately incentivizes facilities to both achieve high Total Performance Scores and improve the quality of care they provide (76 FR 70272). We believe that the methodology set forth for PY 2014 continues to incentivize facilities to meet the goals of the ESRD QIP; therefore, with the exception of the proposed changes in the proposed rule (77 FR 40976), we proposed to adopt a scoring methodology for the PY 2015 ESRD QIP that is nearly identical to the PY 2014 ESRD QIP.

The comments we received on this proposal and our responses are set forth below.

Comment: Several commenters supported our proposal to use the PY 2014 scoring methodology in the PY 2015 ESRD QIP.

Response: We thank commenters for their support. We will finalize our proposals to use the PY 2014 scoring methodology for use in the PY 2015 program with the modifications discussed below. We believe that these modifications improve the efficacy of the program for the reasons discussed.

7. Performance Period for the PY 2015 ESRD QIP

Section 1881(h)(4)(D) of the Act requires the Secretary to establish the performance period with respect to a year. For the PY 2014 ESRD QIP, we finalized a performance period of CY 2012. We stated that we believe that, at this point, a 12-month performance period is the most appropriate for the program because this period accounts for any potential seasonal variations that might affect a facility's score on some of the measures, and also provides adequate incentive and feedback for facilities and Medicare beneficiaries (76 FR 70271). We continue to believe that a 12-month performance period will best meet these policy objectives, and we considered what 12-month period would be closest in time to the payment year but would still allow us to time to operationalize the program, calculate scores, and allow facilities a period of time to preview and ask questions regarding these scores before they are published and impact payment. We determined that CY 2013 is the latest period of time during which we can collect a full 12 months of data and still implement the payment reductions beginning with January 1, 2015 services. Therefore, for the PY 2015 ESRD QIP, we proposed to establish CY 2013 as the performance period for all of the measures. We requested comments on this proposal.

The comments we received on these proposals and our responses are set forth below.

Comment: Commenters supported our proposal to use CY 2013 as the performance period for the PY 2015 ESRD QIP; some commenters specifically supported a performance period that allows us to set standards before the performance period begins. Some commenters, while supporting this performance period, cautioned us against using data from CROWNWeb from this period since CY 2013 will be the first full year CROWNWeb is implemented.

Response: We thank commenters for their support. We note that, because we are not finalizing the Hypercalcemia measure, we are no longer using data from CROWNWeb for purposes of scoring any clinical measure for the PY 2015 ESRD QIP. For purposes of the PY 2015 ESRD QIP, we will be using CROWNWeb to collect data only for the Mineral Metabolism reporting measure. We believe that this is appropriate since facilities will only be required to report data, but will not be scored based on these data for PY 2015. We believe that CROWNWeb is sufficiently implemented to allow successful reporting for CY 2013. We will continue to assess the appropriateness of CROWNWeb data for inclusion for purposes of clinical measures in the ESRD QIP.

Comment: Many commenters asked us to shorten the data lag between the performance period and the payment reduction/public reporting of the data so that the data can remain relevant. Commenters suggested that CROWNWeb could be used to reduce these data lag.

Response: For PY 2015, we have determined that data derived from claims is the most appropriate source on which to score facilities on clinical measures because this source is the most complete and representative of the greatest number of facilities. Because claims take more time to compile and calculate than other data sources to ensure reliability, there is a lag between the time when the claims are submitted for processing and the time that the claims become available to calculate ESRD QIP measure rates. We also believe it is important to allow facilities a period of time to review their scores before the payment adjustments take place. We are considering how we might be able to shorten this timeline in the future. We believe that CROWNWeb will be valuable in this effort once it has been successfully launched for a period of time, and we are confident that the data submission and validity issues have been resolved.

Comment: One commenter suggested that we consider employing rolling 12-month performance periods with payment updated quarterly.

Response: At this time, we are not able to implement a rolling 12-month performance period that is updated on a quarterly basis because we do not have the systems or resources in place to calculate scores, answer inquiries, and provide Performance Score Certificates more than once per year. We will, however, continue to consider this suggestion as the ESRD QIP evolves.

For the reasons stated above, we finalize CY 2013 as the performance period for the PY 2015 ESRD QIP as proposed.

8. Performance Standards for the PY 2015 ESRD QIP

Similar to the PY 2014 ESRD QIP, we proposed to adopt performance standards for the PY 2015 ESRD QIP measures under section 1881(h)(4)(A) of the Act. This section provides that ''the Secretary shall establish performance standards with respect to measures selected * * * for a performance period with respect to a year.'' Section 1881(h)(4)(B) of the Act further provides that the ''performance standards * * * shall include levels of achievement and improvement, as determined appropriate by the Secretary.'' We use the performance standards to establish the minimum score a facility must achieve to avoid a payment reduction.

a. Clinical Measure Performance Standards

With respect to the seven proposed clinical measures, we proposed to set the PY 2015 improvement performance standard and achievement performance standard (collectively, the ''performance standard'') for each measure at the national performance rate (which we would define as the 50th percentile) of all facilities' performance on the measure during CY 2011 (the proposed comparison period—discussed in more detail below).

For the PY 2014 ESRD QIP, we set the performance standards at the national performance rate during a baseline period of July 1, 2010–June 30, 2011. This period of time, however, did not allow us to publish the numerical values for the performance standards concurrently with the final rule because of the length of time needed for us to compile claims-based measure data at

the individual facility level and calculate the measure rates. Instead, we included an estimate of the numerical values for the performance standards in the final rule, using nine months of data, and posted the numerical values of the performance standards based on the full 12 months of data on *http://www.dialysisreports.org/pdf/esrd/public-measures/UpdatedBaseline-2014–FR.pdf* by the end of December 2011. In order to ensure that we have enough time to calculate and assign numerical values to the proposed performance standards for the PY 2015 program, we proposed to set the performance standards based on the national performance rate (that is, the 50th percentile) of facility performance in CY 2011. We noted that by choosing this time period for PY 2015, however, the data on which we base the performance standards would only capture 6 months of more recent data when compared to PY 2014 and would also overlap with 6 months of the data used to calculate the PY 2014 performance standards. We stated our concern that if we finalize this period of time, we would not be adequately addressing stakeholder requests that we take steps to minimize the length of ''data lag'' between the dates used to calculate the performance standards and the payment year. We recognized that stakeholders might prefer that we base performance standards on data as close in time to PY 2015 as possible.

We stated that the period of time closest to the payment year that would allow us to post the numerical values for the performance standards before the end of the first month of the performance period is parallel to that of PY 2014, from July 1, 2011 through June 30, 2012. As with PY 2014, selecting this time period for purposes of calculating numerical values for the performance standards would not allow us to publish these numerical values until late 2012 or early 2013, which is closer in time and may possibly be during the performance period. However, as in PY 2014, we would still be able to provide estimates for the numerical values of the performance standards at the time of final rule publication and post the actual numbers as soon as they are available in December 2012 or January 2013.

Based on these considerations, we proposed CY 2011 as the basis for the performance standards (that is, the national performance rates). We did, however, request comment concerning whether we should instead use data closer in time to the payment year and set the performance standards using July 1, 2011 through June 30, 2012 data.

For two of the PY 2015 measure topics, Kt/V Dialysis Adequacy and Hypercalcemia, we noted that we do not possess data for the entirety of CY 2011, the year on which we proposed to base the performance standards. We did not begin collecting uniform data on the Kt/V hemodialysis adequacy measure until January 1, 2012 (see Change Request 7460), and, under the conditions for coverage, facilities were not required to report serum calcium values that will be used to calculate the Hypercalcemia clinical measure until their submission of May, 2012 data with the June 2012 national implementation of CROWNWeb. Despite these issues, we stated that we do have data on which we can base performance standards. We noted that although facilities are not yet required to report serum calcium levels, approximately 63 percent of facilities, which treat approximately 80 percent of the Medicare ESRD patient population, have been voluntarily reporting these data via CROWNWeb piloting since July 2008. Additionally, we compared the serum calcium values reported by facilities in 2010 as part of a clinical data reporting program called ELab,[6] to values that have been voluntarily reported by facilities in 2010 through CROWNWeb, and the values are significantly similar. We stated our belief that these similarities will also extend to data reported in 2011. Therefore, we proposed to calculate performance standards for the Hypercalcemia measure using the data that we collected via CROWNWeb Pilots collected during CY 2011.

Uniform Kt/V reporting for hemodialysis patients did not begin until January 1, 2012 (CR 7640). Before this time, facilities could use a number of different methodologies to calculate Kt/V values, with the result that the values could be different depending on which methodology was used. We stated in the proposed rule that we have analyzed the data collected during the CROWNWeb pilot and found that 88 percent of facilities that reported to CROWNWeb had reported Kt/V values using a NQF specified calculation method (this method is also specified in Change Request 7640) that yields consistent results and that is part of the specifications for each of the hemodialysis Kt/V measures that we proposed to adopt for the PY 2015 program. Though we are not able to tell what calculation method a facility used by reviewing a claim, we believe it is reasonable to assume that roughly the same percentage of facilities reported Kt/V on their claims prior to 2012 using the same formula that they used to report it under the CROWNWeb pilot. For this reason, we proposed to calculate the performance standards for the three proposed Kt/V measures using CY 2011 claims data. This is the best data we have available at this time to set reliable performance standards for Kt/V. We stated that we understand that stakeholders may be concerned about the nuances of the data and we invited public comment on this proposal.

We noted that if, after consideration of the comments, we decided to not adopt the adult, hemodialysis Kt/V measure for PY 2015, we would continue to use URR as a measure of hemodialysis adequacy for this population. We also noted that the NQF-endorsed measure for Kt/V measure for peritoneal dialysis adequacy does not specify the body surface area formulae or the total body water formulae to utilize; and we would accept the submission of peritoneal adequacy Kt/V values that utilize the methods currently in use as industry standards. We believe it is important to include peritoneal dialysis patients in the ESRD QIP and we solicited comments on the inclusion of the peritoneal dialysis Kt/V adequacy measure. We proposed that, were we to retain the URR measure for adult hemodialysis, we would still adopt the Kt/V peritoneal dialysis measure. We proposed that these measures would still comprise a Dialysis Adequacy measure topic and would be scored in the same manner as we proposed for the Kt/V measures, below.

Even with the challenges outlined above, we believed that the advantages of adopting the Kt/V hemodialysis measure for PY 2015 outweigh the disadvantages. Therefore, we proposed Kt/V as the measure for hemodialysis adequacy for PY 2015, but we specifically solicited comments regarding whether we should continue to use URR for adult hemodialysis patients for PY 2015.[7]

We also considered calculating performance standards for the Kt/V Dialysis Adequacy measure topic based on data from January 1, 2012–June 30, 2012, to ensure that the data was calculated consistently. We are, however, aware that a shortened data period may affect the measure rates' reliability. Therefore, we proposed to calculate performance standards based

[6] *http://www.esrdnet11.org.*

[7] Note that, as further explained below, the issue we have discussed with respect to the reporting of Kt/V values prior to CY 2012 would not be an issue for the calculation of improvement scores because we proposed CY 2012 as the period used to calculate the improvement threshold; beginning January 1, 2012, all facilities are required to report Kt/V uniformly on their claims.

on the data from CY 2011 discussed above, but we invited comment on an alternative 6 month period beginning on or after the date on which uniform reporting began, January 1, 2012.

The comments we received on these proposals and our responses are set forth below.

Comment: Many commenters agreed with our proposal to use CY 2011 as the comparison period for purposes of calculating the performance standards because this period will allow facilities to view these standards when the final rule is published. Others, however, expressed support for using data from July 1, 2011–June 30, 2012 to calculate the performance standards because this period is closest in time to the performance period. Some commenters did not have a preference for the comparison period, but requested that we be consistent in the time periods we choose. Many commenters suggested that, regardless of the time period, we do not use CROWNWeb data to calculate performance standards because the data in CROWNWeb from this time period is largely from large dialysis organizations (LDOs).

Response: Although we appreciate that July 1, 2011–June 30, 2012 is closer in time to the performance period, we believe that it will be more beneficial to facilities if they are familiar with the performance standards against which their performance will be evaluated before the performance period begins. We will continue to evaluate whether it will be feasible in the future to adopt performance standards using data from a period closer in time to the performance period and also make those standards public before the beginning of the performance period. Additionally, as we stated above, we will not be finalizing the Hypercalcemia measure for PY 2015. All of the other clinical measures we are adopting for PY 2015 are claims-based, and we can set the performance standards for those measures without using CROWNWeb data.

Comment: One commenter expressed concern that the standards are too rigid and we expect perfection.

Response: We believe that the standards that we are setting are appropriate. It is the past performance of facilities nationally which determine the performance standards; thus, ESRD facilities have demonstrated their ability to achieve these standards. Additionally, to avoid a payment reduction, facilities need only meet the minimum Total Performance Score. As discussed below, a facility need not have a perfect score on all, or any, of the measures to meet this minimum. Furthermore, we believe it is important to incentivize the best care possible.

For these reasons, we finalize our proposal to establish performance standards for the PY 2015 ESRD QIP clinical measures at the 50th percentile of national performance during CY 2011. The numerical values for the performance standards are set forth below in Table 5.

b. Performance Standards

TABLE 5—FINALIZED NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2015 ESRD QIP CLINICAL MEASURES

Measure	Performance standard %
Hemoglobin > 12 g/dL	1
Vascular Access Type	
% Fistula	60
% Catheter	13
Kt/V	
Adult Hemodialysis	93
Adult, Peritoneal Dialysis	84
Pediatric Hemodialysis	93

In accordance with our statements in the CY 2012 ESRD PPS final rule (76 FR 70273), if the final numerical values for the PY 2015 performance standards are worse than PY 2014 for a measure, we proposed to substitute the PY 2014 performance standard for that measure. We stated our belief that the ESRD QIP should not have lower standards than previous years. We requested comments on this proposal.

The comments we received on these proposals and our responses are set forth below.

Comment: One commenter did not support our proposal to keep performance standards at least as high as they were the previous year and suggests that we, instead, investigate why a performance standard would drop. Another commenter agreed with our proposal and stated that the only reason that performance standards should be lower than they were the previous year is if we discover a major technical issue with the previous year's standards, such as that the performance standards were miscalculated.

Response: We believe it is important to encourage improvement as the ESRD QIP evolves to ensure that beneficiaries continue to receive quality care at achievable levels. Therefore, we will finalize our proposal to utilize previous years' performance standards if they are higher than those of the next year. The performance standards for the measures used in previous years of the ESRD QIP (the Hemoglobin Greater than 12 g/dL measure and the Vascular Access Type measure topic) have not declined. Therefore, for PY 2015, we will use the performance standards in the above table. If we discover that performance on any of the measures is declining in future years, we also intend to investigate the precipitating causes and modify the ESRD QIP as necessary to ensure high quality care for beneficiaries.

c. Performance Standards for the PY 2015 Reporting Measures

We established the performance standards for the reporting measures for PY 2014 based upon whether facilities met certain reporting requirements rather than achieved or improved on specific clinical values. We proposed to establish the same performance standard for the ICH CAHPS reporting measure for PY 2015 that we established for PY 2014. Under this proposed performance standard, facilities would be required to provide an attestation that they successfully administered the ICH CAHPS survey via a third party in accordance with the measure specifications. We proposed that this attestation must be completed in CROWNWeb by January 31, 2014.

For the NHSN Dialysis Event reporting measure, we proposed to set the performance standard as successfully reporting 12 months of data from CY 2013. If a facility has not yet enrolled and trained in the NHSN dialysis event system, we proposed that the performance standard for that facility would also include completion of these requirements.

For the Mineral Metabolism reporting measure, we proposed to set the performance standard as successfully reporting serum phosphorus and calcium values for all qualified patients for 12 months.

For the Anemia Management reporting measure we proposed to set the performance standard as successfully reporting hemoglobin or hematocrit and ESA dosage (if applicable) for all qualified patients for 12 months.

We requested comment on these proposals. We did not receive any comments on these proposals. We will, therefore, finalize the reporting measure performance standards as proposed.

9. Scoring for the PY 2015 ESRD QIP Measures

In order to assess whether a facility has met the performance standards, we finalized a methodology for the PY 2014 program under which we separately score each clinical and reporting measure. We score facilities based on an

achievement and improvement scoring methodology for purposes of assessing their performance on the clinical measures. Under the PY 2014 ESRD QIP scoring methodology, a facility's performance on each of the clinical measures is determined based on the higher of (i) an achievement score or (ii) an improvement score (76 FR 70273). We proposed to use a similar methodology for purposes of scoring facility performance on each of the clinical measures for the PY 2015 ESRD QIP.

As in PY 2014, in determining a facility's achievement score for the PY 2015 program, we proposed that facilities would, based on their performance in CY 2013 (the proposed performance period), receive points along an achievement range, which we would define as a scale that runs from the achievement threshold to the benchmark. We proposed to define the achievement threshold for each of the proposed clinical measures as the 15th percentile of national facility performance during CY 2011. We stated our belief that this achievement threshold will provide an incentive for facilities to continuously improve their performance while not reducing the incentives to facilities that score at or above the national performance rate for the clinical measures (76 FR 70276). We proposed to define the benchmark as the 90th percentile of the national facility performance during CY 2011 because it represents a demonstrably high but achievable standard of excellence that the best performing facilities reached. We further proposed that, for the proposed Kt/V Dialysis Adequacy measures and the proposed Hypercalcemia measure, we would use the same data we proposed above to calculate the performance standards for purposes of calculating the achievement thresholds and the benchmarks for these measures. We requested comment on these proposals.

In determining an improvement score for the clinical measures, we proposed that facilities would receive points along an improvement range, defined as a scale running between the improvement threshold and the benchmark. We proposed to define the improvement threshold as the facility's rate on the measure during CY 2012. The facility's improvement score would be calculated by comparing its performance on the measure during CY 2013 (the proposed performance period) to its performance on the measure during CY 2012. We proposed to base the improvement threshold on data from CY 2012 rather than CY 2011 (the period of time we had proposed to use to calculate the performance standards, achievement thresholds, and benchmarks) because, as we explained above, we do not have complete facility level CY 2011 data that we can use to calculate an improvement threshold for every facility on the Kt/V Dialysis Adequacy measures. Rather than proposing to adopt a policy under which no facility could receive an improvement score on these measures, we proposed to use data from CY 2012 to calculate the improvement thresholds. Additionally, we stated our belief that by using CY 2012 to calculate the improvement thresholds, we will more closely align timing of the payment reduction with the period of time we use to calculate improvement thresholds. We requested comments on our proposal to use data from CY 2012 to calculate improvement thresholds.

When considering the time period we would use to calculate improvement thresholds, we sought to mitigate data lag issues as much as possible by selecting a period in time as close as possible to the performance period. However, to entirely mitigate this data lag, we also considered a period that would take place during the performance period. Using this approach, to calculate an improvement score, we would derive an improvement threshold from either the first quarter of CY 2013 or the first 6 months of CY 2013 and compare it to the facility's measure rate in the last quarter of CY 2013 or the last 6 months of CY 2013, respectively. We ultimately decided to not propose this approach because, when possible, we prefer to use 12 months of data to calculate measure rates to ensure more reliable rates, particularly for low-volume facilities. Additionally, using this approach, part of the performance period for purposes of calculating the facility's performance rate and achievement score (all of CY 2013) could overlap with the data we use to calculate the improvement threshold (first quarter or 6 months of CY 2013). Although we proposed to calculate improvement thresholds based on data from CY 2012, we also requested comment regarding use of these alternative periods for purposes of calculating the improvement thresholds.

The comments we received on these proposals and our responses are set forth below.

Comment: One commenter stated that, to foster continued improvement, we should consider raising the achievement threshold over time to a level greater than 15 percent.

Response: We believe that, at this time, it is appropriate to set the achievement threshold at the 15th percentile so that lower-performing facilities are incentivized to provide high quality care; if the thresholds are set too high, it is possible that a facility would not be incentivized to perform well because the cost to meet the achievement threshold would be so high that it would outweigh the overall loss of revenue resulting from the ESRD QIP payment reduction. Although we do not believe we should award low-performing facilities a large number of points, we do believe it is important to set the standards to incentivize all facilities to perform better.

Comment: One commenter suggested that we rename the achievement threshold the ''Statistical Performance Floor'' because ''achievement'' seems misleading if the floor is set at the 15th percentile. This commenter also recommended that the facility performance rate be renamed the ''Facility's Current Year Performance Rate,'' the benchmark be renamed the ''Exceptional Performance Rate'' since it is at the 90th percentile, and the performance standard be renamed the ''National Average/Median Performance Rate in the Base Year.''

Response: One of the ways we can make the ESRD QIP transparent is by seeking to achieve consistency from year-to-year, provided there is not a contravening interest. Changing the terminology of the achievement threshold, performance rate, performance standards, and benchmark could unnecessarily confuse both facilities and beneficiaries. Additionally, we seek to harmonize CMS' value-based purchasing programs as much as possible, and we use these naming conventions across programs.

Comment: Several commenters argued that we are creating inconsistencies between the Conditions for Coverage (CfCs) and the ESRD QIP; these commenters specifically argued that the CfCs state that a facility cannot be penalized for patient non-compliance, but many of the ESRD QIP measures effectively penalize facilities for patient non-compliance. The commenter suggested that we make allowances for patient noncompliance in the ESRD QIP's design; one commenter specifically recommended that we should require only 90 percent compliance from patients that visit the facility at least seven times per month to reconcile the CfCs and the ESRD QIP.

Response: We do not believe that we are creating inconsistencies between the CfCs and the ESRD QIP, nor do we believe that the ESRD QIP penalizes facilities for patient non-compliance. Although patients' compliance with the plan of care is a factor in some of the

measures, the quality of care is largely controlled by the facility's treatment of patients. Additionally, to the extent that patient non-compliance may be a factor, facilities are not required to obtain perfect results for every patient. To avoid a payment reduction, as we explain below, a facility need only meet the performance standards (that is, the 50th percentile of national performance) for each clinical measure during the comparison period (for PY 2015, this will be CY 2011) and score half of the possible points for the reporting measures.

Comment: Commenters agreed with our proposal to use the facility's rate in CY 2012 to calculate improvement thresholds.

Response: We thank the commenters for their support.

Comment: One commenter suggested that the improvement threshold be renamed the ''Facility's Base Year Performance Rate'' since the improvement threshold does not represent a gain or level of improvement.

Response: As noted above, we believe it is important to use consistent terminology from year-to-year to ensure transparency and comprehension in both the ESRD QIP and across CMS' VBP programs.

For the reasons discussed above, we finalize our proposed definitions of the achievement thresholds, benchmarks, and improvement thresholds. We have calculated the numerical values for the achievement threshold and benchmarks based on data from CY 2011; we will calculate the numerical values for the improvement thresholds based on individual facilities' data from CY 2012. The numerical values for the achievement thresholds and benchmarks for the PY 2015 ESRD QIP clinical measures are set forth below in Table 6.

TABLE 6—FINALIZED NUMERICAL VALUES OF ACHIEVEMENT THRESHOLDS AND BENCHMARKS FOR THE PY 2015 ESRD QIP CLINICAL MEASURES

Measure	Achievement threshold (percent)	Benchmark (percent)
Hemoglobin > 12 g/dL	5	0
Vascular Access Type:		
% Fistula	47	75
% Catheter	22	5
Kt/V:		
Adult Hemodialysis	86	97
Adult, Peritoneal Dialysis	63	94
Pediatric Hemodialysis	83	97

In accordance with our statements in the CY 2012 ESRD PPS final rule (76 FR 70273), if the final PY 2015 numerical values for the achievement thresholds and benchmarks are worse than PY 2014 for a measure, we proposed to substitute the PY 2014 achievement thresholds and benchmarks for that measure. We believe that the ESRD QIP should not have lower standards than previous years. We requested comments on this proposal.

The comments we received on these proposals and our responses are set forth below.

Comment: One commenter did not support our proposal to keep achievement thresholds and benchmarks at least as high as they were the previous year and suggests that we, instead, investigate why these values would drop. Another commenter agreed with our proposal and stated that the only reason that performance standards should be lower than they were the previous year is if we discover a major technical issue with the previous year's standards, such as that the performance standards were miscalculated.

Response: We believe it is important to encourage improvement as the ESRD QIP evolves to ensure that beneficiaries continue to receive quality care at achievable levels. Therefore, we will finalize our proposal to utilize previous years' achievement threshold and benchmarks if they are higher than those of the next year. The achievement thresholds and benchmarks for the measures used in previous years of the ESRD QIP (the Hemoglobin Greater than 12 g/dL measure and the Vascular Access Type measure topic) have not declined. Therefore, for PY 2015, we will use the performance standards in the above table. If we discover that performance on any of the measures is declining in future years, we also intend to investigate the precipitating causes and modify the ESRD QIP as necessary to ensure high quality care for beneficiaries.

a. Scoring Facility Performance on Clinical Measures Based on Achievement

We proposed to award between 0 and 10 points for each of the clinical measures. As noted, we proposed that this score be based upon the higher of an achievement or improvement score on the measure. For purposes of scoring achievement for the measures, we proposed to base the score on where a facility's performance falls relative to the achievement threshold and the benchmark for that measure. We proposed that, identical to PY 2014, if a facility's measure rate during the performance period is:

- Equal to or greater than the benchmark, the facility would receive 10 points for achievement;
- Less than the achievement threshold, the facility would receive 0 points for achievement; or
- Equal to or greater than the achievement threshold, but below the benchmark, the following formula would be used to derive the achievement score:

[9 * ((Facility's performance period rate—achievement threshold)/(benchmark—achievement threshold))] + .5, with all scores rounded to the nearest integer, with half rounded up. Using this formula, a facility would receive a score of 1 to 9 points based on a linear scale disturbing all points proportionately between the achievement threshold and the benchmark so that the interval in performance between the score needed to receive a given number of achievement points and one additional achievement point is the same throughout the range of performance from the achievement threshold to the benchmark.

b. Scoring Facility Performance on Clinical Measures Based on Improvement

We proposed that facilities would earn between 0 and 9 points for each of

the clinical measures based on how much their performance on the measure during CY 2013 improved from their performance on the measure during CY 2012. A unique improvement range for each measure would be established for each facility. We proposed that if a facility's measure rate during the performance period is:

- Less than the improvement threshold, the facility would receive 0 points for improvement; or
- Equal to or greater than the improvement threshold, but below the benchmark, the following formula would be used to derive the improvement score:

[10 * ((Facility performance period rate—Improvement threshold)/(Benchmark—Improvement threshold))]—.5, with all scores rounded to the nearest integer, with half rounded up.

We note that if the facility's score is equal to or greater than the benchmark, it would receive 10 points on the measure per the achievement score methodology discussed above.

The comment we received on these proposals and our responses are set forth below.

Comment: One commenter requested clarification on whether (i) a facility can earn points if its performance rate is below the improvement threshold but above the achievement threshold and (ii) a facility can earn points if its performance rate is below the achievement threshold but above the improvement threshold. A commenter also requested clarification regarding whether, when scoring improvement, we multiply the ((Facility performance period rate—Improvement threshold)/(Benchmark—Improvement threshold))] by 10 before or after we subtract 0.5. Likewise, this commenter requested clarification for the achievement scoring on whether we multiply the ((Facility's performance period rate—achievement threshold)/(benchmark—achievement threshold))] by 9 before or after we add 0.5.

Response: It is possible for a facility to earn achievement points even if that facility did not improve during the performance period as long as that facility's performance period rate exceeds the improvement threshold. Likewise, a facility can earn improvement points even if its measure rate during the performance period is below the achievement threshold provided that facility improved during the performance period. Additionally, the 0.5 is added or subtracted, for achievement and improvement respectively, as the last step in the equations.

For the reasons stated above, we will finalize the proposed methodology for scoring measures on achievement and improvement.

c. Calculating the Reporting Measure Scores

As noted, reporting measures differ from clinical measures in that they are not scored based on clinical values, but rather, are scored based on whether facilities are successful in achieving the reporting requirements associated with each of the measures. The criteria that would apply to each reporting measure are discussed below.

With respect to the proposed Anemia Management, Mineral Metabolism, and NHSN Dialysis Event reporting measures, for each measure, we proposed to award facilities:

(i) 0 points for meeting the reporting requirements for less than 6-consecutive months during the performance period;

(ii) 5 points for meeting the reporting requirements for at least 6-consecutive months during the performance period; and

(iii) 10 points for meeting the reporting requirements for all 12 months of the performance period.

We believe that requiring 6-consecutive months of data rather than 6 non-consecutive months of data for a facility to receive points on these measures will hold facilities to the highest level of quality, therefore, facilities will be encouraged to continue to improve their reporting mechanisms throughout the performance period. We are concerned that awarding points for 6 non-consecutive months of reporting may cause facilities to be less diligent in their reporting efforts overall. We specifically requested comment regarding whether the proposed 6-consecutive month reporting requirement will improve quality more than a non-consecutive month reporting requirement. We also proposed, as discussed in more detail below, that facilities would need to receive a CCN prior to July 1, 2013 in order to receive a score on a reporting measure. Finally, for purposes of the NHSN Dialysis Event reporting measure, we proposed that to be awarded 5 or 10 points, any facility that has not yet enrolled and trained in the NHSN dialysis event system must do so and must agree to the required consent (*http://www.cdc.gov/nhsn/PDFs/PurposesEligibilityRequirements Confidentiality.pdf*).

With respect to the proposed ICH CAHPS reporting measure, we proposed to retain the PY 2014 scoring methodology for the PY 2015 ESRD QIP. An in-center hemodialysis facility will receive a score of 10 points if it attests that it successfully administered the ICH CAHPS survey via a third party during the performance period according to the specification found at *https://www.cahps.ahrq.gov/Surveys-Guidance/ICH.aspx*. Eligible facilities (facilities providing adult, in-center hemodialysis) that do not provide such an attestation would receive 0 points on the measure. We proposed that this attestation must be entered via CROWNWeb by January 31, 2014. We note that the ICH CAHPS survey is only available to adult patients who are treated in-center. For purposes of the ICH CAHPS reporting measure, we determine whether a facility treats adult, in-center patients by referencing the facility's information in CMS data sources (that is, SIMS and CROWNWeb). Facilities report the types of patients that they serve in these data sources. If a facility lists adult in-center services, we proposed that the facility would be required to comply with the ICH CAHPS reporting measure.

We requested comment on the proposed methodology for scoring the PY 2015 ESRD QIP reporting measures. We also requested comment regarding whether facilities should receive points for partially reporting data and whether such reporting need be for consecutive months.

The comments we received on these proposals and our responses are set forth below.

Comment: Several commenters requested that we award points for partial or non-consecutive reporting of data. Other commenters recommended that we modify our scoring of the NHSN Dialysis Event, Anemia Management, and Mineral Metabolism reporting measures to allow facilities to gain points for non-consecutive reporting on a point scale of 0–10. Commenters suggested that two should be subtracted from the number of months for which the dialysis facility successfully meets the reporting requirements (rounding negative scores to zero), meaning that a facility would have to report two months of data before receiving points on the measure. Commenters argued that this approach will encourage facilities to consistently report even if consecutive reporting is not possible. One commenter argued that facilities should be required to report for all months in order to receive any points on this measure; alternatively, this commenter urged us to require facilities to report consecutive months of data.

Response: We thank commenters for these suggestions. The NHSN participation requirements state that facilities must report at least 6 months of data during a calendar year to the

dialysis event module to maintain active status in the NHSN. We believe it is important to align the scoring requirements for the NHSN dialysis event reporting measure for the ESRD QIP with the NHSN requirements, which are intended to improve the quality of the data submitted to the NHSN. Furthermore, we believe the severity of bloodstream infections and other vascular access-related infections among dialysis patients warrants more extensive monitoring in order to prevent future events. We will, therefore, require a minimum of 6 months of NHSN Dialysis Event reporting before awarding facilities points. We believe that facilities should receive credit for reporting non-consecutive months for this measure; we agree with commenters that this approach will encourage reporting because, even if a facility misses a month or many months, it can still receive points on the measure. Additionally, NHSN requirements allow non-consecutive reporting, but strongly encourage regular monthly reporting. We also agree with the commenters who stated that facilities should be awarded points on an incremental scale to incentivize reporting as much as possible. Therefore, we will begin awarding points for 6 months of reporting, and will not require consecutive monthly reporting during the performance period. Additionally, we will award incremental points for reporting more than 6 months of data. We will award points to facilities as follows:

(i) 0 points for reporting less than 6 months of data;

(ii) 5 points for reporting 6 months of data; and

(iii) 10 points for reporting 12 months of data.

(iv) If the facility reports more than 6 but less than 12 months of data, we will award incremental points using the following formula:

$$\frac{\text{Number of Months Facility Successfully Reports}}{12} \times 10$$

We will round the result of this formula (with half rounded up) to generate a measure score from 5–10 points; as noted, facilities will earn points for reporting non-consecutive months.

As we discuss below, because of the time it takes to train and enroll in the NHSN Dialysis Event module, we do not believe that it is feasible for all facilities receiving a CCN in the performance period to report at least 6 months of data. We will not apply the 6 month minimum requirement on these newly opened facilities, as we believe this requirement would place significant undue burden on these facilities to report data during their initial year of operation starting up their care delivery and administration. Therefore, the NHSN Dialysis Event reporting measure will not apply to any facility receiving a CCN on or after January 1, 2013.

For the Mineral Metabolism and Anemia Management reporting measures, we believe that it is beneficial to encourage less than 6 months of reporting so that we can receive data from as many facilities as possible and use this data to develop a robust clinical measure in these areas. We believe that the Anemia Management and Mineral Metabolism reporting measures should also allow facilities to receive credit for reporting non-consecutive months because we believe that this approach will encourage reporting even if a facility fails to report for a month or more. We agree with commenters that a facility should be required to report at least two months before it is awarded points. Two months of reporting translates to reporting at a rate roughly equal to our achievement threshold for clinical measures—15 percent. We have determined that this threshold is an appropriate marker for where a facility should start earning achievement points on the clinical measures, and we believe it should also apply to these reporting measures. Additionally, as we discuss below, we will apply the scoring methodology for the Anemia Management and Mineral Metabolism reporting measures to facilities that receive a CCN during the first 6 months of the performance period. Taking all of these elements into consideration, we are finalizing a scoring methodology that will allow facilities to score points on the Mineral Metabolism and Anemia Management reporting measures provided that they receive a CCN before July 1, 2013. In order to score above a zero on these measures, a facility must report at least three months of data.

Therefore, we finalize that facilities receiving a CCN before July 1, 2013 will score 0–10 points on the Anemia Management and Mineral Metabolism reporting measures using the following formula:

$$\left[\frac{\text{Number of Months Facility Successfully Reports}}{\text{Number of Months in the Performance Period Facility has CCN}} \times 12\right] - 2$$

We will round the result of this formula (with half rounded up) to generate a measure score from 0–10, and we will allow facilities to earn points using the same formula for reporting non-consecutive months.

Additionally, we finalize the ICH CAHPS measure scoring as proposed.

10. Weighting the PY 2015 ESRD QIP Measures and Calculation of the PY 2015 ESRD QIP Total Performance Score

Section 1881(h)(3)(A)(iii) of the Act provides that the methodology for assessing facility total performance shall include a process to weight the performance scores with respect to individual measures to reflect priorities for quality improvement such as weighting the scores to ensure that facilities have strong incentives to meet or exceed anemia management and dialysis adequacy performance standards, as determined appropriate by the Secretary. In determining how to

appropriately weight the PY 2015 ESRD QIP measures for purposes of calculating Total Performance Scores, we considered two criteria. Specifically, we considered the number of measures we had proposed to include in the PY 2015 ESRD QIP as well as the National Quality Strategy priorities.

a. Weighting Individual Measures To Compute Measure Topic Scores for the Kt/V Dialysis Adequacy Measure Topic and the Vascular Access Type Measure Topic

Because the Kt/V Dialysis Adequacy measure topic and the Vascular Access Type measure topic are comprised of multiple measures, it is necessary for us to discuss how we will derive an overall score for each measure topic. For these measure topics, we proposed that each measure be scored separately for each facility using the achievement and improvement methodology discussed above. After calculating the individual measure scores within a measure topic, we proposed to calculate a measure topic score using the following steps: (1) Dividing the number of patients in the denominator of each measure by the sum of the denominators for all of the applicable measures in the measure topic; (2) multiplying that figure by the facility's score on the measure; (3) summing the results achieved for each measure; and (4) rounding this sum (with half rounded up). We proposed that, if a facility does not have enough patients to receive a score on one of the measures in the measure topic (this proposal is discussed below), that measure would not be included in the measure topic score for that facility. Only one measure within the measure topic need have enough cases to be scored in order for the measure topic to be scored and included in the calculation of the Total Performance Score. We stated that we believe it is important to proportionately weight the measures within a measure topic because we seek to give equal importance to each patient. Finally, we proposed that the measure topic score would be equal to one clinical measure in the calculation of the Total Performance Score.

For additional explanation of our proposals to calculate measure topic scores, we provided the following examples:

Example 1: Facility X serves hemodialysis (HD), peritoneal dialysis (PD), and pediatric patients. For HD patients, Facility X's Kt/V measure rate is 50/60. For PD patients, Facility's X's Kt/V measure rate is 15/20. For pediatric patients, Facility X's Kt/V measure rate is 10/20. There are 100 patients included in the measure topic (60+20+20). Assume that the facility's measure rates lead to the following measure scores: HD—7; PD—8; pediatric—5. To compute the Kt/V Dialysis Adequacy measure topic score for Facility X, we would calculate the following: (7*60/100)+(8*20/100)+(5*20/100) = 6.8, which we would round to 7. The Kt/V Dialysis Adequacy measure topic score would then be treated as one clinical measure when calculating the Total Performance Score.

Example 2: Facility Y serves HD patients and PD patients. For HD patients, Facility Y's Kt/V measure rate is 50/60; assume that this rate leads to a score of 6. For PD patients, Facility Y's Kt/V measure rate is 4/7. Facility Y has no Kt/V measure rate for pediatric patients because it does not serve this population. Assume that the minimum case number for scoring a measure is 11. Because there are only seven cases in Facility Y's denominator, Facility Y would not receive a PD Kt/V measure score. Furthermore, Facility Y did not treat any pediatric patients, so it would not receive a pediatric Kt/V measure score. Therefore, the Kt/V Dialysis Adequacy measure topic score for Facility Y would be 6. The Kt/V Dialysis Adequacy would then be treated as one clinical measure when calculating the Total Performance Score.

We requested comment on the proposed method of weighting individual measure scores to derive a measure topic score.

The comments we received on these proposals and our responses are set forth below.

Comment: Some commenters supported our proposals for weighting measure topics. Some commenters, however, raised concerns that, given the small number of pediatric patients relative to adult patients, combining the adequacy measures might result in a score that does not accurately reflect the quality of care provided to pediatric patients treated in adult dialysis facilities. Other commenters suggested that the measure topics should be weighted consistently across facilities to allow meaningful comparisons between facilities; these commenters requested that we modify the weighting so that each measure is weighted based on clinical relevance, importance, and the number of patients in a ''typical'' facility's population.

Response: We disagree with the commenters' statement that combining the adequacy measures might not reflect the quality of care given to certain patients. The weighting scheme ensures that emphasis on each measure in the Kt/V measure topic is proportionate to the number of patients that facility treats. If we were to weight the measure topics consistently across facilities or base the weight on clinical relevance or the typical facility, the scoring methodology would not equally weight the quality of care provided to each, individual patient. That is, one patient's results could count for more points than another patient's results, perhaps incentivizing better care for only certain ESRD populations. It is the goal of the ESRD QIP to provide the best care for every patient, and we believe the proposed weighting for measure topics meets this goal. Therefore, we are finalizing the methodology of weighting measure topics as proposed.

b. Weighting the Total Performance Score

In the proposed rule we stated our belief that weighting the finalized clinical measures/measure topics equally will incentivize facilities to improve and achieve high levels of performance across all of the measures, resulting in overall improvement in the quality of care provided to ESRD patients. We also stated our belief that, while the reporting measures are valuable, the clinical measures value actual patient outcomes and therefore justify a higher combined weight. We did, however, propose to weight the clinical measures slightly less for the PY 2015 ESRD QIP than we did for the PY 2014 ESRD QIP. For the PY 2015 ESRD QIP, we believe it is important to begin to more rigorously incentivize reporting, specifically since for three of the four reporting measures, we now require actual data submission. We intend to use these data for purposes of developing and creating clinical measures in the future; thus, complete and correct data submission in these areas is essential to the program's overall goal of continued and improved ESRD quality care. For these reasons, we proposed to equally weight the clinical measures/measure topics for which a facility receives a score equal to 80 percent of the Total Performance Score; we also proposed to equally weight the reporting measures for which a facility receives a score as 20 percent of the Total Performance Score. We requested comment on this proposed methodology for weighting the clinical and reporting measures.

We have also considered the issue with awarding a Total Performance Score to facilities that do not report data on the proposed minimum number of cases with respect to one or more of the finalized measures/measure topics. As we stated in the CY 2012 ESRD PPS final rule, we believe it is important to include as many facilities as possible in the ESRD QIP. We did, however, revisit our policy of including any facility that receives a score on one measure, whether that measure is a clinical or reporting measure, and we proposed a different approach for PY 2015. We stated our belief that it is preferable to

require a facility to have at least one clinical and one reporting measure to receive a Total Performance Score. By requiring this minimum, we ensure that a facility is not included in the program unless it meets the minimum case requirement for at least one clinical measure/measure topic. In the case of a facility that has sufficient data (11 cases, as discussed below) from the performance period, but lacks sufficient data (11 cases, as discussed below) to calculate the improvement threshold, we proposed to only calculate its achievement score, because it would not be possible to calculate its improvement score. We requested comment on our proposals to require a facility to qualify for a score on at least one reporting and one clinical measure in order to receive a Total Performance Score.

Finally, we proposed that all Total Performance Scores be rounded to the nearest integer, with half being rounded up, and we requested comment on this proposal. For further examples regarding the proposed measure and Total Performance Score calculations, we refer readers to the figures below.

The comments we received on these proposals and our responses are set forth below.

Comment: Many commenters supported our proposed scoring methodology. Commenters specifically supported our proposal to require a facility to have a score for both a clinical and a reporting measure to receive a Total Performance Score. One commenter stated that, because of the importance of preventing HAIs, we should weight the reporting measures at 50 percent of the Total Performance Score. Some commenters stated their belief that we should maintain the 90/10 Total Performance Score weighting because clinical outcomes are more important than simply tracking and relaying information.

Response: We believe, at this time, that it is appropriate to weight all of the clinical measures topics equally and all of the reporting measures equally in order to equally incentivize quality in all of these areas of care. We do, however, agree with the commenter that noted that because of the importance of reporting measures, such the NHSN Dialysis Event measure which tracks HAIs, we should give greater weight to the reporting measures in calculating the Total Performance Score. As stated above, we are not finalizing the Hypercalcemia clinical measure due to our lack of consistent baseline data. Instead, we will collect calcium data through the Mineral Metabolism reporting measure until we have baseline data that is robust enough to support a clinical measure's adoption. Because of our need to collect data from not only LDOs, as we did in the CROWNWeb pilot, but all types of dialysis facilities, our decision to not finalize the Hypercalcemia measure, and the importance of collecting HAI data through the NHSN Dialysis Event reporting measure, we believe it is appropriate to weight the reporting measures more than we had proposed. We continue to believe, however, that clinical outcomes should constitute the majority of the Total Performance Score. Therefore, we finalize that, for the PY 2015 ESRD QIP, each clinical measure/measure topic will be equally weighted to comprise 75 percent of the Total Performance Score, and the reporting measures will be equally weighted to comprise 25 percent of the Total Performance Score.

c. Examples of the PY 2015 ESRD QIP Scoring Methodology

Below, we provide examples to illustrate the scoring methodology for the PY 2015 ESRD QIP. Figures 1–3 illustrate the scoring for a clinical measure. Figure 1 shows Facility A's performance on an example clinical measure. Note that for this example clinical measure, the facility is attempting to achieve a high rate (that is, the higher the measure rate, the higher the measure score). The example benchmark (which is the 90th percentile of performance nationally in CY 2011) calculated for this measure is 74 percent, and the example achievement threshold (which is the 15th percentile of performance nationally in CY 2011) is 46 percent. Facility A's performance rate of 86 percent during the performance period meets or exceeds the benchmark of 76 percent, so Facility A would earn 10 points (the maximum) for achievement for this measure. (Because, in this example, Facility A has earned the maximum number of points possible for this measure, its improvement score is irrelevant.)

Figure 1. Measure Rate at or above the Benchmark

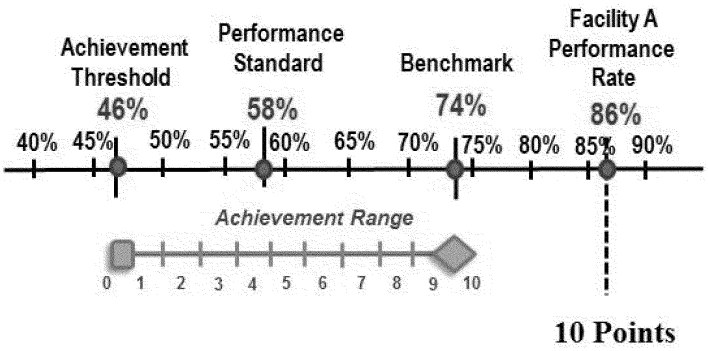
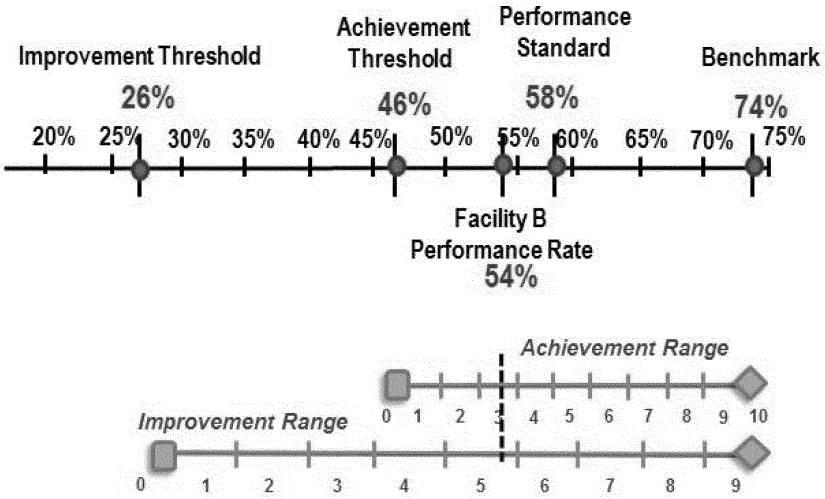


Figure 2 shows the scoring for another facility, Facility B. As illustrated below, the facility's performance on the example clinical measure improved from 26 percent in CY 2012 to 54 percent during the performance period. The achievement threshold is 46 percent, the performance standard is 58 percent, and the benchmark is 74 percent.

Figure 2. Measure Rate within the Achievement Range and within the Improvement Range



Because the facility's performance during the performance period is within both the achievement range and the improvement range, we must calculate both the improvement and achievement score to find the example clinical measure score. To calculate the achievement score, we would employ the formula discussed above.

$$9 \times \left[\frac{\text{Facility Performance Rate} - \text{Achievement Threshold}}{\text{Benchmark} - \text{Achievement Threshold}}\right] + 0.5$$

The result of this formula for this example is [9 * ((54 − 46)/(74 − 46))] + .5, which equals 3.07 and we round to 3.

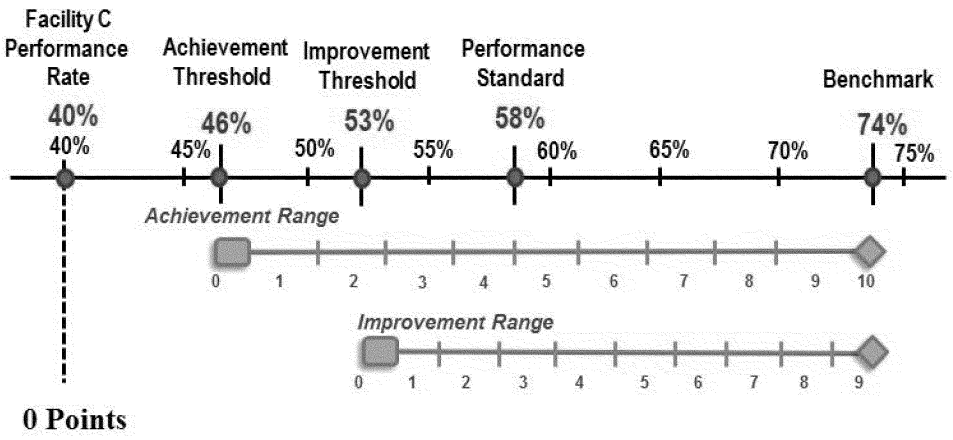
Likewise, to calculate the improvement score, we employ the improvement formula discussed above.

$$10 \times \left[\frac{\text{Facility Performance Rate} - \text{Improvement Threshold}}{\text{Benchmark} - \text{Improvement Threshold}}\right] - 0.5$$

The result of this formula for this example is [10 * ((54 − 26)/(74 − 26))] − .5, which equals 5.33 and we round to 5. Therefore, for this example clinical measure, Facility B's achievement score is 3, and its improvement score is 5. We award Facility B the higher of the two scores. Thus, Facility B's score on this example measure is 5.

In Figure 3 below, Facility C's performance on the example clinical measure drops from 53 percent in CY 2012 to 40 percent in CY 2013, a decline of 13 percent.

Figure 3. Measure Rate below the Achievement Range and the Improvement Range



Because Facility C's performance during the performance period falls below the achievement threshold of 46 percent, it receives 0 points for achievement. Facility C also receives 0 points for improvement because its performance during the performance period was lower than its improvement threshold (its performance during CY 2012). Therefore, in this example, Facility C would receive 0 points for the example clinical measure.

The method illustrated above would be applied to each clinical measure in order to obtain a score for each measure. Scores for reporting measures are calculated based upon their individual criteria, as proposed.

After calculating the scores for each measure, we calculate the Total Performance Score. As an example, applying the weighting criteria to a facility that receives a score on all finalized measures, we would calculate the facility's Total Performance Score using the following formula:

Total Performance Score = [(.25 * Hemoglobin Greater Than 12g/dL Measure) + (.25 * Kt/V Dialysis Adequacy Measure Topic) + (.25 * Vascular Access Type Measure Topic) + (..0625 * NHSN Dialysis Event Reporting Measure) + (.0625 * ICH CAHPS Survey Reporting Measure) + (.0625 * Mineral Metabolism Reporting Measure) + (.0625 * Anemia Management Reporting Measure)] * 10.

The Total Performance Score would be rounded to the nearest integer (and any individual measure values ending in .5 would be rounded to the next higher integer).

However, if, for example, a facility did not receive a score on the Vascular Access Type measure topic, the facility's Total Performance Score would be calculated as follows:

Total Performance Score = [(.375 * Hemoglobin Greater Than 12g/dL Measure) + (.375 * Kt/V Dialysis Adequacy Measure Topic) + (.0625 * NHSN Dialysis Event Reporting Measure) + (.0625 * ICH CAHPS Survey Reporting Measure) + (.0625 * Mineral Metabolism Reporting Measure) + (.0625 * Anemia Management Reporting Measure)] * 10

Again, the Total Performance Score would be rounded to the nearest integer (and any individual measure values ending in .5 would be rounded to the next higher integer).

Finally, if, for example, a facility qualified for only two of the reporting measures, the facility's Total Performance Score would be calculated as follows:

Total Performance Score = [(.25 * Hemoglobin Greater Than 12g/dL Measure) + (.25 * Kt/V Dialysis Adequacy Measure Topic) + (.25 * Vascular Access Type Measure Topic) + (.125 * Mineral Metabolism Reporting Measure) + (.125 * Anemia Management Reporting Measure)] * 10.

Again, the Total Performance Score would be rounded to the nearest integer (and any individual measure values ending in .5 would be rounded to the next higher integer).

11. Minimum Data for Scoring Measures for the PY 2015 ESRD QIP

We proposed to only score facilities on clinical measures for which they have a minimum number of cases during the performance period. We assessed how reliable each clinical measure is using the currently available data. Specifically, we studied the degree the measures assess the actual differences in performance among facilities as opposed to the variation within a facility. Thus, in order for a facility to be scored on any clinical measure, we proposed that the facility must report a minimum number of cases qualifying for that measure over the course of the 12-month performance period. This proposed minimum seeks to ensure that facilities are being evaluated based on the care they provide.

a. Minimum Data for Scoring Clinical Measures for the PY 2015 ESRD QIP

Dialysis facilities tend to have a small, relatively stable patient census, with each facility reporting on an average of 50–60 cases per measure. In previous rules, commenters have asked that we consider the effect of case size on measure reliability in the context of the ESRD QIP. We recognize that as a general principle, reliability improves with increasing case size; that is, the reliability of a measure or score describes numerically to what extent that measure or score assesses the actual differences in performance among facilities as opposed to the random variation within facilities. Furthermore, we wish to be responsive to public comment and to ensure that dialysis facilities with extremely small numbers of patients are not penalized by the ESRD QIP due to random variation in their patient samples. Thus, we developed and proposed a new methodology to make favorable adjustments to the clinical measure rates of facilities with very small numbers of patients. We also proposed a case minimum [8] for clinical measures to protect patient privacy, which we believe could be compromised if the

[8] For clarification purposes, as in previous years, a ''case'' refers to a patient that is included in the measure.

publicly reported data for a facility is based on a small patient population.

Given the ESRD QIP's potential to encourage quality improvement, our goal is to ensure the full participation of as many facilities as possible in the program. However, we must ensure that all measure rates capture a large enough number of patients so that the privacy of each patient is protected. A case minimum allows us to achieve these policy objectives of measurement reliability and patient privacy.

For the first 3 payment years of the ESRD QIP, we set the minimum number of cases to be scored on a clinical measure at 11. Eleven cases has historically been the case minimum for displaying measures on DFC. We have determined that in the context of DFC, 11 cases will meet the requirement that individual patients are not identifiable in the aggregate measure rate. Given that we believe that 11 cases is sufficient to address privacy concerns and that our policy objective is to maximize the number of facilities that participate in the ESRD QIP, we proposed to set a proposed case minimum threshold of 11 cases. Under this proposal, facilities must report at least 11 qualifying cases over the course of the 12-month performance period to be scored on a given clinical measure. We sought public comment on this proposal.

We indicated in the CY 2012 ESRD PPS final rule that we would continue to assess the reliability of our measures in future payment years of the program (76 FR 70259). To further explore this issue in response to comments, we evaluated the reliability of measure rates and the Total Performance Score for facilities of various sizes using the PY 2014 program clinical measures. Specifically, we performed a simulation of the PY 2014 QIP to calculate the Inter-Unit Reliability (IUR) stratified by facility size. The IUR is a statistic commonly adopted for assessing the reliability of measures or scores, and is the ratio of the between-facility variance to the sum of the between-facility variance and the within-facility variance.

We found the reliability of the Total Performance Score to be acceptable for all strata (IUR>0.6). However, we recognize that facilities with very small numbers of patients are more likely to have a lower IUR. In a facility with a low IUR, the case mix might potentially shift its measure rate higher or lower than the rate the same facility would report if it were treating an ''average'' ESRD population. In the context of the ESRD QIP, a favorable skew would not have a negative effect on facility payment, but an unfavorable skew potentially could result in the facility receiving a payment reduction. We cannot identify which specific facilities will have a low IUR until after the performance period has concluded. However, in performing the stratification analysis, we found that a favorable adjustment to the two strata with the lowest number of cases would reduce the risk of penalizing facilities in those strata for random within-facility variation. The average number of cases contributing to the Total Performance Score in the second stratum is 25. Accordingly, we developed and proposed below a favorable adjustment to the measure rates for facilities with at least the minimum case threshold of 11 and fewer than the adjustment threshold of 26 cases. This methodology would give facilities ''the benefit of the doubt'' and ensure that any error in measure rates due to a small number of cases will not adversely affect payment.

Specifically, we proposed that if a facility reports at least 26 cases during the 12-month performance period on a measure, it would be scored based on its raw performance rate on the measure. If the facility reports between 11 and 25 cases during the 12-month performance period, it would be scored based on its raw performance rate plus a favorable reliability adjustment to account for a possible unfavorable skew in the measure rate due to small sample size.

We proposed the following methodology to adjust the measure rate used to score facilities with 11–25 cases for a given measure. The adjustment factors in facility size and the standard error of the measure, which can be estimated using an analysis of variance (ANOVA). This analysis allows us to estimate how much better the measure rate could have been if that facility were treating an ''average'' population of patients and make a favorable adjustment to the facility's score in that amount. For example, as a facility treats more patients, the reliability of the measure rate improves, and the difference between the facility's measure rate and the measure rate we statistically would expect to see if the facility were treating an ''average'' panel of patients decreases. Thus, the magnitude of the adjustment factor increases as the number of cases decreases from 25 to 11.

Because the adjustment factor takes into account a facility's performance (standard error of the measure) and the number of cases for the measure, it is computed separately for each measure. The specific methodology we proposed follows:

- ANOVA provides an estimate *sw* of the square root of within facility variance, given by the within subject mean square.
- Then for the ith facility, the standard error of the average measure (denoted by x_i is given by

$$\mathrm{SE}(x_i) = sw / \sqrt{n_i},$$

where n_i is the number of patients in the ith facility. Now denote C as the minimum case number. We proposed the following adjustment for the original score x_i by introducing a weight depending on facility size.

- Let $w_i = 1 - \frac{n_i}{c}$ if $n_i < C$, and $w_i = 0$ if $n_i \geq C$,

where C is the lower bound of cases for facilities that will not receive any adjustment.

- For measures where large values of x_i are good (that is, for the PY 2015 ESRD QIP, the fistula measure and the Kt/V Dialysis Adequacy measure topic):

o The new score is: $t_i = x_i + w_i * SE(x_i)$. (If $t_i > 100\%$, we set $t_i = 100\%$).

- In cases where lower values of x_i are better (that is, for the PY 2015 ESRD QIP, the Hemoglobin Greater Than 12g/dL and catheter measures):

o The new score is: $t_i = x_i - w_i * SE(x_i)$. (If $t_i < 0\%$, we set $t_i = 0\%$).

We stated our belief that this approach gives facilities an allowance to account for the uncertainty in the estimate x_i by accounting for the size of the patient population in both weights and standard errors. As explained above, this allowance decreases when the case size increases (from 11 to 26 or more)—the larger the case size, the smaller the allowance. For example, when C=26, this implies that for measures with 26 cases and above, no allowance is made. We sought public comment on this methodology and the proposed adjustment threshold. While one model is presented above, we invited comment on alternative approaches that are consistent with our intent to include as many facilities as possible in the ESRD QIP and at the same time address concerns from stakeholders regarding the reliability of

measures where there are small numbers of cases. We stated our belief that this adjustment is appropriate for the ESRD QIP considering the particular measure set and scoring methodology for PY 2015. As the program grows and evolves, we noted that we will continue to assess reliability based on the measures and scoring methodology for that payment year.

The comments we received on these proposals and our responses are set forth below.

Comment: Many commenters supported our proposal to use an adjustment for measure rates, especially because aging patients and patients with comorbidities can negatively affect a small facility's score. Commenters also supported our proposal to use the adjuster for measures with 11–25 cases. Other commenters did not support the proposed adjustment because it is overly complicated, could mislead patients, and could make low-volume facilities appear better than high-volume facilities when they are not, in fact; these commenters suggested that we raise the case minimum to at least 25 cases instead of employing the proposed adjustment methodology. Some commenters expressly stated that the proposed case minimum is not sufficient; other commenters argued that the proposed case minimum should be lowered because the proposal could preclude participation from many low-volume facilities, specifically pediatric facilities.

Response: Were we to set the case minimum at 26 rather than 11, we estimate that an additional 520, or an additional 10 percent of, facilities would be excluded from the program. Although lowering the case minimum would include even more facilities, we do not believe it is appropriate to do so because of not only reliability but also privacy concerns. As we stated in the proposed rule (77 FR 40984), we believe the adjustment balances the competing concerns of reliability, privacy, and inclusion.

Although it can be difficult to understand the adjustment methodology, we do not believe that this concern alone should prevent us from finalizing it as proposed. The adjustment will result in no harm to any facility; although a facility may not be able to predict its Total Performance Score if some of its measures are subject to the adjustment, the facility will know that the adjuster will not negatively affect its score. It could continue to predict its minimum score and use this score as a baseline for assessing whether or not it will receive a payment reduction. Additionally, we believe that the argument that the adjuster could allow smaller facilities to seem better than they are is of little concern. Although the adjuster will affect the measure score, it will not affect the measure rate. The rates that are displayed to the public will be shown without an adjustment. Thus, a beneficiary could continue to meaningfully compare facilities, regardless of the number of patients these facilities serve.

Comment: Some commenters requested that, if we adopted the proposed adjustment, we publish tables with the values of *sw* to make the ESRD QIP as transparent and predictable as possible.

Response: The *sw* values represent the within facility variation. It is specific to each facility and, because it will be based on 2013 data, it cannot be derived until the end of the performance period. Therefore, we are not able to publish the *sw* values at this time.

Comment: Some commenters encouraged us to continue to conduct analyses to determine the appropriate reliability of measures and the minimum case number for future years of the program. Some commenters suggested that, if we are concerned with reliability and minimum case numbers, we employ longer performance periods spanning multiple years. Commenters also encouraged us to align the ESRD QIP minimum case number with other VBP programs.

Response: We will continue to study the reliability of measures and the Total Performance Score. We have and will continue to consider using longer performance periods on a measure-by-measure basis. Although we strive to align the VBP programs as much as possible, each program has unique measures which may necessitate different minimum case numbers. We will continue to look for harmonization as much as is appropriate.

For the reasons stated above, we finalize the case minimum and adjustment for clinical measures as proposed.

b. Minimum Data Requirements for Reporting Measures by New Facilities

For purposes of the PY 2014 ESRD QIP, we stated that a facility that receives a CCN on or after July 1, 2012 has the option to choose whether or not it is scored on each reporting measure (76 FR 70275). We considered using the same approach for PY 2015 as we did in PY 2014 (that is, allowing new facilities to choose whether or not they will be scored on each reporting measure). Under that approach, if a new facility reports enough information to receive 10 points on a reporting measure, the facility is scored on that measure. If a new facility scores zero or 5 points on a reporting measure, it is not scored on that measure. As the program evolves, we believe it is important to continuously push improvement in all facilities—both old and new. Additionally, we wish to incentivize new facilities to put reporting mechanisms in place as soon as possible. For these reasons, we proposed to modify the reporting measure minimum data requirement from that of PY 2014.

For PY 2015, we proposed that any facility receiving a CCN before July 1, 2013 be scored on the reporting measures. However, since a facility receiving a CCN after January 1, 2013 would not be able to report a full 12 months of data, we stated our belief that it is not appropriate to require it to do so in order to receive a full 10 points on the reporting measures. Instead, we proposed to score these facilities proportionately for the time for which they have a CCN during the performance period. To earn 10 points on the ICH CAHPS reporting measure, we proposed to require that a facility receiving a CCN between January 1, 2013 and June 30, 2013 attest that it successfully administered the survey during the time for which it had a CCN during the performance period. For purposes of the Anemia Management, NHSN Dialysis Event, and Mineral Metabolism reporting measures, we proposed that if a facility receives a CCN on or after January 1, 2013, but before July 1, 2013, it would receive 10 points for reporting for all months for which it has a CCN and 5 points for consecutively reporting half of the months for which it has a CCN during the performance period. If a facility has a CCN for an odd number of months, we proposed to round down to calculate the number of months for which it must report to receive 5 points. Finally, we proposed to begin counting the number of months for which a facility is open on the first day of the month after the facility receives a CCN. For example, assume a facility receives a CCN on March 15, 2013. In order for this facility to receive 10 points on the applicable reporting measure, we proposed that it must report data from April 1, 2013–December 31, 2013 (or 9 months of data). In order for it to receive 5 points, we proposed that it must report half of the months for which it is open, consecutively. For the example facility to receive 5 points, it would need to report 4.5 months of data. Since we proposed to round down, this facility

would be required to report 4 months of data to receive 5 points.

We realized that facilities receiving a CCN on or after July 1, 2013, may have difficulty meeting the requirements of the reporting measures, such as enrolling and training for the NHSN Dialysis Event reporting measure or hiring a third-party to administer the ICH CAHPS survey, because of the short period of time left in the performance period. We also stated our belief that it is appropriate to reduce payment for a 1-year period based on less than 6 months of performance. Therefore, we proposed to exclude facilities receiving a CCN on or after July 1, 2013 from the requirements of the reporting measures. Because we finalized, as discussed above, that a facility will not receive a Total Performance Score unless it receives a score on at least one clinical and one reporting measure, finalizing this proposal would result in facilities not being eligible for a payment reduction if they receive a CCN on or after July 1, 2013. We requested comment regarding these proposals. We also elicited comments regarding whether there would be a more appropriate way to score these new facilities on reporting measures so that they may be eligible for inclusion in the ESRD QIP.

The comments we received on these proposals and our responses are set forth below.

Comment: Commenters supported our proposals regarding the reporting measures' minimum data requirements for new facilities; specifically, commenters supported our proposal to exempt facilities receiving a CCN after June 30, 2013 from the reporting measures. Some commenters suggested that a facility that receives a CCN between January 2013 and June 2013 should be required to begin reporting on the first day of the third month after the facility receives a CCN to allow the facility to deploy its IT system and enroll in CROWNWeb and NHSN.

Response: Consistent with our change to allow facilities to score 0–10 incremental points on the Anemia Management and Mineral Metabolism reporting measures, we will finalize changes to our proposed scoring methodology for these measures for facilities receiving a CCN between January 1, 2013 and June 30, 2013. Facilities receiving a CCN between January 1, 2013 and June 30, 2013, will be able to score points in proportion to their overall rate of monthly reporting on the Anemia Management and Mineral Metabolism reporting measures. As we noted above, we believe it is important to require a minimum threshold for facilities to earn points on this measure. Thus, we finalize that a facility receiving a CCN after January 1, 2013 but before June 30, 2013 can score points on the Mineral Metabolism and Anemia Management reporting measures using the following formula:

$$\left[\frac{\text{Number of Months Facility Successfully Reports}}{\text{Number of Months in the Performance Period Facility has CCN}} \times 12\right] - 2$$

We will round the result of this formula (with half rounded up) to achieve a measure score from 0–10.

For purposes of the Anemia Management and Mineral Metabolism reporting measures, we do not agree with commenters that facilities should be required to report the first day of the third month after they receive their CCN. A facility with a CCN may submit claims to Medicare. If a facility is submitting claims, it should be reporting hemoglobin and ESA levels. It should also be reporting in CROWNWeb. Therefore, we do not believe it is necessary to allow facilities more time on these measures, and we finalize that facilities must begin reporting for these measures on the first day of the month after they receive their CCN.

As we have previously noted, we believe that a facility needs a period of time after it receives its CCN to ensure that its systems are in place to report to the NHSN system. As we explained above, we are requiring facilities to report 6 non-consecutive months of data to receive points on the NHSN Dialysis Event measure. Because of the time required to enroll and train in the NHSN system, we do not believe it is equitable to require facilities receiving a CCN during the performance period to comply with this measure. Therefore, we are finalizing that a facility that receives a CCN during the performance period will be not be scored on the NHSN Dialysis Event reporting measure.

For the ICH CAHPS measure, we believe that facilities receiving a CCN before July 1, 2013 should be able to hire a third-party administrator in time to administer the ICH CAHPS survey. Although it may take some time for facilities to put this administrator in place, it can begin doing so before it receives a CCN. Therefore, we finalize our proposals that, to earn 10 points on the ICH CAHPS reporting measure, a facility receiving a CCN between January 1, 2013 and June 30, 2013 must attest that it successfully administered the survey during the time for which it had a CCN during the performance period.

We also finalize that facilities receiving a CCN after June 30, 2013 will be exempt from the Mineral Metabolism, Anemia Management, and ICH CAHPS reporting measures. For the NHSN Dialysis Event reporting measure, facilities will be exempt if they receive a CCN on or after January 1, 2013.

12. Payment Reductions for the PY 2015 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution of payment reductions across facilities such that facilities achieving the lowest Total Performance Scores receive the largest payment reductions. For PY 2014, we adopted an approach under which a facility did not have to meet or exceed the performance standards with respect to each of the finalized clinical measures to avoid receiving a payment reduction under the ESRD QIP. Rather, even if a facility failed to meet or exceed the performance standards with respect to one or more of these measures, the facility could avoid a payment reduction if it achieved a minimum Total Performance Score that is equal to or greater than the minimum Total Performance Score it would receive if it had met the performance standards for each of the clinical measures or, in the case of the Vascular Access Type Measure, for the two subcomponent measures.

For PY 2014, in calculating this minimum Total Performance Score, we excluded the reporting measures

because we believed this approach best underscored the importance of the clinical measures. For PY 2015, we proposed to retain the same approach as in PY 2014. We discuss the methodology for deriving the performance standards for the measure topics, above. We requested comments on these proposals.

Alternately, in order to better incentivize compliance with reporting measures, we also considered raising the minimum Total Performance Score to include 50 percent of the total points a facility could have received had it met all of the reporting requirements for each measure. In other words, because a facility could receive up to 40 points in PY 2015 for meeting all of the reporting measure requirements, we considered raising the minimum Total Performance Score by 20 points (one-half of 40). This approach would ensure that facilities receiving a CCN before August 1, 2013 could still achieve the minimum Total Performance Score by meeting, on average, the performance standards for the clinical measures and achieving as many points on the reporting measures as is possible. We requested comment regarding whether the reporting measures should be scored at greater than 0 when calculating the minimum Total Performance Score.

Section 1881(h)(3)(A)(ii) of the Act requires that facilities achieving the lowest Total Performance Scores receive the largest payment reductions. For PY 2014, we adopted an approach we intend to continue for PY 2015. We believe that this consistency will allow the program to be more understandable to both facilities and the general public. Accordingly, we proposed that the payment reduction scale be the same as the PY 2014 program. Therefore, for each 10 points a facility falls below the minimum Total Performance Score, it would receive an additional 0.5 percent payment reduction on its ESRD payments for PY 2015, with a maximum reduction of 2.0 percent. As we stated in the CY 2012 ESRD PPS final rule (76 FR 70281), we believe that such a sliding scale will incentivize facilities to meet the performance standards and continue to improve their performance because even if a facility fails to achieve the minimum Total Performance Score, the facility will still be incentivized to strive for, and attain, better performance rates in order to reduce the amount of its payment reduction. We requested comments on the proposed payment reduction scale.

The comments we received on these proposals and our responses are set forth below.

Comment: Commenters agreed with our proposal to use the PY 2014 payment reductions scale for the PY 2015 ESRD QIP. Some commenters, however, supported placing more emphasis on the reporting measures in calculating the minimum Total Performance Score since these are the measures over which facilities have the most control. Some commenters suggested that we base payment reductions on actual impact rather than projections of impact, setting tiers of reductions by percentage of facilities we wish to be in each tier. Another commenter urged us to create a more individualized approach to payment reductions because high quality care is markedly different from patient to patient.

Response: At this time, we do not believe it is in the best interest of the program to base payment reductions on actual impact and the percentage of facilities to which we wish to provide payment reductions. Regardless of the impact, we believe that facilities that do not meet the performance standards for each of the clinical measures should face a payment reduction. Were we to base reductions on percentages, the result could be that some high performing facilities receive a payment reduction. Our current payment reduction scale allows every facility to avoid a payment reduction provided that they meet the minimum Total Performance Score.

We agree that it is important to provide individualized care to patients. We believe that the program, incentivizes facilities to furnish individualized care within a certain range of established, clinical acceptable guidelines.

Finally we agree with the commenters that requested we place more emphasis on the reporting measures when calculating the minimum Total Performance Score. We specifically believe that this approach is appropriate now that we have weighted the reporting measure to comprise 25 percent of the Total Performance Score. Were we to continue to score the reporting measures at zero when calculating the minimum Total Performance Score, by increasing the weight of the reporting measures, we would be decreasing the minimum Total Performance Score. This result is contrary to our belief stated in this final rule that the reporting measures should be afforded more importance. Therefore, we will finalize the alternative approach we requested comment on in the proposed rule to include the reporting measures in the minimum Total Performance Score at 50 percent of the total points a facility could have received had it met all of the reporting requirements. As noted above, it is possible to gain a total of 40 points from the reporting measures; thus, we will include half, or 20 of these points, in our calculation of the minimum Total Performance Score. We believe this approach is consistent with our methodology for the clinical measures since we calculate the clinical measure component of the minimum Total Performance Score as the score a facility would have received if it had reached the 50th percentile for all clinical measures.

Comment: One commenter suggested that the 2 percent payment reduction be revisited since such a small percentage will not be a worthwhile incentive as new measures are added. Several commenters expressed concern that the ESRD QIP works as a penalty system and suggested that the ESRD QIP provide incentives as well as penalties, and on balance, be budget-neutral. One commenter suggested that the payment reductions be returned to the penalized facilities for use only to improve care in the areas where they failed to meet quality standards.

Response: Section 1881(h) of the Act does not provide us with the authority to issue bonus payments to facilities based on their performance under the ESRD QIP, to make reductions of more than 2.0 percent, or to redistribute the payment reductions to the originally penalized facilities.

For the reasons stated above, we finalize our proposals for calculating payment reductions except that we will include reporting measures in calculating the minimum Total Performance Score. The reporting measure component of the minimum Total Performance Score will equal the score a facility would have received if it is awarded half of the maximum points it could have received on the reporting measures (that is, 5 points on each measure). Based on this approach, the minimum Total Performance Score is 60 points. Facilities failing to meet this minimum will receive payment reductions in the amounts indicated in Table 7 below.

TABLE 7—FINALIZED PAYMENT REDUCTION SCALE FOR PY 2015

Total performance score	Reduction (%)
100–60	0
59–50	0.5
49–40	1.0
39–30	1.5
29–0	2.0

13. Data Validation

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and Total Performance Scores is accurate. To that end, we have procured the services of a data validation contractor who will be tasked with validating a national sample of facilities' records as they report data under the ESRD QIP. Beginning in CY 2013, we proposed to begin a pilot data validation program for the ESRD QIP. Because data validation for the ESRD QIP is new to both facilities as well as CMS, we believe that the first year of validation should result in no payment reductions to facilities. Accordingly, we proposed that, beginning in CY 2013, we would randomly sample the records of approximately 750 facilities. We anticipate that a CMS-designated contractor would request approximately 10 records from each of these facilities. We proposed that the facility must comply with this request for records within 60-days of receiving notice. The contractor would review these records to ensure accuracy and reliability of the data reported by the facility for purposes of the ESRD QIP.

As noted above, we proposed that, in the first year of this program, no facility will receive a payment reduction resulting from the data validation process. In future years of the program, we noted our intent to evolve our pilot program into a full, data validation effort. We are also discussing a data validation measure whereby facilities would be scored based on the accuracy of their records. Finally, we are contemplating increasing a facility's payment reduction by one tier (for example, from 0.5 percent to 1.0 percent) if its data are incorrect beyond a certain threshold. In future years, we stated our intention to propose more detailed procedures regarding our data validation process that may result in penalties. We requested comment on our data validation proposals for PY 2015 and the methods we are considering for PY 2016.

The comments we received on these proposals and our responses are set forth below.

Comment: Many commenters supported our proposal to have a data validation pilot program that would result in no payment reductions. Some commenters suggested that we continue the pilot until we can evaluate the data from the program, and some commenters suggested that we should share the results of the pilot with the dialysis community before the official program is launched. One commenter requested that, before the pilot program begins, we define the errors being sought and publish these for public comment. Another commenter stated that, before data validation efforts are initiated, CMS should provide clear specifications, data definitions, and reporting requirements because it would be inappropriate to penalize facilities when clarification questions or reporting issues have not been resolved. Commenters also recommended that CMS include the initial data validation in the routine Comprehensive Error Rate Testing (CERT) request for RACs (Recovery Audit Contractors), but cautioned against paying auditors on a contingency fee.

Response: We thank commenters for their support of the pilot data validation program. At this time, we are still finalizing the processes and procedures for the pilot. We will provide this information before the pilot program begins on a publicly available Web site. We will consider the commenters' suggestions as we continue this process. Additionally, as discussed in the sections of this rule outlining the measures, we believe that the specifications, data definitions, and reporting requirements are clear and transparent. If it becomes apparent that there is some significant confusion as to any of these elements, we will clarify these them using the most appropriate means.

Comment: One commenter stated that it does not believe it is appropriate for CMS to develop a data validation measure for the ESRD QIP. This commenter argued that CMS must first explain the scope of accuracy and errors (for example, does it include missing values, transcriptional errors) that CMS requires. Other commenters requested that, before payment is tied to validation, CMS should publish for comment the relationship of errors to payment reductions (with some accorded more weight than others depending on their scope and type) and allow the dialysis community to review the results of the pilot.

Response: We thank commenters for these suggestions. We believe that ensuring data accuracy of reported data is an important component to ensure accurate performance scores and corresponding payments. We continue to consider whether and how we will tie payment to any data validation issues. We will publish any future proposals in rulemaking for public comment.

Comment: Some commenters expressed concern with the burden data validation may place on facilities. One commenter is concerned that producing records within 60 days is too monetarily burdensome and suggests a 120 day period. Another commenter requested that we limit the number of document requests based on provider size and resources and reimburse facilities for data requests. One commenter suggested that the requested data sample be a percentage of patients rather than a fixed number so that small facilities are not disproportionally affected. One commenter asked that the requested records be as current as possible so that they can be easily accessed by facilities that many have data storage protocols. Another commenter specifically noted its support for HAI data validation, but stated its concern that we underestimated the burden on facilities; this commenter requested that we provide more detail on the validation process, specifically the facilities' responsibilities, and encouraged us to partner with NHSN and state and public health partners in developing a standardized process for the validation of HAI data.

Response: We do not believe that our proposals place an undue burden on facilities. We proposed to request only ten records, and we will provide the facility 60 days to produce these records. We do not believe that collecting such a small amount of documentation in such a great deal of time should pose problems for facilities. As we explain later in this rule, we estimate that it will take each facility only 2.5 hours to comply with the requests for these records and will cost approximately $83.08 per facility. We do not believe that 2.5 hours in the span of 2 months (or 2.5 minutes per day) is too little time to comply with these requests nor do we believe it warrants an additional 60 days for compliance. Further, we do not agree that we should request a percentage of documents from facilities rather than a fixed number. If a facility is large, asking for even one percent of its records could prove to be a large burden. Alternatively, requesting that a small facility provide even 10 percent of its records would not provide our data contractor with enough information to assess the validity of the data. By requesting 10 records from each facility, we can ensure a similar burden (2.5 hours and approximately $83.08) for each facility and an analysis of its validity based on the same volume of information.

As noted above, at this time, we are still finalizing the processes and procedures for the pilot. We will provide further information on a publicly available Web site. As we finalize these procedures, we intend to engage various stakeholders to encourage the development of a

standardized process for the validation of data, including data from the CDC for HAIs.

Comment: One commenter requested that we specify a data validation appeals process.

Response: We will consider proposing a data validation appeals process in future rulemaking. Because the proposed program is a pilot and will not have any impact on payment, we do not believe an appeals process is necessary at this time.

Comment: One commenter believes that the various technological resources facilities have should be taken into account when evaluating data validity. This commenter encouraged us to evaluate manual/electronic medical records (EMR) data entry in CROWNWeb.

Response: We will consider commenter's suggestion when we evaluate the data in the pilot program. We will specifically consider if there are variations in the accuracy of data because of the mode of data entry.

Comment: One commenter encouraged us not to implement a payment reduction until all facilities have been asked to submit medical records for purposes of data validation at least one time. Another commenter stated that each facility should have the opportunity to identify data transmission/download errors without the risk of payment penalty.

Response: We thank commenters for the suggestions and will consider them as our pilot program advances.

For the reasons stated above, we finalize our pilot data validation program as proposed, and we will specify the processes and procedures of this pilot on *http://www.dialysisreports.org*.

14. Scoring Facilities Whose Ownership Has Changed

During our first year of implementation of the ESRD QIP, PY 2012, facilities requested guidance regarding how a change in ownership affects any applicable ESRD QIP payment reduction. We proposed that, for all future years of the ESRD QIP, the application of an ESRD QIP payment reduction would depend on whether the facility retains its CCN after the ownership transfer. If the facility's CCN remains the same after the facility is transferred, for purposes of the ESRD QIP, we would consider the facility to be the same facility (despite the change in ownership) and we would apply any ESRD QIP payment reduction for the transferor to the transferee. Likewise, as long as the facility retains the same CCN, we would calculate the measure scores using the data submitted during the applicable period regardless of whether the ownership changed during one of these periods. If, however, a facility receives a new CCN as a result of a change in ownership, we would treat the facility as a new facility for purposes of the ESRD QIP as of the date it received the new CCN. We stated our belief that these proposals are the most operationally efficient and will allow facilities the most certainty when they change ownership. We proposed to apply these rules beginning with the PY 2014 ESRD QIP, and we requested public comment on these proposals.

The comments that we received and our responses to these comments are set forth below.

Comment: Many commenters strongly supported our proposals for scoring transferred facilities. One commenter expressed concern that the proposals will change the marketplace in ways that are not yet known.

Response: We thank commenters for their support. We realize that this proposal may impact how dialysis facilities are acquired in the future. However, we believe that creating rules around how we will treat transferred facilities for purposes of the ESRD QIP will create a marketplace that is more predictable. Therefore, we finalize these rules for transferred facilities as proposed.

15. Public Reporting Requirements

Section 1881(h)(6)(A) of the Act requires the Secretary to establish procedures for making information regarding facilities' performance under the ESRD QIP available to the public, including information on the Total Performance Score (as well as appropriate comparisons of facilities to the national average with respect to such scores) and performance scores for individual measures achieved by each facility. Section 1881(h)(6)(B) of the Act further requires that a facility have an opportunity to review the information to be made public with respect to that facility prior to such information's publication. In addition, section 1881(h)(6)(C) of the Act requires the Secretary to provide each facility with a certificate containing its Total Performance Score to post in patient areas within the facility. Finally, section 1881(h)(6)(D) of the Act requires the Secretary to post a list of facilities and performance-score data on the CMS Web site.

In the PY 2012 ESRD QIP final rule, we adopted uniform requirements based on sections 1881(h)(6)(A) through 1881(h)(6)(D) of the Act, establishing procedures for facilities to review the information to be made public and the procedures for informing the public through facility-posted certificates for the first 3 payment years of the ESRD QIP (76 FR 636 through 639). We proposed that these requirements generally apply to PY 2015 and subsequent payment years. However, we proposed to make some modifications, as outlined below, to these requirements and that these modifications become effective upon the effective date of this final rule. Thus, these requirements, if finalized, would apply in PY 2014 and for subsequent payment years. All other previously finalized requirements would remain the same.

First, for the first year of the program, PY 2012, we did not explicitly state that we would be publishing a list of facility performance on or after December 1 of the year before the payment consequence year. We did, however, make this list available for the pubic via the CMS Web site. For the PY 2013 ESRD QIP and subsequent payment years, and in accordance with section 1881(h)(6)(D) of the Act, we proposed to publish such aggregate list on the CMS Web site at *www.cms.gov* and any other Web site controlled by CMS. This list will include information on the facility, specifically:

(i) Name and address;

(ii) Measure rates (which may include numerators and denominators) and scores;

(iii) And Total Performance Scores.

This list will also indicate those facilities that do not have enough data to calculate one or more measure rates and/or a Total Performance Score. We believe it is important to publish such a list because it allows beneficiaries, the public, and facilities access to this information without having to individually download a certificate for each facility, and, because of such access, we believe it will ultimately improve quality. The data will be more accessible, Medicare beneficiaries and their families will have the information more easily to make choices about their care, and facilities can more readily compare their performance to other facilities or across facilities. Therefore, beginning in January 2013, we proposed to publish a list of facility information described above for each payment year after facilities have the ability to review their scores.

Second, for PY 2012, we required facilities to prominently post certificates within 5 days of us making these certificates available for download from *www.dialysisreports.org* in accordance with section 1881(h)(6)(C) of the Act (76 FR 637). We proposed to modify the

previously finalized requirements for posting certificates in two ways. We no longer believe it is necessary for facilities to post these certificates within 5 days of their availability. The certificates are provided in late December, and it was our experience in the PY 2012 program that many individuals responsible for the certificates were away on holiday during this period of time. Therefore, we proposed to change this requirement so that, beginning with the PY 2014 program, facilities will be required to post their certificates on or before the first business day after January 1 of each payment year. Certificates are typically available for download on or around December 15, and we believe that this two week amount of time is long enough to allow facilities to post them. Therefore, beginning PY 2014, we proposed that facilities be required to post their Performance Score Certificates (PSCs) on or before the first business day after January 1 of each payment year in a prominent place for the duration of that payment year and otherwise comply with the requirements listed in the PY 2012 final rule (76 FR 637).

Third, for the PY 2012 ESRD QIP, we required facilities to post one copy of the certificate in their facility (76 FR 637). Beginning in PY 2014, we proposed to require facilities to post two copies of this certificate, one copy in English and one copy in Spanish. Both of these certificates (which are posted as a single file) will be provided by CMS, both must be posted by the first business day after January 1 of the payment year, and both must be posted for the entirety of such year in a prominent location. We proposed to require the certificate to be posted in both English and Spanish to make the certificate more understandable to native Spanish speakers. Thus, to best serve a greater number of ESRD patients, we proposed to finalize the requirement that facilities must post both an English and a Spanish certificate prominently in their facility. The only additional burden for facilities in adding this Spanish certificate is its printing and posting.

The comments we received on these proposals and our responses are set forth below.

Comment: Commenters supported our proposal to allow facilities until the first business day after January 1 to post certificates. Most commenters agreed with our proposal to require facilities to post both English and Spanish versions of the PSC beginning in PY 2014, stating that the additional burden is very small; one commenter argued that Spanish versions of the PSC are not necessary in all locations and recommended that individual facility administrators determine whether posting a PSC in Spanish is necessary or beneficial based upon the population that the facility serves. Another commenter suggested not only requiring a Spanish PSC but also developing Spanish-language materials explaining the PSCs.

Response: We agree with commenters that the burden of posting a Spanish as well as an English PSC is very little and far outweighs the benefits it could convey upon beneficiaries. We do not agree that it is appropriate for facility administrators to determine whether posting the Spanish PSC is necessary. A facility that does not furnish services to native Spanish speaking patients in 1 year could begin to do so during the next year. As the ESRD QIP evolves, we seek to make the program as transparent as possible for all beneficiaries.

Comment: Some commenters believe that the ESRD QIP should be clearer, and we should develop and make public guidance documents for patients and clinics. These commenters also suggested that we hold open door forums specifically for patients so that they do not interpret the quality of care information incorrectly.

Response: As we noted above, we seek to make the program as transparent as possible, specifically to beneficiaries. We intend to continue to assess the modes and efficacy of our communications to beneficiaries. We will take these comments into account as we do so.

Comment: Some commenters requested that we make available on our Web site individual measure scores (including the numerator and denominator) and the Total Performance Scores; commenters stated that these scores should be organized by facility and state to facilitate choice in care. One commenter requested that this information be published in both English and Spanish. One commenter encouraged us to create a ''one-stop-shop'' for quality information on the internet.

Response: Since the PY 2012 program, we have made aggregate information on measure scores and Total Performance Scores available on *http://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDQualityImproveInit/index.html*. This information includes numerators and denominators for each clinical measure, the scores for each measure, and Total Performance Scores for every facility. The information is organized in alphabetical order by state and facility. We will consider publishing this information in Spanish in future years. Additionally, we seek to align the ESRD QIP with CMS' other VBP program; we continue to assess how information across programs should be presented, and we will considering creating a ''one-stop-shop'' for information related to CMS' programs. At present, a great deal of information on these programs can be found here: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/index.html*.

Comment: One commenter believes that the NHSN measure should be included in DFC because it is key to patient safety.

Response: We thank comments and will consider the appropriateness for inclusion of this measure on DFC in future Web site releases.

Comment: One commenter requested that we confirm that there is consistency in measures reported in DFR, DFC, PSR, and for ESRD QIP purposes.

Response: We thank the commenter for its inquiry regarding the consistency of measures reported through DFR, DFC, the Performance Score Reports (PSR), and for ESRD QIP purposes. There are some differences in the measure descriptions between DFR, DFC, and QIP because each serves its own purposes; the measure rates for the ESRD QIP that are posted on DFR, DFC, and in the PSR are the same. For example, for DFR/DFC, the denominators for the Kt/V measures include out of range values, whereas the ESRD QIP Kt/V measure denominators do not. We seek to align reporting mechanisms as much as possible, but, in some cases, we believe that it is appropriate to present this information differently.

Comment: One commenter recommended that we timely monitor quality data and intervene if trends indicate a decrease in the quality of care.

Response: We are committed to monitoring and evaluating the impacts of the ESRD QIP.

Comment: One commenter urged us to prioritize the development and implementation of a single system to which facilities would report their data in order to simplify reporting and minimize unnecessary burdens on providers, particularly staff members otherwise providing direct care to patients.

Response: We continue to evaluate our reporting systems; we seek to minimize provider burden as much as possible, and we will continue to evaluate ways in which we can do so as the program moves forward.

IV. Limitation on Payments to All Providers, Suppliers and Other Entities Entitled to Bad Debt

A. Background

In accordance with section 1861(v)(1) of the Act and current regulations at 42 CFR 413.89, Medicare pays some or all of the uncollectible deductible and coinsurance amounts to those entities eligible to receive reimbursement for bad debt. To determine if bad debt amounts are allowable, the requirements at § 413.89 must be met. Chapter 3 of the Provider Reimbursement Manual (PRM) (CMS Pub. 15, Part I) provides additional guidance on the standards governing bad debt reimbursement.

Prior to the passage of the Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 112–96), under section 1861(v)(1)(T) of the Act and § 413.89(h)(1) of our regulations, Medicare payments for allowable bad debt amounts for hospitals were reduced by 30 percent for cost reporting periods beginning on or after October 1, 2001. Likewise, under section 1861(v)(1)(V) of the Act and § 413.89(h)(2) of our regulations, Medicare payments for allowable bad debt amounts for patients in skilled nursing facilities (SNFs) that were not dual eligible individuals beginning with cost reporting periods beginning on or after October 1, 2005, were reduced by 30 percent. Section 413.89(h)(2) defines a dual eligible individual for bad debt purposes as an individual that is entitled to benefits under Part A of Medicare and is determined eligible by the State for Medical Assistance under Title XIX of the Act as described in 42 CFR 423.772 paragraph (2) under the definition of a ''full-benefit dual eligible individual.''

For all other providers, suppliers, and entities eligible to receive bad debt payment, including critical access hospitals (CAHs), rural health clinics (RHCs), Federally qualified health centers (FQHCs), community mental health centers (CMHCs), end stage renal diease (ESRD) facilities, swing bed hospitals, as defined at 42 CFR 413.114(b), and patients that are dual eligible individuals in SNFs, Medicare paid 100 percent of allowable bad debt amounts. Additionally, for health maintenance organizations (HMOs) reimbursed on a cost basis and competitive medical plans (CMPs) defined under section 1876 of the Act, and for health care prepayment plans (HCPPs) defined under section 1833(a)(1)(A) of the Act, Medicare pays a portion of bad debt amounts under 42 CFR 417.536(f) of our regulations. Although Medicare previously paid ESRD facilities 100 percent of allowable bad debt amounts, these payments were capped at the facility's reasonable cost in accordance with § 413.178(a). In the proposed rule, we proposed to maintain the cap on bad debt reimbursement to an ESRD facility up to the facility's unrecovered costs. We also proposed to apply the bad debt reduction percentages mandated by section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. No. 112–96), prior to applying the cap up to the ESRD facility's unrecovered costs.

B. Section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 112–96)

Sections 3201(a) and (b) of the Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 112–96) amended section 1861(v)(1)(T) and section 1861(v)(1)(V) of the Act, respectively, by further reducing the percentage of allowable bad debt attributable to the deductibles and coinsurance amounts payable to hospitals (section 1861(v)(1)(T)) and SNFs (section 1861(v)(1)(V)). Section 3201(b) of Public Law 112–96 also revised the SNF bad debt reductions to include both dual eligible beneficiaries and non-dual eligible beneficiaries under section 1861(v)(1)(V) of the Act, and to apply such reductions to swing bed hospitals for cost reporting periods beginning during fiscal year 2013 and subsequent fiscal years.

Finally, section 3201(c) of The Middle Class Tax Extension and Job Creation Act of 2012 added a new subparagraph 1861(v)(1)(W) to the Act, which applied a reduction in bad debt payments to ''providers'' not addressed under subparagraphs 1861(v)(1)(T) or 1861(v)(1)(V) of the Act. For the purpose of subparagraph 1861(v)(1)(W) of the Act, section 3201(c) Public Law 112–96 defined ''providers'' as those providers not previously described in subsections 3201(a) or (b), suppliers, or any other type of entity that receives payment for bad debts under the authority of section 1861(v)(1)(A) of the Act. These providers include, but are not limited to, CAHs, RHCs, FQHCs, CMHCs, HMOs reimbursed on a cost basis, CMPs, HCPPs and ESRD facilities.

C. Summary of Provisions of This Final Rule

1. Self-Implementing Provisions of Section 3201 Public Law 112–96

The provisions of subsections 3201(a), (b), and (c) of The Middle Class Tax Extension and Job Creation Act of 2012 permit no discretion on the part of the Secretary and thus, are self implementing, with the exception of the proposal to maintain the cap on bad deb reimbursement for ESRD facilities, as discussed below.

Comment: We received comments from commenters suggesting that the bad debt reduction percentages be implemented in single digit percent reductions instead of the double digit percent reductions, as mandated by section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012.

Response: While we appreciate the concerns of the provider community regarding bad debt payments to providers eligible to receive bad debt, the percent reductions of bad debt payments are statutorily mandated by section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 and do not provide for discretion. Therefore, we are codifying these provisions, as summarized below, in our regulations.

- Payment of allowable bad debt to hospitals for cost reporting periods beginning during fiscal year 2013 and subsequent fiscal years will be reduced by 35 percent.
- Payment of allowable bad debt to SNFs and swing bed hospitals for cost reporting periods beginning during fiscal year 2013 or a subsequent fiscal year will be reduced by 35 percent for coinsurance amounts for services furnished to a beneficiary who is not a dual eligible individual.
- Payment of allowable bad debt to SNFs and swing bed hospitals for coinsurance for services furnished to a beneficiary who is a dual eligible individual will be:
- For cost reporting periods beginning during fiscal year 2013, reduced by 12 percent;
- For cost reporting periods beginning during fiscal year 2014, reduced by 24 percent and;
- For cost reporting periods beginning during fiscal year 2015, reduced by 35 percent.
- Payment of allowable bad debt to all other providers, suppliers and any other entity that receives payment for bad debts under the authority of section 1861(v)(1)(A) of the Act will be:
- For cost reporting periods beginning during fiscal year 2013, reduced by 12 percent;
- For cost reporting periods beginning during fiscal year 2014, reduced by 24 percent;
- And for cost reporting periods beginning during fiscal year 2015 and subsequent fiscal years, by 35 percent.

A summary of the changes in Medicare bad debt payment percentages required by section 3201 of The Middle Class Tax Extension and Job Creation

Act of 2012 is reflected in Table 8 below:

TABLE 8—SUMMARY OF MEDICARE BAD DEBT REIMBURSEMENT BY PROVIDER TYPES FOR COST REPORTING PERIODS THAT BEGIN DURING FY 2013, 2014, 2015 AND SUBSEQUENT YEARS

Provider type	Allowable bad debt amount during FY 2012 (percent)	Allowable bad debt amount during FY 2013 (percent)	Allowable bad debt amount during FY 2014 (percent)	Allowable bad debt amount during FY 2015 & subsequent FYs (percent)
Hospitals	70	65	65	65
SNFs: Non-Full Dual Eligibles	70	65	65	65
Swing Bed Hospitals: Non-Full Dual Eligibles	100	65	65	65
SNFs: Full Dual Eligibles	100	88	76	65
Hospital Swing Beds: Full Dual Eligibles	100	88	76	65
CAHs	100	88	76	65
ESRD Facilities	100	88	76	65
CMHCs	100	88	76	65
FQHCs	100	88	76	65
RHCs	100	88	76	65
Cost Based HMOs	100	88	76	65
Health Care Pre-Payment Plans	100	88	76	65
Competitive Medical Health Plans	100	88	76	65

2. ESRD Bad Debt Cap and Remove and Reserve § 413.178

In the proposed rule, we proposed to maintain the cap on bad debt reimbursement up to an ESRD facility's unrecovered costs. Bad debt payments are made under section 1861(v)(1)(A) of the Act to prevent non-Medicare patients from subsidizing Medicare patients and vice-versa, also known as the anti-cross subsidization principle. The cap at an ESRD facility's unrecovered costs for bad debt reimbursement was originally implemented to assure that the combination of the composite rate payment and the bad debt payment did not exceed the ESRD facility's total allowable costs of providing services to Medicare beneficiaries, as well as to avoid violating the anti-cross subsidization principle. Thus, by applying the cap, an ESRD facility would not be paid for bad debt amounts that exceeded its unrecovered costs under the composite rate payment system implemented in 1983.

Comment: We received comments from commenters suggesting the maintenance of the cap on bad debt reimbursement to ESRD facilities up to the facilities' unrecovered costs was inconsistent with the bad debt reimbursement policies for all other types of providers eligible to receive bad debt reimbursement and was also inconsistent with Federal court rulings.

Response: After careful consideration of the policy implications of removing the cap on bad debt reimbursement at an ESRD facility's unrecovered costs, we have decided to eliminate the cap. The elimination of the cap on bad debt reimbursement to ESRD facilities will allow ESRD facilities to claim bad debts at an amount exceeding unrecovered costs incurred under a prospective payment system. In addition, removal of the cap on bad debt reimbursement to ESRD facilities complies with the order of the D.C. Circuit Court in *Kidney Center of Hollywood, et al.* v. *Shalala,* 133 F.3d 78 (D.C. Circuit 1998), and will allow us to apply our bad debt policies consistently across all the types of providers eligible to receive bad debt payments. Therefore, we believe the removal of the bad debt reimbursement cap at an ESRD facility's unrecovered cost, is an equitable and reasonable policy choice with respect to bad debt reimbursement to ESRD facilities.

We are eliminating the cap for ESRD facilities for cost reporting periods beginning on or after January 1, 2013, the effective date of this final rule. With this change, ESRD facilities will be reimbursed for bad debt reduced as outlined in the proposed changes to § 413.89(h)(3), described above. However, because the new bad debt reductions for ESRD facilities become effective October 1, 2012, and the removal of the cap on bad debt reimbursement to ESRD facilities will not be effective until January 1, 2013, for cost reporting periods beginning between October 1, 2012 and December 31, 2012, the cap on bad debt reimbursement to ESRD facilities will be calculated with both the required bad debt reductions and the cap on bad debt reimbursement to ESRD facilities. For illustrative purposes only, the following examples present the interaction of the application of the cap on ESRD bad debt payments until January 1, 2013 and the ESRD bad debt reduction effective October 1, 2012:

Example (A), for cost reporting periods beginning before October 1, 2012, only the cap applies as follows:

1. Unrecovered costs = $100.00
2. Aggregate Gross bad debt = $110.00
3. Bad debt amount of $110.00 is capped at the unrecovered costs of $100.00, therefore, the facility receives $100.00.

Example (B), for cost reporting periods beginning between October 1, 2012 and December 31, 2012, the 12 percent reduction applies up to the facilities' unrecovered costs as follows:

1. Unrecovered costs = $100.00
2. Aggregate Gross bad debt = $110.00
3. Bad debt amount of $110.00 is reduced by 12 percent (bad debt reduction in FY 2013) which equals $96.80. Since the reduction is less than the cap, the facility receives $96.80.

Example (C), for cost reporting periods beginning on or after January 1, 2013 and before October 1, 2013, only the 12 percent reduction applies:

1. Unrecovered costs = $100.00
2. Aggregate Gross bad debt = $110.00
3. The $110.00 bad debt amount is reduced by 12 percent (bad debt reduction in FY 2013). The facility receives $96.80 with no cap applied.

We are moving current regulations text at § 413.178(a) to proposed § 413.89(h)(3). The revised regulation text will remove the bad debt cap for ESRD facilities, and include the bad debt reduction percentages applicable to ESRD facilities in accordance with 1861(v)(1)(W).

We are removing current paragraphs (b), (c), and (d)(1) of § 413.178 since these provisions already are set out at § 413.89, Chapter 3 of the PRM Part I,

and in the Medicare cost report instructions in the PRM Part II.

In addition, we are moving the bad debt exception provision applicable to ESRD facilities discussed at § 413.178(d)(2) to proposed § 413.89(i)(2). For consistency, we are also moving the current general bad debt exception set out at § 413.89(i) to new paragraph § 413.89(i)(1).

We are removing and reserving § 413.178.

3. Technical Corrections

We are making a technical correction to 42 CFR 417.536(f)(1) to refer to 42 CFR 413.89 as the appropriate cross reference to Medicare bad debt reimbursement policy, to revise the existing language describing bad debt to conform to § 413.89(a), and to remove requirements that already are set out at § 413.89.

D. Changes to Medicare Bad Debt Policy

In this rule, we are conforming existing regulations text found at § 413.89(h) to the self-implementing provisions of section 3201 of Public Law 112–96. Previously, bad debt reimbursement to an ESRD facility was capped up to the facility's reasonable costs under § 413.178(a). In this final rule, we are moving the current provision at § 413.178(a) to § 413.89(h)(3), and adding ESRD facilities to the list of facilities to which § 413.89 ''Bad debts, charity, and courtesy allowances,'' applies. We are also eliminating duplicate provisions in § 413.178 and reserving § 413.178 for future use. In addition, we are making a technical correction to § 417.536(f)(1) to clarify Medicare bad debt reimbursement policy.

1. Changes to 42 CFR 413.89(h)

Under each paragraph of our existing regulations at § 413.89(h), we describe the limits on bad debt payment to be reductions to the amount of bad debt otherwise treated as allowable costs. Under § 413.89(a), bad debts are deductions from revenue and are not to be included in allowable cost. Therefore, we are clarifying that the limits on bad debt payments are reductions to amount of allowable bad debt.

We are revising § 413.89(h)(1)(iv) to set forth the percentage reduction in reimbursable bad debt payments to hospitals for cost reporting periods beginning during fiscal years 2001 through 2012.

We are adding a new § 413.89(h)(1)(v), which will set forth the percentage reduction in reimbursable bad debt payments required by section 1861(v)(1)(T)(v) of the Act to hospitals for cost reporting periods beginning during fiscal year 2013 and subsequent fiscal years.

We are revising § 413.89(h)(2) to add paragraphs (h)(2)(i) and (h)(2)(ii). Paragraph (h)(2)(i) will set forth the percentage reduction in reimbursable bad debt payments required by section 1861(v)(1)(V)(ii) of the Act for SNFs and swing bed hospitals for cost reporting periods beginning during fiscal years 2006 through 2012 for a patient that was not a dual eligible individual. Paragraph (h)(2)(ii) will set forth the reduction in reimbursable bad debt payments for SNFs and swing bed hospitals, for cost reporting periods beginning during fiscal year 2013 and subsequent fiscal years, for a patient that was a dual eligible individual.

We are revising § 413.89(h)(3) to set forth the percentage reduction in allowable bad debt payments required by section 1861(v)(1)(W) of the Act for ESRD facilities for cost reporting periods beginning during fiscal year 2013, fiscal year 2014 and subsequent fiscal years. We are also revising § 413.89(h)(3) to set forth the applicability of the cap on bad debt reimbursement to ESRD facilities for cost reporting periods beginning between October 1, 2012 and December 31, 2012.

We are adding a new § 413.89(h)(4) to set forth the percentage reduction in reimbursable bad debt payments for all other entities required by section 1861(v)(1)(W) of the Act not described in § 413.89(h)(1), (h)(2), or (h)(3) that are eligible to receive reimbursement of bad debt for cost reporting periods beginning during fiscal year 2013, fiscal year 2014, and subsequent fiscal years.

2. Rationale for Removing 42 CFR 413.178

Previously, § 413.178(a) stated that CMS will reimburse each ESRD facility its allowable Medicare bad debts, as defined in § 413.89(b), up to the facility's costs, as determined under Medicare principles, in a single lump sum payment at the end of the facility's cost reporting period. This cap on bad debt reimbursements will be eliminated and the new reductions in bad debt reimbursements will be applied, as discussed above.

We are revising § 413.89(h)(3) to implement the ESRD facilities' bad debt reduction effective October 1, 2012 in accordance with section 1861(v)(1)(W) of the Act.

We are also removing and reserving § 413.178, since the revised provisions already are set out at § 413.89, in Chapter 3 of the PRM Part I, and in the Medicare cost report instructions in the PRM Part II. We are moving the current general bad debt exception at § 413.89(i) to new paragraph § 413.89(i)(1) in order to move the ESRD facilities' bad debt exception provision previously discussed at § 413.178(d)(2) to new paragraph § 413.89(i)(2).

3. Technical Corrections to 42 CFR 417.536(f)(1)

In this final rule, we are revising the regulations text at 417.536(f)(1) to correct the cross-reference to the Medicare bad debt reimbursement regulation, so that § 417.536(f)(1) will reference 42 CFR 413.89 instead of the outdated reference to § 413.80. In addition, we are revising the language at 42 CFR 417.536(f)(1) to conform to the description of bad debt in § 413.89(a) and we are removing § 417.536(f)(1)(i) and (ii) since these provisions already are set out at § 413.89, in Chapter 3 of the PRM Part I, and in the Medicare cost report instructions in the PRM Part II.

V. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

B. Requirements in Regulation Text

We did not propose and therefore are not finalizing any changes to regulatory text for the ESRD PPS in CY 2013.

C. Additional Information Collection Requirements

This final rule does not impose any new information collection requirements in the regulation text, as specified above. However, this final rule does make reference to several associated information collections that

are not discussed in the regulation text contained in this document. The following is a discussion of these information collections. We are soliciting public comment on each of these issues.

1. ESRD QIP

a. Display of Certificates for the PY 2015 ESRD QIP

Section III.D.15 of this final rule discusses a disclosure requirement for the PY 2014 and PY 2015 ESRD QIP. As stated earlier in this final rule, section 1881(h)(6)(C) of the Act requires the Secretary to provide certificates to dialysis care providers and facilities with their Total Performance Scores under the ESRD QIP. This section also requires each facility that receives an ESRD QIP certificate to display it prominently at the facility.

To comply with this requirement, we proposed to issue one English and one Spanish ESRD QIP certificate beginning in PY 2014 to facilities via a generally accessible electronic file format. We had previously finalized other display requirements for the program, including that each facility prominently display the applicable ESRD QIP certificate in the patient area, take the necessary measures to ensure the security of the certificate in the patient areas, and have staff available to answer questions about the certificate in an understandable manner, taking into account that some patients might have limited English proficiency.

The burden associated with the aforementioned requirements is the time and effort necessary for facilities to print the applicable ESRD QIP certificates, display the certificates prominently in patient areas, ensure the safety of the certificates, and respond to patient inquiries in reference to the certificates. We do not anticipate that posting the Spanish certificate will add more time or burden to the Collection of Information requirements outlined in the CY 2011 ESRD PPS final rule (76 FR 70298 through 70299) for the PY 2014 ESRD QIP. Therefore, this analysis only applies to the burden associated with the PY 2015 and beyond requirements.

We estimate that approximately 5,726 facilities will receive ESRD QIP certificates in PY 2015 and will be required to display them. We also estimate that it will take each facility 10 minutes per year to print, prominently display, and secure the ESRD QIP certificates, for a total estimated annual burden of 954 hours (10/60 hours *5,726 facilities). According to the Bureau of Labor Statistics, the mean hourly wage of a registered nurse is $33.23.[9] Since we anticipate nurses (or administrative staff) will post these certificates, we estimate that the aggregate cost of this requirement will be $31,701 ($33.23/hour × 954 hours). We estimate that approximately one-third of ESRD patients, or 100,000 patients, will ask a question about the ESRD QIP certificate. We further estimate that it will take each facility approximately 5 minutes to answer each patient's question about the applicable ESRD QIP certificate, or 1.52 hours per facility each year. The total estimated annual burden associated with this requirement is 8,704 hours (1.52 hours/facility × 5,726 facilities). The total estimated annual burden for both displaying the ESRD QIP certificates and answering patients' questions about the certificates is 9,658 hours (8,704 hours + 954 hours). While the total estimated annual burden associated with both of these requirements as discussed is 9,658 hours, we do not believe that there will be a significant cost associated with these requirements because we are not requiring facilities to complete new forms. We estimate that the total cost for all ESRD facilities to comply with the collection of information requirements associated with the certificates each year would be less than $320,935 ($33.23/hour × 9,658 hours).

b. NHSN Dialysis Event Reporting Requirement for the PY 2015 ESRD QIP

As stated above in section III.D.2.a of this finalrule, we finalized a measure requiring facilities to reporting dialysis events to the NHSN for he PY 2015 ESRD QIP. Specifically, we will require facilities to submit 12 months of dialysis event data to the NHSN to receive 10 points on the measure. The burden associated with this requirement for existing facilities is the time and effort necessary for facilities to submit 12 months of data in order to receive the maximum number of points. According to our most recent data, 5,525 facilities treat adult in-center hemodialysis and/or pediatric in-center hemodialysis patients and are, then, eligible to receive a score on this measure; therefore, we estimate that approximately 5,525 facilities will submit the required data. Based on data previously collected, we further estimate that the average number of dialysis events is 0.008 per patient per month and that each facility has approximately 75 patients. Accordingly, we estimate the number of dialysis events in a 12-month period for all facilities to be 397,800 (0.09 events/patient/month × 75 patiens/facility × 5,525 facilities × 12 mohths) for the PY 201 ESRD QIP performance period. We estimae it will require 10 minutes to collect and submit data on these events, and the estimated burden for submiting 12 mohths of data will be 66,300 hours (397,800 dialysis events × 10/60 minute). If the dialysis events were distributed evenly across all 5,525 facilities, the reporting would result in an additional 12 hour (66, 300 hours/5,525 facilities), burden for each facility at a cost of $399 ($33.23/hour × 12 hours) per facility. Again, we estimate the mean hourly wage of a registered nurse is $33.23, and we anticipate nurses (for administrative staff) will be responsible for this reporting. In total, we believe that the cost for all ESRD facilities to comply with the reporting requirements associated with NHSN Dialysis Event reporting measure will be approximately $2.2 million ($399 × 5,525 facilities= $2,204,475) per year.

c. ICH CAHPS Survey Attestation Requirement for the PY 2015 ESRD QIP

As stated above in section III.D.1.c of this final rule, we finalized a measure that assesses facility usage of the ICH CAHPS survey as a reporting measure for the PY 2015 ESRD QIP. The burden associated with this requirement is the time and effort necessary for facilities to administer the ICH CAHPS survey through a third party and submit an attestation to CMS that they successfully administered the survey.

We estimate that approximately 5,523 facilities treat adult, in-center hemodialysis patients and are, therefore, eligible to receive a score on this measure. We estimate that all 5,523 facilities will administer the ICH CAHPS survey through a third-party and submit an attestation to that effect. We estimate that it will take each facility's third-party administrator 16 hours per year to be trained on the survey features. We further estimate that it will take each facility approximately 5 minutes to submit the attestation each year. The estimated total annual burden on facilities is 88,829 hours ((16 hours × 5,523 facilities) + ((5/60 minutes) × 5,523 facilities) which is equal to $2,952,818 (88,829 hours × $33.23), or $534 per facility ($2,952, 818/5,523). Again, we estimate the mean hourly wage of a registered nurse is $33.23, and we anticipate nurses (or administrative staff) will be responsible for this reporting. We estimate that it would take each patient 30 minutes to complete the survey (to account for variability in education levels) and that approximately 75 surveys per year

[9] This hourly wage is absent any fringe benefits.

would be taken per facility.[10] Interviewers from each facility would spend a total of approximately 37.5 hours per year with patients completing these surveys (30/60 minutes * 75 minutes) or $1,247 (37.5 hours × $33.23) for an estimated annual burden of 207,113 hours (37.5 hours * 5,523 facilities) which is equal to $6.9 million (207,113 hours × 33.23/hour). We estimate that time burden for ESRD facilities to comply with the collection of information requirements associated with administering the ICH CAHPS survey each year would be approximately $1,781 ($534 + $1,247) for each facility, or $9.9 million ($1,781 × 5,523 facilities =$9,836,463) across all ESRD facilities.

d. Data Validation Requirements

Section III.D.13 of this final rule outlines the data validation processes we are finalizing. We will randomly sample records from 750 facilities; each sampled facility would be required to produce approximately 10 records. The burden associated with this validation requirement is the time and effort necessary to submit validation data to a CMS contractor. Because we anticipate that the sampled facilities will be reimbursed by our validation contractor for the costs associated with copying and mailing the requested records, we only estimate the burden of retrieving and submitting the necessary records. We estimate that it will take each facility approximately 2.5 hours to comply with these requirements. If 750 facilities are tasked with providing the required documentation, the estimated annual burden across all facilities will be 1,875 hours (750 facilities × 2.5 hours) at a total of $62,307 (1,875 hours × $33.23/hour) or $83.08 ($62,307/750) per facility in the sample. Again, we estimate the mean hourly wage of a registered nurse is $33.23, and we anticipate nurses (or administrative staff) will be responsible for providing this information.

The comments we received on this analysis are set forth below.

Comment: One commenter believes that the underlying premise for the CAHPS burden analysis is incorrect. This commenter stated that if the average facility serves 75 patients, it would survey at most 75 patients per year.

Response: We believe that this assumption is a good approximation for this analysis. We realize that facilities may have more than 75 patients or less than 75 patients. Across the ESRD population, however, we believe 75 patients per facility is accurate. According to the ICH CAHPS specifications, if a facility has less than 200 patients, it must draw a census of patients from this facility. Therefore, if the average facility has 75 patients, we believe it would survey at most 75 patients.

Comment: One commenter expressed concern that responding to questions from patients about the Performance Score Certificates (PSCs) could consume too many staff hours.

Response: We recognize that patients may have questions about the PSCs. The ESRD QIP is designed not only to incentivize care, but also to stimulate discussion about the quality of dialysis care. Therefore, we believe that these questions and answers are important in promoting the goals of the program and improvement in care in that they promote patient awareness and understanding of the care they are receiving. Additionally, we believe that these questions will be answered during the course of usual patient care. We will continue to monitor the burden these questions may place upon facilities.

To obtain copies of the supporting statement and any related forms for the paperwork collections referenced above, access CMS' Web site at *http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage.*

If you comment on these information collection and recordkeeping requirements, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–1352–F]; Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov.*

2. Reductions to Bad Debt Payments for All Medicare Providers

The statutorily mandated reductions of bad debt payments to providers, suppliers, and other entities that are currently receiving bad debt payments will not result in any changes to or any additional collection of information requirements. The removal of the cap on bad debt reimbursement to ESRD facilities will result in fewer collection of information requirements for ESRD facilities.

VI. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We examined the impacts of this final rule as required by Executive Order 12866 (September 30, 1993, Regulatory Planning and Review) and Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated economically significant under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget. We have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the final rule.

2. Statement of Need

This rule finalizes a number of routine updates for renal dialysis items and services in CY 2013, implements the third year of the ESRD PPS transition, and makes several policy changes and clarifications to the ESRD PPS. These include updates and changes to the ESRD PPS and composite rate base rates, wage index values, wage index budget-neutrality adjustment factors, outlier payment policy, and transition budget-neutrality adjustment. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2013.

This final rule also implements the QIP for PY 2015 and beyond by establishing measures, a scoring system, and payment reductions to incentivize improvements in dialysis care as directed by section 1881(h) of the Act. Failure to establish QIP program parameters in this rule would prevent continuation of the QIP beyond PY 2014.

This final rule also implements the reduction percentages of bad debt reimbursement required by section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012. This final rule also removes the cap on bad debt reimbursement to an ESRD facility up to the facility's unrecovered costs. Section 3201(c) of The Middle Class Tax

[10] Last year, we stated that we believed that 200 surveys would be administered per facility per year (76 FR 70299). Upon further review, however, we note that the ICH CAHPS specifications require a sample of 200 surveys only for those facilities with a large patient population. Faculties with fewer than 200 patients are required to survey all patients, aiming for a 40 percent response rate. (*http://www.cahps.ahrq.gov/~/media/Files/SurveyDocuments/ICH/Admin_Survey/53_fielding_the_ich_survey.pdf*). Since we estimate that each facility serves approximately 75 patients, we believe that the average facility, at most, would survey 75 patients per year.

Extension and Job Creation Act of 2012 adds a new subparagraph—1861(v)(1)(W) to the Act and applies a reduction in bad debt payments to ''providers'' not addressed under subparagraphs 1861(v)(1)(T) or 1861(v)(1)(V) of the Act. For the purpose of subparagraph 1861(v)(1)(W) of the Act, section 3201(c) of The Middle Class Tax Extension and Job Creation Act of 2012 defined ''providers'' as a supplier or any other type of entity that receives payment for bad debts under the authority of section 1861(v)(1)(A) of the Act. These providers include, but are not limited to, CAHs, RHCs, FQHCs, CMHCs, HMOs reimbursed on a cost basis, CMPs, HCPPs and ESRD facilities.

3. Overall Impact

We estimate that the final revisions to the ESRD PPS will result in an increase of approximately $250 million in payments, from Medicare, to ESRD facilities in CY 2013, which includes the amount associated with the increase in the ESRDB market basket reduced by the productivity adjustment, updates to outlier amounts, and the effect of changing the blended payments from 50 percent under the composite rate payment and 50 percent under the ESRD PPS to 25 percent under the composite rate payment and 75 percent under the ESRD PPS.

We estimate that the requirements related to the ESRD QIP for PY 2015 will cost approximately $12.4 million and the predicted payment reductions will equal about $12.1 million to result in a total impact from the proposed ESRD QIP requirements of $24.6 million.

In section IV of this final rule, we discuss the provisions required by section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012, which apply percentage reductions in bad debt reimbursement to all providers eligible to receive bad debt reimbursement; these provisions are specifically prescribed by statute and thus, are self-implementing. Table 9 in section IV.C.1 of the CY 2013 proposed rule (77 FR 40988) depicts a comparison of the bad debt payment percentages prior to and after FY 2013. We estimate these self implementing provisions of section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 will result in savings to the Medicare program of $10.92 billion over the period from 2012 through 2022.

Fiscal year	Medicare program savings from reductions in bad debt
2013	240 million.
2014	600 million.
2015	900 million.
2016	1.06 billion.
2017	1.14 billion.
2018	1.21 billion.
2019	1.30 billion.
2020	1.39 billion.
2021	1.49 billion.
2022	1.59 billion.
Aggregate FY Total Savings.	10.92 billion.

Additionally, in section IV of this final rule, we discuss the removal of the cap on bad debt reimbursement to ESRD facilities. We estimate the removal of this cap will result in a cost to the Medicare program in the amount of $170 million from 2013 through 2022.

Fiscal year	Medicare program cost resulting from cap removal
2013	10 million.
2014	20 million.
2015	10 million.
2016	10 million.
2017	20 million.
2018	20 million.
2019	20 million.
2020	20 million.
2021	20 million.
2022	20 million.
Aggregate FY Total Cost.	170 million.

B. Detailed Economic Analysis

1. CY 2013 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments (that is, payments made under the 100 percent ESRD PPS and those under the ESRD PPS blended payment during the transition) in CY 2012 to estimated payments in CY 2013. To estimate the impact among various classes of ESRD facilities, it is imperative that the estimates of payments in CY 2012 and CY 2013 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used the June 2012 update of CY 2011 National Claims History file as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2011 claims to 2012 and 2013 using various updates. The updates to the ESRD PPS base rate and the base composite rate portion of the blended rate during the transition are described in section II.C of this final rule. In addition, in order to prepare an impact analysis, since some ESRD facilities opted to be paid the blended payment amount during the transition, we made various assumptions about price growth for the formerly separately billable drugs and laboratory tests with regard to the composite portion of the ESRD PPS blended payment during the transition. These rates of price growth are briefly outlined below, and are described in more detail in the CY 2011 ESRD PPS final rule (75 FR 49078 through 49080).

We used the CY 2011 amounts for the CYs 2012 and 2013 amounts for Supplies and Other Services, since this category primarily includes the $0.50 administration fee for separately billable Part B drugs and this fee continues to be an appropriate amount. Because some ESRD facilities will receive blended payments during the transition and receive payment for ESRD drugs and biologicals based on their average sales price plus 6 percent (ASP+6), we estimated price growth for these drugs and biologicals based on ASP+6 percent. We updated the last available quarter of actual ASP data for the top twelve drugs (the fourth quarter of 2012) thru 2013 by using the quarterly growth in the Producer Price Index (PPI) for Drugs, consistent with the method for addressing price growth in the ESRDB market basket. This resulted in increases of 3.0 percent, 0.2 percent, 1.4 percent and 1.0 percent, respectively, for the first quarter of 2013 thru the fourth quarter of 2013. Since the top twelve drugs account for over 99 percent of total former separately billable Part B drug payments, we used a weighted average growth of the top twelve drugs for the remainder. Table 8 below shows the updates used for the drugs.

We updated payments for laboratory tests paid under the laboratory fee schedule to 2012 and 2013 using the statutorily required update of the CPI–U increase with any legislative adjustments. For this final rule, the growth from 2011 to 2012 is 0.7 percent and the growth from 2011 to 2013 is −1.1 percent.

TABLE 9—PRICE INCREASES FROM 2011 TO 2012 AND 2011 TO 2013 OF FORMER SEPARATELY BILLABLE PART B DRUGS

Separately billable drugs	Total growth 2011 to 2012 (percent)	Total growth 2011 to 2013 (percent)
EPO	−0.3	5.0
Paricalcitol	−31.6	−36.5
Sodium_ferric_glut	−24.8	−33.3
Iron_sucrose	−14.7	−14.2
Levocarnitine	12.2	−2.3
Doxercalciferol	−68.3	−68.5
Calcitriol	64.6	15.7
Vancomycin	−12.4	−15.4
Alteplase	15.5	24.4
Aranesp	6.5	12.3
Daptomycin	11.5	19.0
Ferumoxytol	−7.8	−4.3
Weight for others	−8.1	−4.6

Table 10 below shows the impact of the estimated CY 2013 ESRD payments compared to estimated payments to ESRD facilities in CY 2012.

TABLE 10—IMPACT OF CHANGES IN PAYMENTS TO ESRD FACILITIES FOR THE CY 2013 ESRD FINAL RULE

[Percent change in total payments to ESRD facilities (both program and beneficiaries)]

Facility type	A Number of facilities	B Number of treatments (in millions)	C Effect of 2013 changes in outlier policy [3] (percent)	D Effect of 2013 changes in wage indexes (percent)	E Effect of total 2013 changes [4] (percent)
All Facilities	5,726	41.4	0.4	0.0	3.0
Type					
Freestanding	5,176	38.0	0.5	0.0	2.9
Hospital based	550	3.4	0.3	0.1	3.6
Ownership Type					
Large dialysis organization	3,719	27.3	0.5	0.0	2.9
Regional chain	926	7.1	0.3	0.1	3.0
Independent	636	4.4	0.2	0.0	3.0
Hospital based [1]	434	2.6	0.3	0.2	3.6
Unknown	11	0.0	0.3	1.5	4.4
Geographic Location					
Rural	1,267	6.8	0.5	−0.2	2.9
Urban	4,459	34.6	0.4	0.0	3.0
Census Region					
East North Central	941	6.3	0.5	0.1	3.1
East South Central	472	3.1	0.6	−0.5	2.5
Middle Atlantic	641	5.1	0.4	0.0	3.1
Mountain	335	1.9	0.3	−0.3	2.6
New England	171	1.4	0.5	0.5	3.5
Pacific	667	5.6	0.2	0.6	3.4
Puerto Rico and Virgin Islands	41	0.3	0.2	−2.4	0.6
South Atlantic	1,259	9.5	0.6	−0.2	2.8
West North Central	416	2.2	0.4	0.1	3.2
West South Central	783	6.0	0.5	−0.2	2.8
Facility Size					
Less than 4,000 treatments [2]	1,105	2.5	0.4	0.0	3.0
4,000 to 9,999 treatments	2,225	11.6	0.5	0.0	3.0
10,000 or more treatments	2,370	27.2	0.4	0.0	3.0
Unknown	26	0.0	0.2	0.1	3.2
Percentage of Pediatric Patients					
Less than 2%	5,616	41.0	0.5	0.0	3.0
Between 2% and 19%	44	0.4	0.3	−0.1	3.0
Between 20% and 49%	8	0.0	0.1	−0.1	4.1
More than 50%	58	0.1	−0.2	0.0	2.2

[1] Includes hospital based facilities not reported to have large dialysis organization or regional chain ownership.

[2] Of the 1,105 Facilities with less than 4,000 treatments, only 332 qualify for the low-volume adjustment. The low-volume adjustment is mandated by Congress, and is not applied to pediatric patients. The impact to these Low volume Facilities is a 3.3% increase in payments.

[3] Includes the effects of the final payment policy on thrombolytics for those facilities that are paid under the blend.

[4] Includes the effect of Market Basket minus productivity increase of 2.3% to the ESRD PPS base and the Composite Rate.
Includes the effect of the change in the drug add-on percentage from 14.3% to 14.0% for those facilities that opted to be paid under the transition.
Includes the effect of the blend changing from 50/50 to 25/75 for those facilities that choose to be paid under the transition.
Includes the effect of the Transition Budget-Neutrality Factor of 0.1 percent for all facilities.
Note: Totals do not necessarily equal the sum of rounded parts.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the final changes to the outlier payment policy described in section II.C.7 of this final rule is shown in column C. For CY 2013, the impact on all facilities as a result of the changes to the outlier payment policy would be a 0.4 percent increase in estimated payments. The estimated impact of the changes to outlier payment policy ranges from a 0.2 percent decrease to a 0.6 percent increase. Most ESRD facilities are anticipated to experience a positive effect in their estimated CY 2013 payments as a result of the final outlier policy changes.

Column D shows the effect of the wage index on ESRD facilities and reflects the CY 2013 wage index values for the composite rate portion of the blended payment during the transition and the ESRD PPS payments. Facilities located in the census region of Puerto Rico and the Virgin Islands would receive a 2.4 percent decrease in estimated payments in CY 2013. Since most of the facilities in this category are located in Puerto Rico, the decrease is primarily due to the reduction in the wage index floor, (which only affects facilities in Puerto Rico in CY 2013). The other categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.5 percent decrease to a 1.5 percent increase due to the update of the wage index.

Column E reflects the overall impact (that is, the effect of the final outlier policy changes, the effect of the final wage index, the effect of the ESRDB market basket increase minus productivity adjustment, the effect of the change in the blended payment percentage from 50 percent of payments based on the composite rate system and 50 percent based on the ESRD PPS in 2012, to 25/75, respectively, for 2013, for those facilities that opted to be paid under the transition, and the effect of the 0.1 percent transition budget-neutrality adjustment increase). We expect that overall, ESRD facilities will experience a 3.0 percent increase in estimated payments in 2013. ESRD facilities in Puerto Rico and the Virgin Islands are expected to receive a 0.6 percent increase in their estimated payments in CY 2013. This smaller increase is primarily due to the negative impact of the wage index. The other categories of types of facilities in the impact table show positive impacts ranging from an increase of 2.2 percent to 4.4 percent in their 2013 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, ESRD facilities are paid directly for the renal dialysis bundle and other provider types such as laboratories, DME suppliers, and pharmacies, may no longer bill Medicare directly for renal dialysis services. Rather, effective January 1, 2011, such other providers can only furnish renal dialysis services under arrangements with ESRD facilities and must seek payment from ESRD facilities rather than Medicare. Under the ESRD PPS, Medicare pays ESRD facilities one payment for renal dialysis services, which may have been separately paid to suppliers by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2013, the third year of the ESRD PPS, we estimate that the final ESRD PPS will have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in 2013 will be approximately $8.4 billion. This estimate is based on various price update factors discussed in section VI.B in this final rule and takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 4.0 percent in CY 2013.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount or blended payment amount for patients treated in facilities going through the ESRD PPS transition. As a result of the projected 3.0 percent overall increase in the ESRD PPS payment amounts in CY 2013, we estimate that there will be an increase in beneficiary co-insurance payments of 3.0 percent in CY 2013, which translates to approximately $60 million.

e. Alternatives Considered

We considered eliminating the AY modifier use by ESRD facilities in CY 2013, which could address program integrity concerns but could also require Medicare beneficiaries to incur additional injections, medical visits and co-insurance liabilities and accordingly, we did not pursue this alternative. Rather, we decided to monitor the use of the AY modifier and consider the elimination of the AY modifier in future rulemaking if we determine that it is being used inappropriately.

2. ESRD QIP

a. Effects of the PY 2015 ESRD QIP

The ESRD QIP provisions are intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries as a result of payment changes under the ESRD PPS by implementing an ESRD QIP that reduces ESRD payments by up to 2 percent for dialysis facilities that fail to meet or exceed a Total Performance Score with respect to performance standards established by the Secretary with respect to certain specified measures. The methodology that we are finalizing to determine a facility's Total Performance Score is described in section III.D.9 and III.D.10 of this final rule. Any reductions in ESRD payments would begin on January 1, 2015 for services furnished on or after January 1, 2015.

As a result, based on the ESRD QIP outlined in this final rule, we estimate that, of the total number of dialysis facilities (including those not receiving an ESRD QIP Total Performance Score), approximately 20 percent or 1,093 of the facilities would likely receive a payment reduction for PY 2015. Facilities that do not receive a TPS are not eligible for a payment reduction.

The ESRD QIP impact assessment assumes an initial count of 5,726 dialysis facilities paid through the ESRD PPS. Table 11 shows the overall estimated distribution of payment reductions resulting from the PY 2015 ESRD QIP.

TABLE 11—ESTIMATED DISTRIBUTION OF PY 2015 ESRD QIP PAYMENT REDUCTIONS

Payment reduction (percent)	Number of facilities	Percent of facilities
0.0	4308	79.8
0.5	599	11.1
1.0	309	5.7
1.5	97	1.8
2.0	88	1.6

TABLE 11—ESTIMATED DISTRIBUTION OF PY 2015 ESRD QIP PAYMENT REDUCTIONS—Continued

*Note: this table excludes 325 facilities that did not receive a score because they did not have enough data to receive a Total Performance Score.

To estimate whether or not a facility would receive a payment reduction under the proposed approach, we scored each facility on achievement and improvement for each of the proposed clinical measures using the most recent data available for each measure shown in Table 12.

TABLE 12—DATA USED TO ESTIMATE PY 2015 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, performance standards, benchmarks, and improvement thresholds	Performance period
Hemoglobin Greater Than 12 g/dL	Jan 2010–Dec 2010	Jan 2011–Dec 2011.
Vascular Access Type		
% Fistula	Oct 2010–Apr 2011	May 2011–Dec 2011.
% Catheter	Oct 2010–Apr 2011	May 2011–Dec 2011.
Kt/V		
Adult HD	Jul 2010–Mar 2011	Apr 2011–Dec 2011.
Adult PD	Jul 2010–Mar 2011	Apr 2011–Dec 2011.
Pediatric HD	Jul 2010–Mar 2011	Apr 2011–Dec 2011.

We used claims data for these calculations. Clinical measures with less than 11 cases for a facility were not included in that facility's Total Performance Score. Clinical measures with 11–25 cases for a facility received an adjustment as outlined in section III.C.11.a of this final rule. Each facility's Total Performance Score was compared to the estimated minimum Total Performance Score and the payment reduction table found in section III.D.12 of this final rule. Facilities were required to have a score on at least one clinical measure to receive a Total Performance Score. For these simulations, reporting measures were not included due to lack of data availability. Therefore, the simulated facility Total Performance Scores were calculated using only the clinical measure scores.

To estimate the total payment reductions in PY 2015 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2011 and December 2011 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: (Total ESRD payment in January 2011 and December 2011 times the estimated payment reduction percentage). For PY 2015 the total payment reduction for all of the 1,093 facilities expected to receive a reduction is approximately $12 million ($12,087,940). Further, we estimate that the total costs associated with the collection of information requirements for PY 2015 described in section V.C. of this final rule would be approximately $12.4 million for all ESRD facilities. As a result, we estimate that ESRD facilities will experience an aggregate impact of $24.5 million ($12,087,940 + 12,424,180 = $24,512,120) as a result of the PY 2015 ESRD QIP.

Table 13 below shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2015. The table details the distribution of ESRD facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities). Given that the time periods used for these calculations will differ from those we will use for the PY 2015 ESRD QIP, the actual impact of the PY 2015 ESRD QIP may vary significantly from the values provided here.

TABLE 13—IMPACT OF ESRD QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR CY 2015

	Number of facilities	Number of Medicare treatments 2009 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	5,726	41.4	5,401	1,093	−0.17
Facility Type:					
Freestanding	5,176	38.0	4,989	931	−0.15
Hospital-based	550	3.4	412	162	−0.41
Ownership Type:					
Large Dialysis	3,719	27.3	3,612	662	−0.14
Regional Chain	926	7.1	882	151	−0.14

TABLE 13—IMPACT OF ESRD QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR CY 2015—Continued

	Number of facilities	Number of Medicare treatments 2009 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
Independent	636	4.4	584	150	−0.22
Hospital-based (non-chain)	434	2.6	318	128	−0.43
Unknown	11	0.0	5	2	−0.30
Facility Size:					
Large Entities	4,645	34.4	4,494	813	−0.14
Small Entities [1]	1,070	7.0	902	278	−0.30
Unknown	11	0.0	5	2	−0.30
Urban/Rural Status:					
1) Rural	1,267	6.8	1,188	263	−0.18
2) Urban	4,459	34.6	4,213	830	−0.16
Census Region:					
Northeast	810	6.5	752	166	−0.20
Midwest	1,352	8.5	1,238	310	−0.21
South	2,510	18.7	2,420	445	−0.15
West	1,001	7.5	952	154	−0.13
U.S. Territories [2]	53	0.3	39	18	−0.37
Census Division:					
East North Central	941	6.3	856	227	−0.23
East South Central	472	3.1	451	77	−0.15
Middle Atlantic	641	5.1	593	143	−0.22
Mountain	335	1.9	321	64	−0.15
New England	171	1.4	159	23	−0.13
Pacific	667	5.6	631	90	−0.11
South Atlantic	1,259	9.5	1,217	236	−0.16
West North Central	416	2.2	382	83	−0.17
West South Central	783	6.0	752	132	−0.13
U.S. Territories [2]	41	0.3	39	18	−0.37
Facility Size (# of total treatments):					
Less than 4,000 treatments	1,105	2.5	864	214	−0.27
4,000–9,999 treatments	2,225	11.6	2,190	420	−0.15
Over 10,000 treatments	2,370	27.2	2,345	459	−0.14
Unknown	26	0.0	2	0	−0.00

[1] Small Entities include hospital-based and satellite facilities and non-chain facilities based on DFC self-reported status.
[2] Includes Puerto Rico and Virgin Islands.

The comments we received on this analysis are set forth below.

Comment: Several commenters requested that we provide, for both PY 2014 and PY 2015, the data, assumptions, and methodology used to calculate the rate of improvement, performance standards, achievement thresholds, and benchmarks for all measures to allow stakeholders to have the opportunity to assess the impact on facilities so that the community may provide meaningful comment. Commenters also argued that we have underestimated the PY 2014 average payment reduction (i.e., by 36 percent), and requested that we provide the model, data, and assumption we used for these estimates.

Response: As we noted above, the PY 2014 final rule was finalized on November 1, 2011 (76 FR 70228). We direct commenters to this rule for our analysis of the PY 2014 ESRD QIP. The methodology and assumptions that we used to calculate the estimated rate of improvement, performance standards, achievement thresholds, and standards are set forth in this section.

b. Alternatives Considered for the PY 2015 ESRD QIP In developing the PY 2015 ESRD QIP, we selected measures that we believe are important indicators of patient outcomes and quality of care as discussed in sections III.C, and III.D of this final rule. Poor management of anemia and inadequate dialysis, for example, can lead to otherwise-avoidable hospitalizations, decreased quality of life, and death. Infections are also a leading cause of hospitalization and death among hemodialysis patients, but there are proven infection control methods that have been shown effective in reducing morbidity and mortality. We also considered proposing to adopt the Standardized Hospitalization Ratio Admissions (SHR) measure and the Standardized Mortality Ratio (SMR) measures as part of the PY 2015 ESRD QIP. While we decided not to propose to adopt the SHR and SMR measures for the PY 2015 ESRD QIP, we will publicly report these measure rates/ratios via DFC to encourage facilities to improve their care. We believe the measures selected for the ESRD QIP will allow us to continue focusing on improving the quality of care that Medicare beneficiaries receive from ESRD dialysis facilities.

In developing the scoring methodology for the PY 2015 ESRD QIP, we considered a number of alternatives including various improvement ranges, achievement thresholds, and benchmarks. We also considered whether some of the new measures should be scored based only on achievement. We also discussed scoring some of the clinical measures using a binary methodology (that is, facilities receive either zero or 10 points for missing or achieving a standard, respectively). We ultimately decided to mirror the PY 2014 ESRD QIP scoring methodology as closely as possible. We aim to design a scoring methodology that is straightforward and transparent to facilities, patients, and other stakeholders, and we believe that one of

the ways to obtain this transparency is to be as consistent as possible from year-to-year of the program. We believe that this consistency will allow us to better assess the impacts of the ESRD QIP upon facilities and beneficiaries. Finally, we believe that all scoring methodologies for Medicare VBP programs should be aligned as appropriate given their specific statutory requirements, and the scoring methodology for the ESRD QIP is similar to the Hospital Inpatient VBP Program.

When deciding upon how to best score the Vascular Access Type and Kt/V Dialysis Adequacy measure topics, we considered combining all of the measures within the measure topic into one composite measure (that is, having one, combined numerator and one, combined denominator for all of the measures within the topic) rather than individually scoring each measure and weighting it appropriately in the measure topic. We believe that it is important to mirror the NQF specifications for each measure as much as possible; we also heeded the suggestion of the Measures Application Partnership to further test composite measures before implementing them. Therefore, we decided to score measure topics where each measure within the measure topic is scored individually and then weighted appropriately.

We considered requiring facilities to report data for 100 percent of their patients for the Mineral Metabolism and Anemia Management reporting measures in order to ensure complete, accurate data collection. We ultimately decided that, because there are some situations where a facility cannot control whether a patient's blood is drawn (for example, hospitalization), we should adopt a reporting threshold of less than 100 percent.

We also considered multiple baseline periods for purposes of scoring facilities on achievement and improvement. We considered periods of the same time and duration, periods occurring at different times, and periods with various durations. We ultimately decided that a baseline period of 12-months for both the achievement and improvement scores is best because it is consistent with the PY 2014 program. Additionally, a 12-month baseline period prevents issues related to seasonality. We finalized achievement and improvement baseline periods occurring over different periods of time because we believe that this approach mitigates data lag as much as possible and also allows us to score all of the measures on both achievement and improvement. Finally, we finalized an achievement baseline period spanning a calendar year (CY 2011) because this approach allows us to publish the numerical values for the performance standards before the beginning of the performance period.

In deciding upon the minimum number of cases required for a facility to be scored on a measure, we reviewed and discussed many options. We considered keeping the program the same as PY 2014 by excluding measures with less than 11 cases and applying no adjustment. We also discussed including an adjustment for measures with 11–25 cases. Finally, we discussed an adjustment applicable to measures with 26–50 cases. We believe that we should set the case minimum at 11 and adopt an adjustment for measures with 11–25 cases.

Finally, in deciding upon the calculation of the minimum Total Performance Score, we considered scoring the reporting measures at zero, consistent with PY 2014. We decided, however, to finalize a minimum Total Performance Score that includes half of the maximum score a facility could receive on these measures. We believe that this methodology appropriately places emphasis on complete reporting from all facilities.

We did not receive any comments related to this analysis of the alternatives that we considered for the PY 2015 ESRD QIP.

3. Reductions to Bad Debt Payments for All Medicare Providers

Section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 that requires reductions in bad debt reimbursement to all providers, supplies and other entities eligible to receive bad debt reimbursement will have a significant impact on the operations of all affected entities. However, these provisions are specifically prescribed by statute and thus, are self-implementing. It is estimated that these provisions will result in savings in CY 2013 of $330 million. Removal of the cap on bad debt reimbursement to ESRD facilities up to a facility's unrecovered cost will have an impact on ESRD facilities by increasing their bad debt reimbursement amounts. It is estimated that the removal of this cap will result in $10 million in increased payments to ESRD facilities for CY 2013. Therefore, it is estimated that the combined overall savings in the CY 2013 would be $320 million.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 14 below, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this final rule.

TABLE 14—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS

ESRD PPS for CY 2013	
Category	Transfers
Annualized Monetized Transfers	$250 million.
From Whom to Whom	Federal government to ESRD providers.
Increased Beneficiary Co-insurance Payments	$60 million.
From Whom to Whom	Beneficiaries to ESRD providers.
ESRD QIP for PY 2015	
Annualized Monetized Transfers	−$12.1 million.*
From Whom to Whom	Federal government to ESRD providers.
Category	Costs
Annualized Monetized ESRD Provider Costs	12.4 million.**

TABLE 14—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS—Continued

Savings from Congressionally Mandated Reductions of Bad Debt Payments in CY 2013

Category	Transfers
Annualized Monetized Bad Debt Payments	$ − 320 million.
From Whom to Whom	Federal government to Medicare providers.

* It is the reduced payment to the ESRD facilities, which fall below the quality standards as stated in section III.D.12 of this proposed rule.
** It is the cost associated with the collection of information requirements for all ESRD facilities.

VII. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354) (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 19 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than $34.5 million in any 1 year. Individuals and States are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's Web site at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf* (Kidney Dialysis Centers are listed as 621492 with a size standard of $34.5 million).

The claims data used to estimate payments to ESRD facilities in this RFA analysis and RIA do not identify which dialysis facilities are part of a large dialysis organization (LDO), regional chain, or other type of ownership because each individual dialysis facility has its own provider number and bills Medicare using this number. Therefore, in previous RFA analyses and RIAs presented in proposed and final rules that updated the basic case-mix adjusted composite payment system, we considered each ESRD facility to be a small entity for purposes of the RFA analysis. However, we conducted a special analysis for this final rule that enabled us to identify the ESRD facilities that are part of an LDO or regional chain and therefore, were able to identify individual ESRD facilities that will be considered small entities.

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 19 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 9. Using the definitions in this ownership category, we consider the 636 facilities that are independent and the 434 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by LDOs and regional chains would have total revenues of more than $34.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates in this rule, a hospital-based ESRD facility (as defined by ownership type) is estimated to receive a 3.6 percent increase in payments for CY 2013. An independent facility (as defined by ownership type) is estimated to receive a 3.0 percent increase in payments for 2013.

Based on the ESRD QIP payment reduction impacts to ESRD facilities for PY 2015, we estimate that of the 1,093 ESRD facilities expected to receive a payment reduction, 278 ESRD small entity facilities will experience a payment reduction (ranging from 0.5 percent up to 2.0 of total payments). We anticipate the payment reductions to average approximately $11,059 per facility among the 1,093 facilities receiving a payment reduction, with an average of $12,866 per small entity facilities receiving a payment reduction. The projected impacts for these small entities are estimates based on current data. The actual impacts may differ. Using our projections of facility performance, we then estimated the impact of anticipated payment reductions on ESRD small entities, by comparing the total payment reductions for the 278 small entities expected to receive a payment reduction, with the aggregate ESRD payments to all small entities. We estimate that there are a total of 1,070 small entity facilities. For this entire group of 1,070 ESRD small entity facilities, a decrease of 0.30% percent in aggregate ESRD payments is observed.

The comment we received on this analysis is set forth below.

Comment: One commenter expressed concern that we have not provided additional funding for the ESRD QIP COI requirements to alleviate the aggregate associated cost; commenter is specifically concerned of the impact on small facilities.

Response: We recognize that a facility may have additional costs resulting from the ESRD QIP. We believe that these costs, however, are necessary in improving care and do not outweigh the utility of the program. We will continue to monitor these costs, paying specific attention to their effect upon small facilities.

Therefore, the Secretary has determined that this final rule will not have a significant economic 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. Any such regulatory impact 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. We do not believe this final rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 180 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 180 rural hospital-based dialysis facilities will experience an estimated 3.5 percent increase in payments. As a result, this final rule is estimated to not have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

Section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 that requires reductions in bad debt reimbursement to all providers, supplies and other entities eligible to receive bad debt reimbursement will have a significant impact on the operations of a substantial number of small entities and small rural hospitals. However, these provisions are specifically prescribed by the Congress and thus, are self-implementing. Additionally, we do not believe that the removal of the cap on bad debt reimbursements to ESRD facilities up to their unrecovered costs will have a significant impact on the operations of a substantial number of small entities and small rural hospitals. Thus, we are not providing a Regulatory Flexibility Act Analysis to codify the statutorily mandated reductions in bad debt payments, nor for the removal of the cap on bad debt reimbursement as it pertains to ESRD facilities.

VIII. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year $100 million in 1995 dollars, updated annually for inflation. In 2012, that threshold is approximately $139 million. This final rule does not include any mandates that will impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of $139 million.

IX. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of States, local or Tribal governments.

X. Files Available to the Public via the Internet

This section lists the Addenda referred to in the preamble of this final rule. Beginning in CY 2012, the Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the Internet. We will continue to post the Addenda through the Internet.

Readers who experience any problems accessing the Addenda that are posted on the CMS Web site at *http://www.cms.gov/ESRDPayment/PAY/list.asp*, should contact Michelle Cruse at (410) 786–7540.

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END–STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 1. The authority citation for part 413 is revised to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332) and sec. 3201 of Pub. L. 112–96 (126 Stat. 156).

Subpart F—Specific Categories of Costs

■ 2. Section 413.89 is amended by revising paragraphs (h)(1) introductory text, (h)(1)(iv), (h)(2), (h)(3), and (i), and by adding paragraphs (h)(1)(v) and (h)(4) to read as follows:

§ 413.89 Bad debts, charity, and courtesy allowances.

* * * * *

(h) * * *

(1) *Hospitals.* In determining reasonable costs for hospitals, the amount of allowable bad debt (as defined in paragraph (e) of this section) is reduced:

* * * * *

(iv) For cost reporting periods beginning during fiscal years 2001 through 2012, by 30 percent.

(v) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent.

(2) *Skilled nursing facilities and swing bed hospitals.* For the purposes of this paragraph (h)(2), a dual eligible individual is defined as an individual that is entitled to benefits under Part A of Medicare and is determined eligible by the State for medical assistance under Title XIX of the Act as described under paragraph (2) of the definition of a ''full-benefit dual eligible individual'' at § 423.772 of this chapter. In determining reasonable costs for a skilled nursing facility and for post-hospital SNF care furnished in a swing bed hospital, as defined in § 413.114(b), the amount of allowable bad debt (as defined in paragraph (e) of this section) is reduced:

(i) *For non-dual eligible individuals*—(A) For cost reporting periods beginning during fiscal years 2006 through 2012, by 30 percent, for a patient in a skilled nursing facility.

(B) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent, for a patient in a skilled nursing facility or receiving post-hospital SNF care in a swing bed hospital.

(ii) *For dual eligible individuals*—(A) For cost reporting periods beginning during fiscal year 2013, by 12 percent, for a patient in a skilled nursing facility or a patient receiving post-hospital SNF care in a swing bed hospital.

(B) For cost reporting periods beginning during fiscal year 2014, by 24 percent, for a patient in a skilled nursing facility or a patient receiving post-hospital SNF care in a swing bed hospital.

(C) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent, for a patient in a skilled nursing facility or a patient receiving post-hospital SNF care in a swing bed hospital.

(3) *End-stage renal dialysis facilities.* In determining reasonable costs for an end-stage renal dialysis facility, the amount of allowable bad debt (as defined in paragraph (e) of this section) is:

(i) For cost reporting periods beginning before October 1, 2012, reimbursed up to the facility's costs.

(ii) For cost reporting periods beginning on or after October 1, 2012 and before January 1, 2013, reduced by 12 percent with the resulting amount reimbursed up to the facility's costs.

(iii) For cost reporting periods beginning on or after January 1, 2013 and before October 1, 2013, reduced by 12 percent.

(iv) For cost reporting periods beginning during fiscal year 2014, reduced by 24 percent.

(v) For cost reporting periods beginning during a subsequent fiscal year, reduced by 35 percent.

(4) *All other providers.* In determining reasonable costs for all other providers, suppliers and other entities not described elsewhere in paragraph (h) of this section that are eligible to receive reimbursement for bad debts under this section, the amount of allowable bad debts (as defined in paragraph (e) of this section) is reduced:

(i) For cost reporting periods beginning during fiscal year 2013, by 12 percent.

(ii) For cost reporting periods beginning during fiscal year 2014, by 24 percent.

(iii) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent.

(i) *Exceptions applicable to bad debt reimbursement.* (1) Bad debts arising from covered services paid under a reasonable charge-based methodology or a fee schedule are not reimbursable under the program.

(2) For end-stage renal dialysis services furnished on or after January 1, 2011 and paid for under the end-stage renal dialysis prospective payment system described in § 413.215, bad debts arising from covered items or services that, prior to January 1, 2011 were paid under a reasonable charge-based methodology or a fee schedule, including but not limited to drugs, laboratory tests, and supplies are not reimbursable under the program.

§ 413.178 [Removed and Reserved]

■ 3. Section 413.178 is removed and reserved.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 4. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

Subpart O—Medicare Payment: Cost Basis

■ 5. Section 417.536 is amended by revising paragraph (f)(1) to read as follows:

§ 417.536 Cost payment principles.

* * * * *

(f) * * *

(1) Bad debts attributable to Medicare deductible and coinsurance amounts are allowable only if the requirements of § 413.89 of this chapter are met, subject to the limitations described under § 413.89(h) and the exceptions for services described under § 413.89(i).

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 26, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–26903 Filed 11–2–12; 4:15 pm]

BILLING CODE 4120–01–P

Reader Aids

Federal Register

Vol. 77, No. 218

Friday, November 9, 2012

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**
TTY for the deaf-and-hard-of-hearing	**741–6086**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.fdsys.gov.**

Federal Register information and research tools, including Public Inspection List, indexes, and links to GPO Access are located at: **www.ofr.gov.**

E-mail

FEDREGTOC-L (Federal Register Table of Contents LISTSERV) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **http://listserv.access.gpo.gov** and select *Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings);* then follow the instructions.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC-L and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

Reminders. Effective January 1, 2009, the Reminders, including Rules Going Into Effect and Comments Due Next Week, no longer appear in the Reader Aids section of the Federal Register. This information can be found online at **http://www.regulations.gov.**

CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at **http://bookstore.gpo.gov/.**

FEDERAL REGISTER PAGES AND DATE, NOVEMBER

66067–66148 1
66149–66360 2
66361–66514 5
66515–66702 6
66703–66914 7
66915–67238 8
67239–67532 9

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
8894 66507
8895 66515
8896 66517
8897 66519
8898 66521
8899 66523
8900 66525
8901 66527

Executive Orders:
13629 66353

Administrative Orders:
Notices:
Notice of November 1, 2012 66359

7 CFR

205 67239

12 CFR

19 66529
109 66529
204 66361
615 66362
652 66375

Proposed Rules
1026 66748
1238 66566

14 CFR

25 67251
39 ..... 66534, 67254, 67256, 67261, 67263, 67267
71 ..... 66067, 66068, 66069
97 ..... 66535, 66536
400 67269

Proposed Rules
25 ..... 67308, 67309
33 66936
39 ..... 66409, 66411, 66413, 66415, 66417, 66566, 66757, 66760, 66762, 66764, 66767, 66769, 66771, 66772

15 CFR

Proposed Rules
764 66777
766 66777

16 CFR

1223 66703

17 CFR

1 66288
4 66288
5 66288
7 66288
8 66288
15 66288
16 66288
18 66288
21 66288
22 66288
36 66288
38 66288
41 66288
140 66288
145 66288
155 66288
166 66288
240 66220

18 CFR

Proposed Rules
284 66568

26 CFR

1 66915

Proposed Rules
1 66938

29 CFR

1401 66539
1926 67270

Proposed Rules
1926 67313

30 CFR

Proposed Rules
943 66574

31 CFR

552 67276
561 66918

33 CFR

100 66713
117 66714
165 66541

Proposed Rules
100 66938
110 66942
117 67319

34 CFR

674 66088
682 66088
685 66088

37 CFR

202 66920

38 CFR

9 66069

Proposed Rules
3 66419

39 CFR

111 66149

40 CFR

9 66149

52 .....66388, 66398, 66405, 66543, 66545, 66547, 66548, 66715, 66921, 66927, 66929
180 .....66715, 66721, 66723, 67282
300.....66729
721.....66149
Proposed Rules
52 .....66421, 66422, 66429, 66780, 66945, 67322
174.....66781
180.....66781
300.....66783

41 CFR

303.....66554

42 CFR

409.....67068
413.....67450
417.....67450
424.....67068
438.....66670
441.....66670
447.....66670
484.....67068
488.....67068
489.....67068
498.....67068

44 CFR

64.....66733
67.....66555, 66737
206.....67285
Proposed Rules
67 .....66165, 66785, 66788, 66790, 66791, 67324, 67325

47 CFR

64.....66935
73.....66743
76.....67290
Proposed Rules
25.....67172

49 CFR

Proposed Rules
1121.....66165
1150.....66165
1180.....66165

50 CFR

17.....67302
21.....66406
622.....66744, 67303
648.....66746, 67305
679.....66564
Proposed Rules
424.....66946
648.....66169, 66947
660.....66577, 67327

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws*.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO's Federal Digital System (FDsys) at *http://www.gpo.gov/fdsys*. Some laws may not yet be available.

S. 3624/P.L. 112–196

Military Commercial Driver's License Act of 2012 (Oct. 19, 2012; 126 Stat. 1459)

Last List October 11, 2012

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.