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Presidential Documents

Title 3—

The President

Proclamation 8691 of July 1, 2011

40th Anniversary of the 26th Amendment

By the President of the United States of America

A Proclamation

Forty years ago, the 26th Amendment to the United States Constitution took effect, lowering the universal voting age in America from 21 years to 18 years. Millions of young Americans were extended the right to vote, empowering more young people than ever before to help shape our country. On this anniversary, we remember the commitment of all those who fought for the right to vote and celebrate the contributions of young adults to our Nation.

The right to vote has been secured by generations of leaders over our history, from the women's groups of the early 20th century to the civil rights activists of the 1960s. For young people, the movement to lower America's voting age took years of hard work and tough advocacy to make the dream a reality. Yet, once proposed in Congress in 1971, the 26th Amendment was ratified in the shortest time span of any Constitutional Amendment in American history.

In the midst of the Vietnam War, our Nation bestowed upon our young people the ability to change the status quo and entrusted them with a new voice in government. Today, young adults across America continue to exercise this enormous responsibility of citizenship. Countless young people are involved in the political process, dedicated to ensuring their voices are heard.

Ideas from young Americans are important to my Administration, and they will help shape the future of our Nation. We are committed to supporting and developing young leaders from all beliefs and backgrounds, and from urban and rural communities alike. This year, I launched ''100 Youth Roundtables,'' an initiative to facilitate substantive dialogue between my Administration and young Americans. We hosted a Young Entrepreneur Summit to listen to budding entrepreneurs and better assess their needs. And this summer, we are beginning a ''How to Make Change'' series for young Americans from all walks of life who are seeking change in their communities and our world.

Young adults have been a driving force for change in the last century, bringing new ideas and high hopes to our national dialogue. Today, we remember the efforts of those who fought for their seat at the table, and we encourage coming generations to claim their place in our democracy.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim July 1, 2011, as the 40th Anniversary of the 26th Amendment. I call upon all Americans to participate in ceremonies and activities that honor young Americans, and those who have fought for freedom and justice in our country.

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

[FR Doc. 2011–17287
Filed 7–7–11; 8:45 am]
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Rules and Regulations

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

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0624; Directorate Identifier 2010–NE–11–AD; Amendment 39–16724; AD 2011–13–01]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc (RR) RB211–524 Series Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

An investigation into the loss of a TRU during landing has revealed that this incident was preceded by the detachment of the TRUs fixed structure front ring rivet lines on the rear flange. It was concluded that the loss of rivet lines was directly associated with a previous translating cowl gearbox stubshaft fracture and the subsequent repair of the fixed structure to Engine Manual repair No. FRS5887. This repair instructs the replacement of the damaged section of the structure but does not require the rivets adjacent to the repair to be replaced although latest analysis has shown that the rivets may have weakened as a result of a translating cowl gearbox stubshaft failure.

We are issuing this AD to prevent failure of the attachment rivets resulting in loss of engine structural integrity, which may result in release of the thrust reverser unit from the engine.

DATES: This AD becomes effective August 12, 2011.

We must receive comments on this AD by August 8, 2011.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of August 12, 2011.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Alan Strom, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; *e-mail: alan.strom@faa.gov;* telephone (781) 238–7143; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2009–0253, dated November 30, 2009 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

An investigation into the loss of a TRU during landing has revealed that this incident was preceded by the detachment of the TRUs fixed structure front ring rivet lines on the rear flange. It was concluded that the loss of rivet lines was directly associated with a previous translating cowl gearbox stubshaft fracture and the subsequent repair of the fixed structure to Engine Manual repair No. FRS5887. This repair instructs the replacement of the damaged section of the structure but does not require the rivets adjacent to the repair to be replaced although latest analysis has shown that the rivets may have weakened as a result of a translating cowl gearbox stubshaft failure.

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

Relevant Service Information

Rolls-Royce has issued RR Alert Service Bulletin RB.211–78–AG084, Revision 5, dated February 4, 2011. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This AD

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

Differences Between the AD and the MCAI or Service Information

EASA AD 2009–0253, dated November 30, 2009, requires the following compliance times:

For engines on which the thrust reverser unit (TRU) was previously repaired using either engine manual repair No. FRS4976 or engine manual repair No. FRS5887 and FRS6669 as a result of a translating cowl gearbox stubshaft failure, the MCAI requires compliance before March 31, 2010. This AD requires compliance within 215 cycles-in-service (CIS) after the effective date of this AD.

For engines on which the TRU was previously repaired using engine manual repair No. FRS5887 only, the

MCAI requires compliance before December 31, 2012. This AD requires compliance within 2,225 CIS after the effective date of this AD.

FAA's Determination of the Effective Date

Since no domestic operators use this product, notice and opportunity for public comment before issuing this AD are unnecessary. Therefore, we are adopting this regulation immediately.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–0624; Directorate Identifier 2010–NE–11–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

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

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 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); and

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

We prepared a regulatory evaluation of the estimated costs to comply with this 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 AD:

2011–13–01 Rolls-Royce plc (RR): Amendment 39–16724; Docket No. FAA–2011–0624; Directorate Identifier 2010–NE–11–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective August 12, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to RB211–524D4–19, –524D4–B–19, –524D4–39, –524D4–B–39, –524D4X–19, –524D4X–B–19, –524H–36, –524H2–19, –524H–T–36, –524H2–T–19, –524G2–19, –524G3–19, –524G2–T–19, and –524G3–T–19 engines with thrust reverser units (TRUs) that have a part number (P/N) specified in paragraph 1.A. of RR Alert Service Bulletin (ASB) RB.211–78–AG084, Revision 5, dated February 4, 2011, installed. These engines are installed on, but not limited to, Boeing 747 series and 767 series airplanes.

Reason

(d) The EASA AD 2009–0253, dated November 30, 2009, states the following:

An investigation into the loss of a TRU during landing has revealed that this incident was preceded by the detachment of the TRUs fixed structure front ring rivet lines on the rear flange. It was concluded that the loss of rivet lines was directly associated with a previous translating cowl gearbox stubshaft fracture and the subsequent repair of the fixed structure to Engine Manual repair No. FRS5887. This repair instructs the replacement of the damaged section of the structure but does not require the rivets adjacent to the repair to be replaced although latest analysis has shown that the rivets may have weakened as a result of a translating cowl gearbox stubshaft failure.

We are issuing this AD to prevent failure of the attachment rivets resulting in loss of engine structural integrity, which may result in release of the thrust reverser unit from the engine.

(e) If no repairs were performed as a result of a stubshaft failure, no further action is necessary.

Actions and Compliance

(f) Unless already done, do the following actions:

(1) If the TRU has previously had engine manual repair No. FRS5887 and either engine manual repair No. FRS4976 or engine manual repair No. FRS6669 as a result of a translating cowl gearbox stubshaft failure, then perform the actions specified in Section 3. Accomplishment Instructions of RR ASB RB.211–78–AG084, Revision 5, dated February 4, 2011, within 215 cycles-in-service (CIS) after the effective date of this AD.

(2) If the TRU has previously only had engine manual repair No. FRS5887 as a result of a translating cowl gearbox stubshaft failure, then perform the actions specified in Section 3. Accomplishment Instructions of RR ASB RB.211–78–AG084, Revision 5, dated February 4, 2011, within 2,225 CIS after the effective date of this AD.

Previous Credit

(g) Actions specified in paragraph (f)(1) and (f)(2) of this AD that are performed using RR ASB RB.211–78–AG084, Revision 4, dated December 22, 2009, RR ASB RB.211–78–AG084, Revision 3, dated November 6, 2009, comply with paragraph (f)(1) and (f)(2) of this AD.

FAA AD Differences

(h) This AD differs from the Mandatory Continuing Airworthiness Information (MCAI) and/or service information as follows:

(1) For engines on which the TRU was previously repaired using either engine manual repair No. FRS4976 or engine manual

repair No. FRS6669 and engine manual repair FRS5887 as a result of a translating cowl gearbox stubshaft failure, the MCAI requires compliance before March 31, 2010. This AD requires compliance within 215 cycles-in-service (CIS) after the effective date of this AD.

(2) For engines on which the TRU was previously repaired using engine manual repair No. FRS5887 only, the MCAI requires compliance before December 31, 2012. This AD requires compliance within 2,225 CIS after the effective date of this AD.

Other FAA AD Provisions

Alternative Methods of Compliance (AMOCs)

(i) The Manager, Engine Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

Related Information

(j) Refer to MCAI EASA Airworthiness Directive 2009–0253, dated November 30, 2009, for related information.

(k) Contact Alan Strom, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; *e-mail: alan.strom@faa.gov;* telephone (781) 238–7143; fax (781) 238–7199, for more information about this AD.

Material Incorporated by Reference

(l) You must use Rolls-Royce (RR) Alert Service Bulletin (ASB) RB.211–78–AG084, Revision 5, dated February 4, 2011, to do the actions required by this AD, unless the AD specifies otherwise.

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

(2) For service information identified in this AD, contact Rolls-Royce plc, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; telephone 011 44 1332 242424; fax 011 44 1332 249936.

(3) You may review copies at the FAA, New England Region, 12 New England Executive Park, Burlington, MA; or 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 Burlington, Massachusetts, on June 8, 2011.

Peter A. White,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2011–16954 Filed 7–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0714; Directorate Identifier 2011–CE–024–AD; Amendment 39–16744; AD 2011–14–09]

RIN 2120–AA64

Airworthiness Directives; Various Aircraft Equipped With Rotax Aircraft Engines 912 A Series Engine

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above that will supersede an existing AD. This AD results from mandatory continuing airworthiness information (MCAI) issued by the aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

During a production process review, a deviation in hardening of certain Part Number (P/N) 944072 washers has been detected, which exceeds the hardness of the design specification.

The affected washers are part of the magneto ring flywheel hub installation and have been installed on a limited number of engines. No defective washers have been shipped as spare parts.

This condition, if not corrected, could lead to cracks in the washer, loosening of the magneto flywheel hub and consequent ignition failure, possibly resulting in damage to the engine, in-flight engine shutdown and forced landing, damage to the aeroplane and injury to occupants.

This AD requires actions that are intended to address the unsafe condition described in the MCAI.

DATES: This AD becomes effective July 25, 2011.

As of June 16, 2011 (76 FR 31465, June 1, 2011), the Director of the Federal Register approved the incorporation by reference of Rotax Aircraft Engines Mandatory Service Bulletin SB–912–058 SB–914–041, dated April 15, 2011, listed in this AD.

We must receive comments on this AD by August 22, 2011.

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

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

For service information identified in this AD, contact BRP–Rotax GmbH & Co. KG, Welser Strasse 32, A–4623 Gunskirchen, Austria; *phone:* +43 7246 601 0; *fax:* +43 7246 601 9130; *Internet: http://www.rotax-aircraft-engines.com.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Sarjapur Nagarajan, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; *telephone:* (816) 329–4145; *fax:* (816) 329–4090; *e-mail: sarjapur.nagarajan@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

On May 10, 2011, we issued AD 2011–11–03, Amendment 39–16702 (76 FR 31465, June 1, 2011). That AD required actions intended to address an unsafe condition on the products listed above.

Since we issued AD 2011–11–03, we determined that we inadvertently omitted certain airplanes equipped with Rotax 912 A series engines from the Applicability section. We have also determined that we included certain airplanes in the Applicability section that are not equipped with Rotax 912 A series engines.

Relevant Service Information

Rotax Aircraft Engines has issued Mandatory Service Bulletin SB–912–058 and SB–914–041 (same document),

dated April 15, 2011. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the AD

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

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might have also required different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are described in a separate paragraph of the AD. These requirements take precedence over those copied from the MCAI.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because cracks in the washer of the magneto ring flywheel hub could cause loosening of the magneto flywheel hub. This failure could result in ignition failure and/or damage to the engine, causing in-flight engine shutdown leading to a forced landing. A forced landing could result in damage to the airplane and injury to the occupants. Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2011–0714; Directorate Identifier 2011–CE–024–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

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

Costs of Compliance

We estimate that this AD will affect 112 products of U.S. registry. We also estimate that it would take about 24 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Required parts would cost about $20 per product.

Based on these figures, we estimate the cost of the AD on U.S. operators to be $230,720, or $2,060 per product.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

We prepared a regulatory evaluation of the estimated costs to comply with this 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 removing Amendment 39–16702 (76 FR 31465, June 1, 2011), and adding the following new AD:

2011–14–09 Various Aircraft: Amendment 39–16744; Docket No. FAA–2011–0714; Directorate Identifier 2011–CE–024–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective July 25, 2011.

Affected ADs

(b) This AD supersedes AD 2011–11–03; Amendment 39–16702.

Applicability

(c) This AD applies to all serial numbers of the following aircraft, equipped with a Rotax Aircraft Engines 912 A series engine,

serial number 4,410.888 through 4,410.899, installed and certificated in any category:

GROUP 1 AIRPLANES

[airplanes previously affected by AD 2011–11–03]

Type certificate holder	Aircraft model	Engine model
Aeromot-Indústria Mecânico-Metalúrgica Ltda	AMT–200	912 A2.
Diamond Aircraft Industries	HK 36 R "SUPER DIMONA"	912 A.
Diamond Aircraft Industries Inc.	DA20–A1	912 A3.
HOAC–Austria	DV 20 KATANA	912 A3.
Iniziative Industriali Italiane S.p.A.	Sky Arrow 650 TC	912 A2.
SCHEIBE–Flugzeugbau GmbH	SF 25C	912 A2.

GROUP 2 AIRPLANES

[airplanes not previously affected by AD 2011–11–03]

Type certificate holder	Aircraft model	Engine model
DIAMOND AIRCRAFT INDUSTRIES GmbH	HK 36 TS and HK 36 TC	912 A3.

Subject

(d) Air Transport Association of America (ATA) Code 74: Ignition.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

During a production process review, a deviation in hardening of certain Part Number (P/N) 944072 washers has been detected, which exceeds the hardness of the design specification.

The affected washers are part of the magneto ring flywheel hub installation and have been installed on a limited number of engines. No defective washers have been shipped as spare parts.

This condition, if not corrected, could lead to cracks in the washer, loosening of the magneto flywheel hub and consequent ignition failure, possibly resulting in damage to the engine, in-flight engine shutdown and forced landing, damage to the aeroplane and injury to occupants.

For the reasons described above, this AD requires, for the affected engines, the replacement of the P/N 944072 washer and associated gasket ring P/N 950141 with serviceable parts, having the same P/N.

This AD also prohibits installation of an affected engine on an aeroplane, unless the washer on that engine has been replaced as required by this AD.

Actions and Compliance

(f) Unless already done, do the following actions:

(1) Replace washer, part number (P/N) 944072, and associated gasket ring, P/N 950141, on the magneto ring flywheel hub with FAA-approved serviceable parts with the same P/Ns. Do the replacements following the Accomplishment Instructions in Rotax Aircraft Engines Mandatory Service Bulletin SB–912–058 and SB–914–041 (same document), dated April 15, 2011.

(i) *For Group 1 airplanes (airplanes previously affected by AD 2011–11–03):* Within the next 10 hours time-in-service (TIS) after June 16, 2011 (the effective date retained from AD 2011–11–03) or within 4 months after June 16, 2011 (the effective date retained from AD 2011–11–03), whichever occurs first.

(ii) *For Group 2 airplanes (airplanes not previously affected by AD 2011–11–03):* Within the next 10 hours TIS after July 25, 2011 (the effective date of this AD) or within 4 months after July 25, 2011 (the effective date of this AD), whichever occurs first.

(2) Do not install a Rotax Aircraft Engines 912 A series engine listed in paragraph (c) of this AD unless the washer, P/N 944072, and the gasket ring, P/N 950141, have been replaced as required in paragraph (f)(1) of this AD.

(i) *For Group 1 airplanes (airplanes previously affected by AD 2011–11–03):* As of June 16, 2011 (the effective date retained from AD 2011–11–03).

(ii) *For Group 2 airplanes (airplanes not previously affected by AD 2011–11–03):* As of July 25, 2011 (the effective date of this AD).

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: EASA AD 2011–0067–E, dated April 15, 2011, requires returning the removed P/N 944072 to Rotax Aircraft Engines. We are not requiring this because FAA regulation, specifically 14 CFR 43.10, already requires disposition of unairworthy parts.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to *Attn:* Sarjapur Nagarajan, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; *telephone:* (816) 329–4145; *fax:* (816) 329–4090. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

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

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

Related Information

(h) Refer to MCAI European Aviation Safety Agency (EASA) AD No. 2011–0067–E, dated April 15, 2011, and Rotax Aircraft Engines Mandatory Service Bulletin SB–912–058 and SB–914–041 (same document), dated April 15, 2011, for related information.

Material Incorporated by Reference

(i) You must use Rotax Aircraft Engines Mandatory Service Bulletin SB–912–058 SB–914–041, dated April 15, 2011, to do the actions required by this AD, unless the AD specifies otherwise.

(1) On June 16, 2011 (76 FR 31465, June 1, 2011), the Director of the Federal Register previously approved the incorporation by

reference of Rotax Aircraft Engines Mandatory Service Bulletin SB–912–058 SB–914–041, dated April 15, 2011.

(2) For service information identified in this AD, contact BRP-Rotax GmbH & Co. KG, Welser Strasse 32, A–4623 Gunskirchen, Austria; *phone:* +43 7246 601 0; *fax:* +43 7246 601 9130; *Internet: http://www.rotax-aircraft-engines.com.*

(3) You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

(4) You may also review copies of the service information incorporated by reference for this AD at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Kansas City, Missouri, on July 1, 2011.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–17144 Filed 7–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0115; Directorate Identifier 2010–NE–40–AD; Amendment 39–16728; AD 2011–13–05]

RIN 2120–AA64

Airworthiness Directives; Turbomeca S.A. ARRIEL 2B and 2B1 Turboshaft Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

Several cases of Gas Generator (GG) Turbine Blade rupture occurred in service on ARRIEL 2 twin engine applications and recently one on a single engine helicopter. For the case occurring in flight on a single engine helicopter (ARRIEL 2B1 engine), the pilot performed an emergency autorotation, landing the helicopter without further incident.

We are issuing this AD to prevent rupture of a GG turbine blade, which could result in an uncommanded in-flight shutdown and an emergency autorotation landing or accident.

DATES: This AD becomes effective August 12, 2011. The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 12, 2011.

ADDRESSES: The Docket Operations office is located at Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

FOR FURTHER INFORMATION CONTACT: Rose Len, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; *e-mail: rose.len@faa.gov; phone:* (781) 238–7772; fax (781) 238–7199.

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 February 18, 2011 (76 FR 9515). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

Several cases of Gas Generator (GG) Turbine Blade rupture occurred in service on ARRIEL 2 twin engine applications and recently one on a single engine helicopter. For the case occurring in flight on a single engine helicopter (ARRIEL 2B1 engine), the pilot performed an emergency autorotation, landing the helicopter without further incident.

The design of ARRIEL 2 engines (containment shield around the GG turbine) allows debris from a blade or the disc inter-blade area to be contained in the event of rupture. However, the rupture of a GG Turbine Blade may lead to an uncommanded In Flight Shut-Down which, on a single-engine helicopter, could ultimately lead to an emergency autorotation landing.

The most probable root cause of the ruptures is an excitation of one of the vibration modes of the GG Turbine Blade in conjunction with several secondary contributing factors which are deemed sufficient to reduce the stress margin of the blade to a level consistent with the rate of occurrences of ruptures encountered.

Turboméca has released TU166 modification which consists in inserting Blade dampers between the GG Turbine Disc and the GG Turbine Blade platform. Introduction of these dampers minimizes the effects of HP blade vibratory excitation and increases the blade tolerance for this type of stress.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

Costs of Compliance

Based on the service information, we estimate that this AD would affect about 537 products of U.S. registry. We also estimate that it would take about 60 work-hours per product to comply with this AD. The average labor rate is $85 per work-hour. Required parts would cost about $3,900 per product. Based on these figures, we estimate the cost of the AD on U.S. operators to be $4,833,000.

Authority for This Rulemaking

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

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

Regulatory Findings

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 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); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this 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 this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (*phone:* (800) 647–5527) is provided 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:

2011–13–05 Turbomeca S.A.: Amendment 39–16728. Docket No. FAA–2011–0115; Directorate Identifier 2010–NE–40–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective August 12, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Turbomeca S.A. ARRIEL 2B and 2B1 turboshaft engines not modified by TU166 modification. These engines are installed on, but not limited to, Eurocopter AS 350 B3 and EC 130 B4 helicopters.

Reason

(d) This AD results from:

Several cases of Gas Generator (GG) Turbine Blade rupture occurred in service on ARRIEL 2 twin engine applications and recently one on a single engine helicopter. For the case occurring in flight on a single engine helicopter (ARRIEL 2B1 engine), the pilot performed an emergency autorotation, landing the helicopter without further incident.

We are issuing this AD to prevent rupture of a GG turbine blade, which could result in an uncommanded in-flight shutdown and an emergency autorotation landing or accident.

Actions and Compliance

(e) Unless already done, do the following actions.

(1) Accomplish TU166 modification in accordance with the instructions specified within Turboméca Mandatory Service Bulletin (MSB) A292 72 3166 Version B, dated September 20, 2010, when the GG Turbine is replaced or when the engine or Module M03 is going through overhaul or repair, or within 1,300 cycles-in-service after the effective date of this AD, whichever occurs first.

(2) Accomplishment, before the effective date of this AD, of TU166 modification in accordance with the instructions of Turboméca MSB A292 72 3166 Version A, dated August 17, 2010, satisfies the requirement of paragraph (e)(1) of this AD.

FAA AD Differences

(f) This AD differs from the Mandatory Continuing Airworthiness Information (MCAI) and or service information by the following:

(1) European Aviation Safety Agency (EASA) AD No. 2010–0198, dated October 1, 2010, applies to the ARRIEL 2B1A engine. This AD does not apply to that model because it has no U.S. type certificate.

(2) EASA AD No. 2010–198 has a compliance date of ''but no later than 25 months after the effective date of this AD. This AD has a compliance time of ''1,300 cycles-in-service,'' based on average fleet usage data supplied by Turbomeca.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

Alternative Methods of Compliance (AMOCs)

(h) The Manager, Engine Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

Related Information

(i) Refer to MCAI EASA Airworthiness Directive 2010–0198, dated October 1, 2010, for related information.

(j) Contact Rose Len, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; *e-mail: rose.len@faa.gov; phone:* (781) 238–7772; fax (781) 238–7199, for more information about this AD.

Material Incorporated by Reference

(k) You must use Turbomeca S.A. Mandatory Service Bulletin A292 72 3166 Version B, dated September 20, 2010, to do the actions required by this AD, unless the AD specifies otherwise.

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

(2) For service information identified in this AD, contact Turbomeca S.A., 40220 Tarnos, France; *e-mail: noria-dallas@turbomeca.com;* telephone 33 05 59 74 40 00, fax 33 05 59 74 45 15, or go to: *http://www.turbomeca-support.com.*

(3) You may review copies at the FAA, New England Region, 12 New England Executive Park, Burlington, MA; or 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 Burlington, Massachusetts, on June 14, 2011.

Peter A. White,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2011–16955 Filed 7–7–11; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 230, 240 and 260

[Release Nos. 33–9232; 34–64800; 39–2476; File No. S7–02–09]

RIN 3235–AK26

Extension of Temporary Exemptions for Eligible Credit Default Swaps To Facilitate Operation of Central Counterparties To Clear and Settle Credit Default Swaps

AGENCY: Securities and Exchange Commission.

ACTION: Final temporary rules; extension.

SUMMARY: We are extending the expiration dates in our temporary rules that provide exemptions under the Securities Act of 1933, the Securities Exchange Act of 1934, and the Trust Indenture Act of 1939 for certain credit default swaps in order to continue facilitating the operation of one or more central counterparties for those credit default swaps as we consider rules implementing the clearing provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

DATES: *Effective Date:* These amendments are effective July 8, 2011, and the expiration dates in the temporary rules and amendments published January 22, 2009 (74 FR 3967), extended in a release published on September 17, 2009 (74 FR 47719), and further extended in a release published on November 26, 2010 (75 FR 72660), are further extended from July 16, 2011 to April 16, 2012. If the Commission adopts permanent exemptions for security-based swaps

issued by certain clearing agencies before April 16, 2012, the Commission will terminate the effectiveness of the temporary rules as part of that rulemaking.

FOR FURTHER INFORMATION CONTACT: Andrew Schoeffler, Special Counsel, Office of Capital Market Trends, Division of Corporation Finance, at (202) 551–3860, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–3628.

SUPPLEMENTARY INFORMATION: We are adopting amendments to the following rules: temporary Rule 239T and Rule 146 under the Securities Act of 1933 (''Securities Act''),[1] temporary Rule 12a–10T and Rule 12h–1(h)T under the Securities Exchange Act of 1934 (''Exchange Act''),[2] and temporary Rule 4d–11T under the Trust Indenture Act of 1939 (''TIA'').[3]

I. Background

In January 2009, we adopted interim final temporary Rule 239T and a temporary amendment to Rule 146 under the Securities Act, interim final temporary Rules 12a–10T and 12h–1(h)T under the Exchange Act, and interim final temporary Rule 4d–11T under the TIA (collectively, the ''Temporary Rules''), and in September 2009, we extended the expiration dates in these rules from September 25, 2009 to November 30, 2010 and in November 2010, we further extended the expiration dates in these rules to July 16, 2011.[4] We adopted these rules in connection with temporary exemptive orders[5] we issued to clearing agencies acting as central counterparties (''CCP''), which exempted the CCPs from the requirement to register as clearing agencies under Section 17A of the Exchange Act[6] solely to perform the functions of a clearing agency for certain credit default swap (''CDS'') transactions. The CCP exemptive orders also exempted certain eligible contract participants[7] and others from certain Exchange Act requirements with respect to certain CDS.[8] Also at that time, we temporarily exempted any exchange that effects transactions in certain CDS from the requirements under Sections 5 and 6 of the Exchange Act[9] to register as a national securities exchange, and any broker or dealer that effects transactions on an exchange in certain CDS from the requirements of Section 5 of the Exchange Act.

We adopted the Temporary Rules and the CCP exemptive orders to help foster the prompt development of CCPs for CDS because we believed and continue to believe that the existence of CCPs for CDS would be important in helping to reduce counterparty risks inherent in the CDS market. Today, CDS agreements generally are negotiated and entered into bilaterally, but eligible trades may be submitted to the CCP for novation, which results in the bilateral contract being extinguished and replaced by two new contracts where the CCP is the buyer to the original seller and the seller to the original buyer.[10] The operation of a well-regulated CCP can significantly reduce counterparty risks by preventing the failure of a single-market participant from having a disproportionate effect on the overall market, since bilateral counterparty risk is eliminated as the creditworthiness of the original counterparties is replaced by the creditworthiness of the CCP.

At the time of the adoption of the Temporary Rules and the CCP exemptive orders, the OTC market for CDS was a source of concern to us and other financial regulators due to the systemic risk posed by CDS, the possible inability of parties to meet their obligations as counterparties under the CDS, and the potential resulting adverse effects on other markets and the

[1] 15 U.S.C. 77a *et. seq.*

[2] 15 U.S.C. 78a *et. seq.*

[3] 15 U.S.C. 77aaa *et. seq.*

[4] *See Temporary Exemptions for Eligible Credit Default Swaps to Facilitate Operation of Central Counterparties to Clear and Settle Credit Default Swaps,* Release No. 33–8999 (Jan. 14, 2009), 74 FR 3967 (Jan. 22, 2009) (the ''Temporary CDS Exemptions Release''); *Extension of Temporary Exemptions for Eligible Credit Default Swaps to Facilitate Operation of Central Counterparties to Clear and Settle Credit Default Swaps,* Release No. 33–9063 (Sep. 14, 2009), 74 FR 47719 (Sep. 17, 2009); and *Extension of Temporary Exemptions for Eligible Credit Default Swaps to Facilitate Operation of Central Counterparties to Clear and Settle Credit Default Swaps,* Release No. 33–9158 (Nov. 19, 2010), 75 FR 72660 (Nov. 26, 2010).

[5] *See Order Granting Temporary Exemptions under the Securities Exchange Act of 1934 in Connection with Request on Behalf of ICE Clear Europe Limited Related to Central Clearing of Credit Default Swaps, and Request for Comments,* Release No. 34–60372 (Jul. 23, 2009), 74 FR 37748 (Jul. 29, 2009), *Order Extending Temporary Conditional Exemptions Under the Securities Exchange Act of 1934 in Connection With Request on Behalf of ICE Clear Europe, Limited Related to Central Clearing of Credit Default Swaps, and Request for Comments,* Release No. 34–61973 (Apr. 23, 2010), 75 FR 22656 (Apr. 29, 2010), and *Order Extending Temporary Conditional Exemptions under the Securities Exchange Act of 1934 in Connection with Request on Behalf of ICE Clear Europe, Limited Related to Central Clearing of Credit Default Swaps and Request for Comment,* Release No. 34–63389 (Nov. 29, 2010), 75 FR 75520 (Dec. 3, 2010); *Order Granting Temporary Exemptions under the Securities Exchange Act of 1934 in Connection with Request on Behalf of Eurex Clearing AG Related to Central Clearing of Credit Default Swaps, and Request for Comments,* Release No. 34–60373 (Jul. 23, 2009), 74 FR 37740 (Jul. 29, 2009), *Order Extending and Modifying Temporary Conditional Exemptions Under the Securities Exchange Act of 1934 in Connection With Request on Behalf of Eurex Clearing AG Related to Central Clearing of Credit Default Swaps, and Request for Comment,* Release No. 34–61975 (Apr. 23, 2010), 75 FR 22641 (Apr. 29, 2010), and *Order Extending Temporary Conditional Exemptions under the Securities Exchange Act of 1934 in Connection with Request on Behalf of Eurex Clearing, AG Related to Central Clearing of Credit Default Swaps and Request for Comment,* Release No. 34–63390 (Nov. 29, 2010), 75 FR 75518 (Dec. 3, 2010); *Order Granting Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection With Request of Chicago Mercantile Exchange Inc. and Citadel Investment Group, L.L.C. Related to Central Clearing of Credit Default Swaps, and Request for Comments,* Release No. 34–59578 (Mar. 13, 2009), 74 FR 11781 (Mar. 19, 2009), *Order Extending and Modifying Temporary Exemptions under the Securities Exchange Act of 1934 in Connection with Request of Chicago Mercantile Exchange Inc. Related to Central Clearing of Credit Default Swaps, and Request for Comments,* Release No. 34–61164 (Dec. 14, 2009), 74 FR 67258 (Dec. 18, 2009), *Order Extending Temporary Exemptions under the Securities Exchange Act of 1934 in Connection with Request of Chicago Mercantile Exchange Inc. Related to Central Clearing of Credit Default Swaps, and Request for Comments,* Release No. 34–61803 (Mar. 30, 2010), 75 FR 17181 (Apr. 5, 2010), and *Order Extending Temporary Conditional Exemptions under the Securities Exchange Act of 1934 in Connection with Request of Chicago Mercantile Exchange Inc. Related to Central Clearing of Credit Default Swaps and Request for Comment,* Release No. 34–63388 (Nov. 29, 2010), 75 FR 75522 (Dec. 3, 2010); *Order Granting Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection With Request on Behalf of ICE US Trust LLC Related to Central Clearing of Credit Default Swaps, and Request for Comments,* Release No. 34–59527 (Mar. 6, 2009), 74 FR 10791 (Mar. 12, 2009), *Order Extending and Modifying Temporary Exemptions under the Securities Exchange Act of 1934 in Connection with Request from ICE Trust U.S. LLC Related to Central Clearing of Credit Default Swaps, and Request for Comments,* Release No. 34–61119 (Dec. 4, 2009), 74 FR 65554 (Dec. 10, 2009); *Order Extending Temporary Exemptions under the Securities Exchange Act of 1934 in Connection with Request of ICE Trust U.S. LLC Related to Central Clearing of Credit Default Swaps, and Request for Comments,* Release No. 34–61662 (Mar. 5, 2010), 75 FR 11589 (Mar. 11, 2010), and *Order Extending and Modifying Temporary Exemptions under the Securities Exchange Act of 1934 in Connection with Request of ICE Trust U.S. LLC Related to Central Clearing of Credit Default Swaps and Request for Comment,* Release No. 34–63387 (Nov. 29, 2010), 75 FR 75502 (Dec. 3, 2010); and *Order Granting Temporary Exemptions Under the Securities Exchange Act of 1934 in Connection with Request of LIFFE Administration and Management and LCH.Clearnet Ltd. Related to Central Clearing Of Credit Default Swaps, and Request for Comments,* Release No. 34–59164 (Dec. 24, 2008), 74 FR 139 (Jan. 2, 2009). LIFFE A&M and LCH.Clearnet Ltd. allowed their order to lapse without seeking renewal.

[6] 15 U.S.C. 78q-1.

[7] *See* 7 U.S.C. 1a(12).

[8] *See generally* the actions noted in footnote 5, *supra.*

[9] 15 U.S.C. 78e and 78f.

[10] ''Novation'' is a ''process through which the original obligation between a buyer and seller is discharged through the substitution of the CCP as seller to buyer and buyer to seller, creating two new contracts.'' Committee on Payment and Settlement Systems, Technical Committee of the International Organization of Securities Commissioners, *Recommendations for Central Counterparties* (Nov. 2004) at 66.

financial system.[11] In response, in January 2009, we took action to help foster the prompt development of CCPs for CDS, including granting conditional exemptions from certain provisions of the Federal securities laws. Since the adoption of the Temporary Rules and the CCP exemptive orders, several clearing agencies have been actively engaged as CCPs in clearing CDS transactions in accordance with our exemptions.

We subsequently extended the expiration dates in the Temporary Rules from September 30, 2009 to November 30, 2010 [12] and then from November 30, 2010 to July 16, 2011.[13] The latter extension was adopted to enable the CCPs to continue to clear eligible CDS in accordance with the Temporary Rules and the CCP exemptive orders pending implementation of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the ''Dodd-Frank Act'').[14] Title VII of the Dodd-Frank Act (''Title VII'') is intended to address regulatory gaps in the existing regulatory structure for the over-the-counter (''OTC'') derivatives markets by providing the Commission and the Commodity Futures Trading Commission (''CFTC'') with the authority to regulate OTC derivatives. The primary goals of Title VII, among others, are to increase the transparency, efficiency and fairness of the OTC derivatives markets, improve investor protection and to reduce the potential for counterparty and systemic risk.[15] To this end, Title VII imposes a comprehensive regime for the regulation of ''swaps'' and ''security-based swaps'' (as those terms are defined in Title VII), including the clearing, exchange trading, and reporting of transactions in security-based swaps.[16] Certain CDS are security-based swaps as defined under Title VII.

Title VII amends the Exchange Act to require, among other things, that security-based swaps be cleared through a clearing agency that is registered with the Commission or that is exempt from registration if the security-based swap is of a type that the Commission determines is required to be cleared, unless an exception from mandatory clearing applies.[17] Title VII also provides that a depository institution registered with the CFTC that cleared swaps as a multilateral clearing organization or a derivatives clearing organization registered with the CFTC that cleared swaps pursuant to an exemption from registration as a clearing agency prior to the date of enactment of the Dodd-Frank Act is deemed registered as a clearing agency for the purposes of clearing security-based swaps (the ''Deemed Registered Provision'').[18] The Deemed Registered Provision and the other general provisions of Title VII become effective on July 16, 2011.[19]

The Dodd-Frank Act also directs us to adopt regulations regarding, among other things clearing agencies for, and the clearing of, security-based swaps, which include CDS. Under Title VII, all security-based swaps, including certain types of CDS, are defined as securities under the Securities Act and the Exchange Act. As part of our review of the applications of the Securities Act, the Exchange Act and the TIA to security-based swaps and the implications for the clearing and exchange trading provisions of the Dodd-Frank Act and our rules implementing them, we are evaluating the necessity and appropriateness of exemptions from the registration requirements of the Securities Act and Exchange Act and the indenture qualification provisions of the TIA for security-based swaps that will be cleared by clearing agencies. To this end, we have proposed exemptions under the Securities Act, the Exchange Act, and the TIA for security-based swaps issued by certain clearing agencies satisfying certain conditions.[20] The Temporary Rules are an interim measure pending final action on the proposed permanent exemptions. However, the Temporary Rules are needed upon the effective date of Title VII to continue facilitating the operation of the CCPs in clearing eligible CDS as we consider rules implementing the clearing provisions of Title VII, including any applicable permanent exemptions.

The implementation of Title VII is a substantial undertaking and we are working toward fulfilling its requirements in a thorough and deliberative manner that includes significant public input and coordination with other regulators. To date, we have adopted an interim final rule regarding the reporting of outstanding security-based swaps entered into prior to the date of enactment of the Dodd-Frank Act [21] and proposed thirteen other rulemakings required by Title VII, including the permanent exemptions noted above,[22] rules regarding standards for the operation and governance of clearing agencies,[23] the obligations of security-

[11] In addition to the potential systemic risks that CDS pose to financial stability, we were concerned about other potential risks in this market, including operational risks, risks relating to manipulation and fraud, and regulatory arbitrage risks.

[12] *See Extension of Temporary Exemptions for Eligible Credit Default Swaps to Facilitate Operation of Central Counterparties to Clear and Settle Credit Default Swaps,* Release No. 33–9063 (Sep. 14, 2009), 74 FR 47719 (Sep. 17, 2009). In September 2009, we extended the expiration dates in the Temporary Rules to November 30, 2010 because, among other reasons, a number of legislative initiatives relating to the regulation of derivatives, including CDS, had been introduced by members of Congress and recommended by the United States Department of the Treasury (''Treasury''), and Congress had not yet taken definitive action with respect to any of the legislative initiatives or the Treasury proposals.

[13] *See Extension of Temporary Exemptions for Eligible Credit Default Swaps to Facilitate Operation of Central Counterparties to Clear and Settle Credit Default Swaps,* Release No. 33–9158 (Nov. 19, 2010), 75 FR 72660 (Nov. 26, 2010).

[14] The Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[15] *Id.* at preamble.

[16] Section 761(a)(6) of the Dodd-Frank Act defines a ''security-based swap'' as any agreement, contract, or transaction that is a swap based on a narrow-based security index, a single security or loan, including any interest therein or on the value thereof; or the occurrence, nonoccurrence, or extent of the occurrence of an event relating to a single issuer of a security or the issuers of securities in a narrow-based security index, provided that such event directly affects the financial statements, financial condition, or financial obligations of the issuer.

[17] *See* Public Law 111–203, § 763(a) (adding Exchange Act Section 3C(a)(1)).

[18] *See* Public Law 111–203, § 763(b) (adding Exchange Act Section 17A(l)). Section 763(b) of the Dodd-Frank Act provides that certain security-based swap clearing agencies will be deemed registered as clearing agencies for the purpose of clearing security-based swaps. Currently, four security-based swap clearing agencies have temporary conditional exemptions from clearing agency registration under Section 17A solely to perform the functions of a clearing agency for certain CDS, and three of these security-based swap clearing agencies will be subject the Deemed Registered Provision. While the Deemed Registered Provision eliminates the need to extend our temporary exemptive orders relating to registration of clearing agencies, it does not resolve other issues addressed by our temporary exemptive orders relating to Sections 5 and 6 of the Exchange Act.

[19] Public Law 111–203, § 774 states ''[u]nless otherwise provided, the provisions of this subtitle shall take effect on the later of 360 days after the date of the enactment of this subtitle or, to the extent a provision of this subtitle requires a rulemaking, not less than 60 days after publication of the final rule or regulation implementing such provision of this subtitle.''

[20] *See Exemptions For Security-Based Swaps Issued By Certain Clearing Agencies,* Release No. 33–9222 (June 9, 2011), 76 FR 34920 (June 15, 2011). The permanent exemptions would exempt transactions by clearing agencies in security-based swaps from all provisions of the Securities Act, other than the Section 17(a) anti-fraud provisions, as well as exempt these security-based swaps from Exchange Act registration requirements and from the provisions of the TIA, provided certain conditions are met.

[21] *See Reporting of Security-Based Swap Transaction Data,* Release No. 34–63094 (Oct. 13, 2010), 75 FR 64643 (Oct. 20, 2010).

[22] *See* footnote 20, *supra.*

[23] *See Clearing Agency Standards for Operation and Governance,* Release No. 34–64017 (Mar. 3, 2011), 76 FR 14472 (Mar. 16, 2011).

based swap data repositories,[24] the registration and regulation of security-based swap execution facilities,[25] the confirmation of security-based swap transactions,[26] trade reporting, data elements, and public dissemination of trade information for security-based swaps,[27] the exception to the mandatory clearing requirement for end users,[28] the mandatory clearing of security-based swaps,[29] definitions and interpretive guidance for key terms in Title VII,[30] and the mitigation of conflicts of interest involving security-based swaps.[31] We have also proposed anti-fraud and anti-manipulation rules regarding security-based swaps.[32] Title VII also calls for additional rulemakings regarding the registration procedures and external business conduct standards for security-based swap dealers and major security-based swap participants.

At the time of adoption of the Temporary Rules in January 2009, we requested comment on various aspects of the Temporary Rules. We received a total of 15 letters, only two of which commented specifically on the Temporary Rules.[33] Although those two letters generally supported allowing CCPs to clear and settle CDS transactions in accordance with the terms of the Temporary Rules, neither of the commenters specifically addressed the duration of the Temporary Rules and temporary amendments.[34] The other commenters raised issues not directly related to this rulemaking. No comments have been submitted to us regarding the Temporary Rules since that time.

Throughout the entire Title VII implementation process, we have sought to engage in an open and transparent implementation process, seeking input on the various rulemakings from interested parties even before issuing formal rule proposals. We have enhanced our public consultative process by expanding the opportunity for public comment beyond what is required by law. For instance, we have made available to the public a series of e-mail boxes to which interested parties can send preliminary comments before rules are proposed and the official comment periods begin.[35] These e-mail boxes are on the Commission's Web site, organized by topic. We also specifically solicited comment, along with the CFTC, on the definitions contained in Title VII.[36] In addition, our staff has sought the views of affected parties. This approach has resulted in meetings with a broad cross-section of interested parties. To further this public outreach effort, our staff has held joint public roundtables and hearings with the CFTC staff on select key topics, including most recently discussing the schedule for implementing final rules for swaps and security-based swaps under Title VII.[37]

We are still in the process of proposing and adopting numerous rulemakings relating to the implementation of Title VII, including the provisions relating to the clearing of security-based swaps. While we have taken significant steps to implement the rulemaking required by Title VII, we do not expect to complete the rulemaking we are directed to carry out under Title VII before July 16, 2011, the current termination date for the Temporary Rules. Due to the uncertainty of the timing regarding the adoption of final rules implementing the clearing provisions of Title VII, including any applicable permanent exemptions, we believe that it is important that the CCPs continue to be able to clear eligible CDS without concern that the Temporary Rules are unavailable. As such, we have determined that it is necessary and appropriate to extend the expiration dates in the Temporary Rules to April 16, 2012. If the Commission adopts permanent exemptions for security-based swaps issued by certain clearing agencies before April 16, 2012, the Commission will terminate the effectiveness of the temporary rules as part of that rulemaking.

We are only extending the expiration dates in the Temporary Rules; we are not making any other changes to the Temporary Rules. The Temporary Rules were modeled on other exemptions we have provided in the past to facilitate trading in certain securities.[38] They are limited in scope; in general, they facilitate the operation of the CCPs in clearing eligible CDS.

II. Amendment of Expiration Dates in the Temporary Rules

In January 2009, we adopted the Temporary Rules on a temporary basis until September 25, 2009. We subsequently extended the expiration dates in the Temporary Rules to November 30, 2010 and we further extended the expiration dates to July 16, 2011 to allow CCPs that were clearing and settling CDS transactions in the U.S. and in Europe to continue to clear and settle CDS transactions. Since the adoption of the Temporary Rules and the issuance of the CCP exemptive orders, several clearing agencies have

[24] *See Security-Based Swap Data Repository Registration, Duties, and Core Principles,* Release No. 34–63347 (Nov. 19, 2010), 75 FR 77306 (Dec. 10, 2010).

[25] *See Registration and Regulation of Security-Based Swap Execution Facilities,* Release No. 34–63825 (Feb. 2, 2011), 76 FR 10948 (Feb. 28, 2011).

[26] *See Trade Acknowledgment and Verification of Security-Based Swap Transactions,* Release No. 34–63727 (Jan. 14, 2011), 76 FR 3859 (Jan. 21, 2011).

[27] *See Regulation SBSR—Reporting and Dissemination of Security-Based Swap Information,* Release No. 34–63346 (Nov. 19, 2010), 75 FR 75208 (Dec. 2, 2010).

[28] *See End-User Exception to Mandatory Clearing of Security-Based Swaps,* Release No. 34–63556 (Dec. 15, 2010), 75 FR 79992 (Dec. 21, 2010).

[29] *See Process for Submissions for Review of Security-Based Swaps for Mandatory Clearing and Notice Filing Requirements for Clearing Agencies; Technical Amendments to Rule 19b–4 and Form 19b–4 Applicable to All Self-Regulatory Organizations,* Release No. 34–63557 (Dec. 15, 2010), 75 FR 82490 (Dec. 30, 2010).

[30] *See Further Definition of ''Swap Dealer,'' ''Security-Based Swap Dealer,'' ''Major Swap Participant,'' ''Major Security-Based Swap Participant'' and ''Eligible Contract Participant'',* Release No. 34–63452 (Dec. 7, 2010), 75 FR 80174 (Dec. 21, 2010); and *Further Definition of ''Swap,'' ''Security-Based Swap,'' and ''Security-Based Swap Agreement''; Mixed Swaps; Security-Based Swap Agreement Recordkeeping,* Release No. 33–9204 (Apr. 29, 2011), 76 FR 29818 (May 23, 2011), corrected in Release No. 33–9204A (June 1, 2011), 76 FR 32880 (June 7, 2011).

[31] *See Ownership Limitations and Governance Requirements for Security-Based Swap Clearing Agencies, Security-Based Swap Execution Facilities, and National Securities Exchanges with Respect to Security-Based Swaps under Regulation MC,* Release No. 34–63107 (Oct. 14, 2010), 75 FR 65882 (Oct. 26, 2010).

[32] *See Prohibition Against Fraud, Manipulation, and Deception in Connection with Security-Based Swaps,* Release No. 34–63236 (Nov. 3, 2010), 75 FR 68560 (Nov. 8, 2010).

[33] The public comments we received are available for Web site viewing and printing at the Commission's Public Reference Room at 100 F St., NE., Washington, DC 20549 in File No. S7–02–09. They are also available online at *http://www.sec.gov/comments/s7-02-09/s70209.shtml.*

[34] *See* letters from the Yale Law School Capital Markets and Financial Instruments Clinic (Mar. 23, 2009) and from IDX Capital (Mar. 23, 2009).

[35] *See* Public Comments on SEC Regulatory Initiatives Under the Dodd-Frank Act, available at *http://www.sec.gov/spotlight/regreformcomments.shtml.*

[36] *See Definitions Contained in Title VII of Dodd-Frank Wall Street Reform and Consumer Protection Act,* Release No. 34–62717 (Aug. 13, 2010), 75 FR 51429 (Aug. 20, 2010) (advance joint notice of proposed rulemaking regarding definitions).

[37] Roundtable on Clearing and Listing of Swaps and Security-Based Swaps (Aug. 20, 2010); Roundtable on Swap and Security-Based Swap Matters (Sep. 14–15, 2010); Roundtable to Discuss Issues Related to Clearing of Credit Default Swaps (Oct. 22, 2010); Roundtable to Discuss Issues Related to Capital and Margin for Swaps and Security-Based Swaps (Dec. 10, 2010); and Roundtable on Implementation Phasing for Final Rules for Swaps and Security-Based Swaps Under Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act (May 2–3, 2011).

[38] *See, e.g.,* Securities Act Section 3(a)(14) [15 U.S.C. 77c(a)(14)], Securities Act Rule 238 [17 CFR 230.238]; Exchange Act Section 12(a) [15 U.S.C. 78l(a)], and Exchange Act Rules 12h–1(d) and (e) [17 CFR 240.12h–1(d) and (e)] (providing similar exemptions from provisions of the Federal securities laws for standardized options and securities futures products).

been actively engaged as CCPs in clearing CDS transactions in reliance on our exemptions. We believe that the clearing of CDS transactions by these clearing agencies has contributed and we anticipate it will continue to contribute to increased transparency and the reduction of systemic risk in the CDS market.

Since the adoption of the Temporary Rules and issuance of the CCP exemptive orders, ICE Trust U.S. LLC (''ICE Trust'') and ICE Clear Europe, Ltd. (''ICE Clear Europe'') have been actively engaged as CCPs in clearing CDS transactions in reliance on our exemptions. Most cleared CDS transactions have cleared at ICE Trust or ICE Clear Europe.[39] However, Eurex Clearing AG and the Chicago Mercantile Exchange Inc. are also authorized to operate as CCPs pursuant to the CCP exemptive orders.[40] We believe that the clearing of CDS transactions by the CCPs subject to the CCP exemptive orders has contributed and we anticipate will continue to contribute to increased transparency and the reduction of systemic risk in the CDS market.

The extension of the Temporary Rules is designed to facilitate the continued operation of CCPs for eligible CDS, which we believe is in the public interest. Once we adopt final rules implementing the clearing provisions of Title VII, including any applicable permanent exemptions, the Temporary Rules affecting solely eligible CDS will no longer be necessary. However, until such time, the Temporary Rules are needed to continue facilitating the operation of the CCPs in clearing eligible CDS without being required to comply with the registration requirements of the Securities Act and Exchange Act and the indenture qualification provisions of the TIA. Therefore, due to the limited time the Temporary Rules will be needed, and our ongoing efforts to implement the provisions of Title VII, we are extending the expiration dates in the Temporary Rules to April 16, 2012. If the Commission adopts permanent exemptions for security-based swaps issued by certain clearing agencies before April 16, 2012, the Commission will terminate the effectiveness of the temporary rules as part of that rulemaking.

III. Certain Administrative Law Matters

Section 553(b) of the Administrative Procedure Act (''APA'')[41] generally requires an agency to publish notice of a proposed rule making in the **Federal Register**. This requirement does not apply, however, if the agency ''for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.''[42] For the reasons we discuss throughout this release, we believe that there is good cause to extend the expiration dates in the Temporary Rules to April 16, 2012. If the Commission adopts permanent exemptions for security-based swaps issued by certain clearing agencies before April 16, 2012, the Commission will terminate the effectiveness of the temporary rules as part of that rulemaking.

We sought comment on the Temporary Rules and as noted above, we received little comment when they were originally promulgated. In addition to the specific comments that we sought and received in connection with the Temporary Rules in January 2009, we have sought public input on implementing the provisions of Title VII, which requires extensive public notice and comment rulemaking regarding proposals that will supplant and subsume the exemptive rules we have crafted as a temporary measure.[43] Further, we have sought and will continue to seek public comment in connection with proposed rulemakings to implement the specific provisions of Title VII relating to the treatment of security-based swaps under the Securities Act and the Exchange Act, including any applicable permanent exemptions. Commenters have full opportunity to provide their views on this new comprehensive regulatory regime.

Absent an extension, the Temporary Rules will expire on July 16, 2011. The Temporary Rules have been in place since January 2009, and CCPs have relied on them in clearing eligible CDS. Extending the expiration dates in the Temporary Rules will not affect the substantive provisions of the Temporary Rules. Extending the expiration dates in the Temporary Rules will allow CCPs to continue to clear eligible CDS without compliance with the registration requirements of the Securities Act and Exchange Act and indenture qualification provisions of the TIA as we consider rules implementing the clearing provisions of Title VII, including any applicable permanent exemptions. Therefore, we believe there is good cause to extend the expiration dates in the Temporary Rules and find that notice and solicitation of comment on the extension to be impracticable, unnecessary, or contrary to the public interest.[44]

The APA also generally requires that an agency publish an adopted rule in the **Federal Register** 30 days before it becomes effective.[45] However, this requirement does not apply if the agency finds good cause not to delay the effective date.[46] For reasons similar to those explained above, the Commission finds good cause not to delay the effective date.

IV. Paperwork Reduction Act

The Temporary Rules do not impose any new ''collections of information'' within the meaning of the Paperwork Reduction Act of 1995 (''PRA''),[47] nor do they create any new filing, reporting, recordkeeping, or disclosure reporting requirements for a CCP that is or will be issuing or clearing eligible CDS. Accordingly, we did not submit the Temporary Rules to the Office of Management and Budget for review in accordance with the PRA when we adopted them in January 2009.[48] We requested comment on whether our conclusion that there are no collections of information is correct, and we did not receive any comment. The extension of the expiration dates in the Temporary Rules does not change our analysis.

V. Cost-Benefit Analysis

In January 2009, we adopted the Temporary Rules, which exempt eligible CDS that are or will be issued or cleared by a CCP and offered and sold only to eligible contract participants from all provisions of the Securities Act, other than the Section 17(a) anti-fraud provision, as well as from the registration requirements under Section 12 of the Exchange Act and from the provisions of the TIA. In September 2009, we adopted amendments to such rules to extend their expiration date to November 30, 2010. We subsequently

[39] As of June 3, 2011, ICE Trust U.S. LLC has cleared 249,249 CDS transactions with a notional value of $11.1 trillion. As of June 3, 2011, ICE Clear Europe, Ltd. has cleared 272,612 CDS transactions with a notional value of €5.5 trillion. *See https://www.theice.com/marketdata/reports/ReportCenter.shtml.*

[40] See footnote 5, *supra.*

[41] 5 U.S.C. 553(b).

[42] 5 U.S.C. 553(b)(B).

[43] *See* footnote 35, *supra.* None of these comments addressed the Temporary Rules.

[44] This finding also satisfies the requirements of 5 U.S.C. 808(2), allowing the rule amendments to become effective notwithstanding the requirements of 5 U.S.C. 801 (if a Federal agency finds that notice and public comment are ''impractical, unnecessary or contrary to the public interest,'' a rule ''shall take effect at such time as the Federal agency promulgating the rule determines.'').

[45] 5 U.S.C. 553(d).

[46] 5 U.S.C. 553(d)(3).

[47] 44 U.S.C. 3501 *et seq.*

[48] 44 U.S.C. 3507(d) and 5 CFR 1320.11.

adopted amendments to such rules to further extend their expiration date from November 30, 2010 to July 16, 2011. The Temporary Rules were intended to facilitate the operation of one or more CCPs to act as a clearing agency in the CDS market to reduce some of the risks in the CDS market. Today, we are adopting amendments to the Temporary Rules to further extend the expiration dates. Since the adoption of the Temporary Rules and the issuance of the exemptive orders, ICE Trust and ICE Clear Europe have been actively engaged as a CCP in clearing CDS transactions in accordance with our exemptions.

The Dodd-Frank Act was enacted on July 21, 2010. Among other things, the Dodd-Frank Act amends the Exchange Act to require that transactions in security-based swaps be cleared through a clearing agency that is either registered with the Commission or exempt from registration if the transactions are of a type that the Commission determines must be cleared, unless an exemption from mandatory clearing applies. As noted above, the Dodd-Frank Act directs us to regulate, among other things, clearing agencies for, and the clearing of, security-based swaps, which include certain CDS, and in separate rulemakings we have and will propose rules to implement the clearing provisions of the Dodd-Frank Act, among others. Extending the expiration dates in the Temporary Rules will continue to facilitate the operation of the CCPs in clearing eligible CDS as we consider rules implementing the clearing provisions of Title VII, including any applicable permanent exemptions.

A. Benefits

Absent the exemptions provided by the Temporary Rules, a CCP may have to file a registration statement covering the offer and sale of eligible CDS that are security-based swaps, may have to satisfy the applicable provisions of the TIA, and may have to register the class of eligible CDS that are security-based swaps that it has issued or cleared under the Exchange Act. The Temporary Rules and the CCP exemptive orders have facilitated the operation of CCPs in the CDS market. Since the adoption of the Temporary Rules, several clearing agencies have been actively engaged as CCPs in clearing CDS transactions in accordance with our exemptions. We believe that extending the expiration dates in the Temporary Rules will continue to facilitate the operation of CCPs [49] and the use by eligible contract participants of CDS CCPs. We believe that the operation of the CCPs in accordance with our exemptions has increased transparency,[50] increased available information about exposures to particular reference entities or reference securities,[51] and reduced risks to participants in the market for CCP-cleared CDS.[52] Not extending the expiration dates in the Temporary Rules could cause significant disruptions in this market. Therefore, we believe that extending the expiration dates in the Temporary Rules provides important benefits to CDS market participants.

B. Costs

We recognize that a consequence of extending the exemptions will be the unavailability of certain remedies under the Securities Act and the Exchange Act and certain protections under the TIA. While an investor will be able to pursue an antifraud action in connection with the purchase and sale of eligible CDS under Exchange Act Section 10(b),[53] it will not be able to pursue civil remedies under Sections 11 or 12 of the Securities Act.[54] We could still pursue an antifraud action in the offer and sale of eligible CDS issued or cleared by a CCP.[55] We believe that the incremental costs from the extension of the expiration dates in the Temporary Rules will be minimal because the amendments are merely an extension of the expiration dates in the Temporary Rules and such extension will not affect information and remedies available to investors as a result of the Temporary Rules.

[49] *See* Karen Brettell, *Banks to submit 95 pct of eligible CDS for clearing* (Sep. 1, 2009), *available at http://www.reuters.com/article/euRegulatoryNews/idUSN0150814420090901?pageNumber=1&virtualBrandChannel=10522.*

[50] *See* Testimony of Mark Lenczowski, Managing Director and Assistant General Counsel at JPMorgan Chase & Co., to the Senate Agriculture Committee (Jun. 4, 2009) (In his testimony, Mr. Lenczowski indicated, in the context of CDS clearing by ICE Trust, that ''[c]learing is a highly transparent process * * * '').

[51] *See* footnote 35, *supra.* None of these comments addressed the Temporary Rules.

[52] *See* Press Release, IntercontinentalExchange, ICE Clear Europe Clears Euro 51 Billion in Third Week of European CDS Processing; Announces New CDS Clearing Member (Aug. 17, 2009), *available at http://ir.theice.com/releasedetail.cfm?ReleaseID=403509. See also,* Press Release, Eurex Clearing AG, Eurex Credit Clear Clears First Single Name CDS Worldwide (Aug. 28, 2009), *available at http://www.eurexclearing.com/about/press/press_647_en.html.*

[53] 15 U.S.C. 78j(b).

[54] 15 U.S.C. 77k and 77l.

[55] *See* 15 U.S.C. 77q and 78j(b).

VI. Consideration of Impact on the Economy, Burden on Competition and Promotion of Efficiency, Competition and Capital Formation

Section 23(a)(2) of the Exchange Act [56] requires us, when adopting rules under the Exchange Act, to consider the impact that any new rule would have on competition. Section 23(a)(2) prohibits us from adopting any rule that would impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. In addition, Section 2(b) [57] of the Securities Act and Section 3(f) [58] of the Exchange Act require us, when engaging in rulemaking where we are required to consider or determine whether an action is necessary or appropriate in the public interest, to also consider, in addition to protection of investors, whether the action will promote efficiency, competition, and capital formation.

The Temporary Rules we are extending today exempt eligible CDS issued or cleared by a CCP from all provisions of the Securities Act, other than the Section 17(a) antifraud provision, as well as from the registration requirements under Section 12 of the Exchange Act and the provisions of the TIA. Because these exemptions are available to any registered or deemed registered CCP offering and selling eligible CDS, we do not believe that extending the exemptions imposes a burden on competition. We also anticipate that extending the ability to settle CDS through CCPs will continue to improve the transparency of the CDS market and provide greater assurance to participants as to the capacity of the eligible CDS counterparty to perform its obligations under the eligible CDS. ICE Trust, for example, makes available on its Web site information about open interests, or net exposure, volume and pricing of CDS transactions. We believe that increased transparency in the CDS market could help to minimize market disruption and thereby facilitate the capital formation process.

VII. Regulatory Flexibility Act Certification

The Commission hereby certifies pursuant to 5 U.S.C. 605(b) that extending the Temporary Rules will not have a significant economic impact on a substantial number of small entities. The Temporary Rules exempt eligible CDS that are or will be issued or cleared by a CCP. None of the entities that are

[56] 15 U.S.C. 78w(a)(2).

[57] 15 U.S.C. 77b(b).

[58] 15 U.S.C. 78c(f).

eligible to meet the requirements of these exemptions is a small entity.

VIII. Statutory Authority and Text of the Rules and Amendments

The amendments described in this release are being adopted under the authority set forth in Sections 18, 19 and 28 of the Securities Act; Sections 12(h), 23(a) and 36 of the Exchange Act; and Section 304(d) of the TIA.

List of Subjects in 17 CFR Parts 230, 240 and 260

Reporting and recordkeeping requirements, Securities.

Text of the Rules and Amendments

We are temporarily amending 17 CFR parts 230, 240, and 260 as follows and the expiration dates in the temporary rules and amendments published January 22, 2009 (74 FR 3967), extended in a release published on September 17, 2009 (74 FR 47719), and further extended in a release published on November 26, 2010 (75 FR 72660), are further extended from July 16, 2011 to April 16, 2012.

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

1. The authority citation for part 230 continues to read, in part, as follows:

Authority: 15 U.S.C. 77b, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78l, 78m, 78n, 78o, 78t, 78w, 78ll(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, unless otherwise noted.

* * * * *

§§ 230.146 and 230.239T [Amended]

■ 2. In § 230.146(c)T, in the last sentence, remove the words ''July 16, 2011'' and add, in their place, the words ''April 16, 2012''.

■ 3. In § 230.239T(e), remove the words ''July 16, 2011'' and add, in their place, the words ''April 16, 2012''.

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 4. The authority citation for part 240 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78l, 78m, 78n, 78o, 78o–4, 78p, 78q, 78s, 78u–5, 78w, 78x, 78ll, 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.;* and 18 U.S.C. 1350; and 12 U.S.C. 5221(e)(3) unless otherwise noted.

* * * * *

§§ 240.12a–10T and 240.12h–1 [Amended]

■ 5. In § 240.12a–10T(b), remove the words ''July 16, 2011'' and add, in their place, the words ''April 16, 2012''.

■ 6. In § 240.12h–1(h)T, in the last sentence, remove the words ''July 16, 2011'' and add, in their place, the words ''April 16, 2012''.

PART 260—GENERAL RULES AND REGULATIONS, TRUST INDENTURE ACT OF 1939

■ 7. The authority citation for part 260 continues to read as follows:

Authority: 15 U.S.C. 77eee, 77ggg, 77nnn, 77sss, 78ll(d), 80b–3, 80b–4, and 80b–11.

* * * * *

§ 260.4d–11T [Amended]

■ 8. In § 260.4d–11T, in the last sentence, remove the words ''July 16, 2011'' and add, in their place, the words ''April 16, 2012''.

By the Commission.

Dated: July 1, 2011.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–17132 Filed 7–7–11; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2011–N–0003]

Oral Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Virbac AH, Inc., to Cross Vetpharm Group Ltd.

DATES: This rule is effective July 8, 2011.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8300, e-mail: *steven.vaughn@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 092–150 for Purina Horse & Colt Wormer (pyrantel tartrate) to Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland. Accordingly, the regulations are amended in 21 CFR 520.2045 to reflect the transfer of ownership.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.2045 [Amended]

■ 2. In paragraph (b)(2) of § 520.2045, remove ''051311'' and in its place add ''061623''.

Dated: July 1, 2011.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2011–17151 Filed 7–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 549

[BOP–1088–F]

RIN 1120–AB20

Psychiatric Evaluation and Treatment

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule.

SUMMARY: In this document, the Bureau of Prisons (Bureau) finalizes regulations on providing psychiatric treatment and medication to inmates. These revised regulations are clarified and updated to reflect current caselaw.

DATES: This rule is effective on August 12, 2011.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307–2105.

SUPPLEMENTARY INFORMATION: The Bureau finalizes regulations on

providing psychiatric treatment and medication to inmates. We first published a proposed regulation document on this subject in the **Federal Register** on December 29, 2003 (68 FR 74892). We then withdrew that proposed regulation document and proposed revised regulations on June 16, 2008 (73 FR 33957). We received four comments, which we address below.

Two commenters addressed § 549.45(b) of the proposed regulation, which states that, ''[p]ursuant to 18 U.S.C. § 4042, the Bureau is authorized to provide for the safekeeping, care, and subsistence, of all persons charged with offenses against the United States, or held as witnesses or otherwise. Accordingly, if an examiner determines pursuant to § 549.43 of this subpart that an inmate not subject to hospitalization pursuant to 18 U.S.C. Chapter 313 should be hospitalized for psychiatric care or treatment, and the inmate is unwilling or unable to consent, the Bureau will provide the inmate with an administrative hearing to determine whether hospitalization for psychiatric care or treatment is warranted. The hearing will comply with the applicable procedural safeguards set forth in § 549.46(a).''

The commenters believe that ''the administrative hearing process'' under this section ''is a standard that provides less procedural protection to the inmate than does a court determination.'' The commenters felt that ''such a standard is unreasonable and unfair to the inmates covered by § 549.45(b)'' because these inmates may include ''material witnesses and other detainees who may not have been convicted,'' and are, therefore, ''entitled to a level of review equal to or surpassing that of sentenced inmates.''

In response, we note that proposed § 549.45 states that a court determination is necessary for involuntary hospitalization or commitment of inmates pursuant to 18 U.S.C. Chapter 313, who are in need of psychiatric care or treatment, but are unwilling or unable to voluntarily consent. Section 4245 in that chapter specifically provides for involuntary hospitalization by court order of a person serving a sentence of imprisonment if needed for psychiatric care or treatment. The necessity of a court determination for these types of inmates is, therefore, prescribed by statute.

In contrast, however, no court determination is prescribed by statute with regard to involuntary hospitalization of inmates who are not subject to hospitalization under 18 U.S.C. 4245 (because not serving a sentence of imprisonment), such as alien detainees subject to an order of deportation, exclusion or removal, material witnesses, contempt of court commitments, *etc.*

Nevertheless, the Director has chosen to provide administrative due process with regard to involuntary hospitalization of such inmates, ''[b]ecause prisoners facing involuntary transfer to a mental hospital are threatened with immediate deprivation of liberty interests they are currently enjoying, and because of the inherent risk of a mistaken transfer,'' adhering to the principles set forth in *Vitek* v. *Jones,* 445 U.S. 480 at 495, 100 S.Ct. 1254 at 1265 (1980).

We note that the availability of this administrative hearing procedure in appropriate cases does not limit the Bureau's ability to seek judicial hospitalization or commitment of inmates under any applicable provision of Chapter 313, such as judicial commitment of inmates, whether sentenced or unsentenced, as sexually dangerous persons under 18 U.S.C. 4248.

However, because the commenters appear to question or misunderstand the due process procedures that the Bureau implements through this final rule that specifically apply to the involuntary hospitalization of inmates who are not subject to hospitalization under 18 U.S.C. 4245, we alter § 549.45(b) as follows: We delete the reference to the due process procedures in § 549.46(a) and simply restate them, tailored for reference to involuntary hospitalization instead of involuntary administration of psychiatric medication, in the relevant regulation, § 549.45(b).

Also, the American Psychiatric Association (APA) and the American Civil Liberties Union (ACLU) commented regarding the Bureau's use of the phrase 'qualified health services staff' in § 549.44 of the proposed regulation. The APA recommended that the Bureau ''clarify this section by either revising the proposed language in the regulation or issuing a policy guide which defines which personnel are considered 'qualified health services staff' for the purposes of these sections.'' The ACLU provided a similar comment. The Bureau will issue a policy guide, as suggested by the APA, which will clarify the qualifications for staff with regard to voluntary hospitalization in a suitable facility for psychiatric care or treatment, and voluntary administration of psychiatric medication. Bureau policy guides are called Program Statements, and are designed specifically to provide more detailed staff guidance with regard to implementing Bureau regulations, policies, and programs. Because Program Statements are the primary vehicle for staff guidance, it would be appropriate to detail health services staff qualifications in the relevant Bureau Program Statements.

Also, the APA would ''urge that [the Bureau] state that only licensed physicians are qualified to make decisions about the administration of psychopharmacologic medications and that, when possible, a psychiatrist should be consulted. This clarification would provide assurance that inmates are receiving appropriate mental health treatment and that consent to any hospitalization or medication is truly warranted and voluntary and meets state and Federal law requirements.'' Likewise, the ACLU commented that ''the regulations should be amended to clarify that the exception authorizing more cursory procedures for emergencies requires that any treatment be 'medically' appropriate, even in an emergency.''

In response, we state that Bureau policy currently requires that psychiatric medications be prescribed only by Bureau medical health professionals that have a permanent, full, and unrestricted license to practice medicine in a state, District of Columbia, the Commonwealth of Puerto Rico, or a territory of the United States. Bureau policy on pharmacy services is predicated on the requirement that the use of psychiatric medications and controlled substances be restricted to physicians only and prescribed only when medically appropriate. Further, if an order for psychiatric medication is prepared or written by a mid-level practitioner (Physician's Assistant or Nurse Practitioner), it must be signed by a licensed physician before it can be filled by a pharmacist.

Another commenter suggested that the Bureau ''recognize psychiatric advance practice nurses as part of the treatment team in correctional facilities.'' While the Bureau does utilize nurse practitioners, physician's assistants, and nurses, as stated above, any prescription for psychiatric medication must be signed by a licensed physician.

For the aforementioned reasons, we now finalize the proposed rule published on June 16, 2008 (73 FR 33957), with minor changes for clarity.

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review'', section 1(b), Principles of

Regulation. The Director has determined that this regulation is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), and accordingly this regulation has not been reviewed by the Office of Management and Budget.

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, under Executive Order 13132, we determine that this regulation does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act

The Director, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), reviewed this regulation and by approving it certifies that it will not have a significant economic impact upon a substantial number of small entities for the following reasons: This regulation pertains to the correctional management of offenders committed to the custody of the Attorney General or the Director, and its economic impact is limited to the Bureau's appropriated funds.

Unfunded Mandates Reform Act of 1995

This regulation will not result in the expenditure by State, local and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This regulation is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This regulation will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 28 CFR Part 549

Prisoners.

Thomas R. Kane,

Acting Director, Federal Bureau of Prisons.

Under the rulemaking authority vested in the Attorney General in 5 U.S.C. 552(a) and delegated to the Director, Bureau of Prisons, we amend 28 CFR part 549 as follows.

PART 549—MEDICAL SERVICES

■ 1. Revise the authority citation for 28 CFR part 549 to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. 876b; 18 U.S.C. 3621, 3622, 3524, 4001, 4005, 4042, 4045, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), Chapter 313, 5006–5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510.

■ 2. Revise subpart C of part 549 to read as follows:

Subpart C—Psychiatric Evaluation and Treatment

Sec.

549.40 Purpose and scope.
549.41 Hospitalization in a suitable facility.
549.42 Use of psychiatric medications.
549.43 Transfer for psychiatric or psychological examination.
549.44 Voluntary hospitalization in a suitable facility for psychiatric care or treatment and voluntary administration of psychiatric medication.
549.45 Involuntary hospitalization in a suitable facility for psychiatric care or treatment.
549.46 Procedures for involuntary administration of psychiatric medication.

Subpart C—Psychiatric Evaluation and Treatment

§ 549.40 Purpose and scope.

(a) This subpart describes procedures for voluntary and involuntary psychiatric evaluation, hospitalization, care, and treatment, in a suitable facility, for persons in Bureau of Prisons (Bureau) custody. These procedures are authorized by 18 U.S.C. Chapter 313 and 18 U.S.C. 4042.

(b) This subpart applies to inmates in Bureau custody, as defined in 28 CFR part 500.

§ 549.41 Hospitalization in a suitable facility.

As used in 18 U.S.C. Chapter 313 and this subpart, ''hospitalization in a suitable facility'' includes the Bureau's designation of inmates to medical referral centers or correctional institutions that provide the required care or treatment.

§ 549.42 Use of psychiatric medications.

Psychiatric medications will be used only for treatment of diagnosable mental illnesses and disorders, and their symptoms, for which such medication is accepted treatment. Psychiatric medication will be administered only after following the applicable procedures in this subpart.

§ 549.43 Transfer for psychiatric or psychological examination.

The Bureau may transfer an inmate to a suitable facility for psychiatric or psychological examination to determine whether hospitalization in a suitable facility for psychiatric care or treatment is needed.

§ 549.44 Voluntary hospitalization in a suitable facility for psychiatric care or treatment, and voluntary administration of psychiatric medication.

(a) *Hospitalization.* An inmate may be hospitalized in a suitable facility for psychiatric care or treatment after providing informed and voluntary consent when, in the professional medical judgment of qualified health services staff, such care or treatment is required and prescribed.

(b) *Psychiatric medication.* An inmate may also provide informed and voluntary consent to the administration of psychiatric medication that complies with the requirements of § 549.42 of this subpart.

(c) *Voluntary consent.* An inmate's ability to provide informed and voluntary consent for both hospitalization in a suitable facility for psychiatric care or treatment, and administration of psychiatric medications, will be assessed by qualified health services staff and documented in the inmate's medical record. Additionally, the inmate must sign a consent form to accept hospitalization in a suitable facility for psychiatric care or treatment and the administration of psychiatric medications. These forms will be maintained in the inmate's medical record.

§ 549.45 Involuntary hospitalization in a suitable facility for psychiatric care or treatment.

(a) *Hospitalization of inmates pursuant to 18 U.S.C. Chapter 313.* A court determination is necessary for involuntary hospitalization or commitment of inmates pursuant to 18 U.S.C. Chapter 313, who are in need of psychiatric care or treatment, but are unwilling or unable to voluntarily consent.

(b) *Hospitalization of inmates not subject to hospitalization pursuant to 18 U.S.C. chapter 313.* Pursuant to 18

U.S.C. 4042, the Bureau is authorized to provide for the safekeeping, care, and subsistence, of all persons charged with offenses against the United States, or held as witnesses or otherwise. Accordingly, if an examiner determines pursuant to § 549.43 of this subpart that an inmate not subject to hospitalization pursuant to 18 U.S.C. chapter 313 should be hospitalized for psychiatric care or treatment, and the inmate is unwilling or unable to consent, the Bureau will provide the inmate with an administrative hearing to determine whether hospitalization for psychiatric care or treatment is warranted. The hearing will provide the following procedural safeguards:

(1) The inmate will not be involuntarily administered psychiatric medication before the hearing except in the case of psychiatric emergencies, as defined in § 549.46(b)(1).

(2) The inmate must be provided 24-hours advance written notice of the date, time, place, and purpose, of the hearing, including an explanation of the reasons for the proposal to hospitalize the inmate for psychiatric care or treatment.

(3) The inmate must be informed of the right to appear at the hearing, to present evidence, to have a staff representative, to request witnesses, and to request that witnesses be questioned by the staff representative or by the person conducting the hearing. If the inmate does not request a staff representative, or requests a staff representative with insufficient experience or education, or one who is not reasonably available, the institution mental health division administrator must appoint a qualified staff representative.

(4) The hearing is to be conducted by a psychiatrist other than the attending psychiatrist, and who is not currently involved in the diagnosis or treatment of the inmate.

(5) Witnesses should be called if they are reasonably available and have information relevant to the inmate's mental condition or need for hospitalization. Witnesses who will provide only repetitive information need not be called.

(6) A treating/evaluating psychiatrist/clinician, who has reviewed the case, must be present at the hearing and must present clinical data and background information relative to the inmate's need for hospitalization. Members of the treating/evaluating team may also be called as witnesses at the hearing to provide relevant information.

(7) The psychiatrist conducting the hearing must determine whether involuntary hospitalization is necessary because the inmate is presently suffering from a mental disease or defect for the treatment of which he is in need of custody for care or treatment in a suitable facility.

(8) The psychiatrist must prepare a written report regarding the initial decision. The inmate must be promptly provided a copy of the initial decision report, and informed that he/she may appeal it to the institution's mental health division administrator. The inmate's appeal, which may be handwritten, must be submitted within 24 hours after receipt of the hearing officer's report. Upon request of the inmate, the staff representative will assist the inmate in preparing and submitting the appeal.

(9) If the inmate appeals the initial decision, hospitalization must not occur before the administrator issues a decision on the appeal. The inmate's appeal will ordinarily be reviewed by the administrator or his designee within 24 hours of its submission. The administrator will review the initial decision and ensure that the inmate received all necessary procedural protections, and that the justification for hospitalization is appropriate.

(c) *Psychiatric medication.* Following an inmate's involuntary hospitalization for psychiatric care or treatment as provided in this section, psychiatric medication may be involuntarily administered only after following the administrative procedures provided in § 549.46 of this subpart.

§ 549.46 Procedures for involuntary administration of psychiatric medication.

Except as provided in paragraph (b) of this section, the Bureau will follow the administrative procedures of paragraph (a) of this section before involuntarily administering psychiatric medication to any inmate.

(a) *Procedures.* When an inmate is unwilling or unable to provide voluntary written informed consent for recommended psychiatric medication, the inmate will be scheduled for an administrative hearing. The hearing will provide the following procedural safeguards:

(1) Unless an exception exists as provided in paragraph (b) of this section, the inmate will not be involuntarily administered psychiatric medication before the hearing.

(2) The inmate must be provided 24-hours advance written notice of the date, time, place, and purpose, of the hearing, including an explanation of the reasons for the psychiatric medication proposal.

(3) The inmate must be informed of the right to appear at the hearing, to present evidence, to have a staff representative, to request witnesses, and to request that witnesses be questioned by the staff representative or by the person conducting the hearing. If the inmate does not request a staff representative, or requests a staff representative with insufficient experience or education, or one who is not reasonably available, the institution mental health division administrator must appoint a qualified staff representative.

(4) The hearing is to be conducted by a psychiatrist other than the attending psychiatrist, and who is not currently involved in the diagnosis or treatment of the inmate.

(5) Witnesses should be called if they are reasonably available and have information relevant to the inmate's mental condition or need for psychiatric medication. Witnesses who will provide only repetitive information need not be called.

(6) A treating/evaluating psychiatrist/clinician, who has reviewed the case, must be present at the hearing and must present clinical data and background information relative to the inmate's need for psychiatric medication. Members of the treating/evaluating team may also be called as witnesses at the hearing to provide relevant information.

(7) The psychiatrist conducting the hearing must determine whether involuntary administration of psychiatric medication is necessary because, as a result of the mental illness or disorder, the inmate is dangerous to self or others, poses a serious threat of damage to property affecting the security or orderly running of the institution, or is gravely disabled (manifested by extreme deterioration in personal functioning).

(8) The psychiatrist must prepare a written report regarding the initial decision. The inmate must be promptly provided a copy of the initial decision report, and informed that he/she may appeal it to the institution's mental health division administrator. The inmate's appeal, which may be handwritten, must be submitted within 24 hours after receipt of the hearing officer's report. Upon request of the inmate, the staff representative will assist the inmate in preparing and submitting the appeal.

(9) If the inmate appeals the initial decision, psychiatric medication must not be administered before the administrator issues a decision on the appeal, unless an exception exists as provided in paragraph (b) of this section. The inmate's appeal will ordinarily be reviewed by the administrator or his designee within 24

hours of its submission. The administrator will review the initial decision and ensure that the inmate received all necessary procedural protections, and that the justification for administering psychiatric medication is appropriate.

(10) If an inmate was afforded an administrative hearing which resulted in the involuntary administration of psychiatric medication, and the inmate subsequently consented to the administration of such medication, and then later revokes his consent, a follow-up hearing will be held before resuming the involuntary administration of psychiatric medication. All such follow-up hearings will fully comply with the procedures outlined in paragraphs (a)(1) through (10) of this section.

(b) *Exceptions.* The Bureau may involuntarily administer psychiatric medication to inmates in the following circumstances without following the procedures outlined in paragraph (a) of this section:

(1) *Psychiatric emergencies.*

(i) During a psychiatric emergency, psychiatric medication may be administered only when the medication constitutes an appropriate treatment for the mental illness or disorder and its symptoms, and alternatives (*e.g.,* seclusion or physical restraint) are not available or indicated, or would not be effective. If psychiatric medication is still recommended after the psychiatric emergency, and the emergency criteria no longer exist, it may only be administered after following the procedures in §§ 549.44 or 549.46 of this subpart.

(ii) For purposes of this subpart, a psychiatric emergency exists when a person suffering from a mental illness or disorder creates an immediate threat of:

(A) Bodily harm to self or others;

(B) Serious destruction of property affecting the security or orderly running of the institution; or

(C) Extreme deterioration in personal functioning secondary to the mental illness or disorder.

(2) *Court orders for the purpose of restoring competency to stand trial.* Absent a psychiatric emergency as defined above, § 549.46(a) of this subpart does not apply to the involuntary administration of psychiatric medication for the sole purpose of restoring a person's competency to stand trial. Only a Federal court of competent jurisdiction may order the involuntary administration of psychiatric medication for the sole purpose of restoring a person's competency to stand trial.

[FR Doc. 2011–17160 Filed 7–7–11; 8:45 am]

BILLING CODE 4410–05–P

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy (DoN) is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG)(Admiralty and Maritime Law) has determined that USS PITTSBURGH (SSN 720) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

DATES: This rule is effective July 8, 2011 and is applicable beginning June 29, 2011.

FOR FURTHER INFORMATION CONTACT: Lieutenant Jaewon Choi, (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave., SE., Suite 3000, Washington Navy Yard, DC 20374–5066, telephone 202–685–5040.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the DoN amends 32 CFR part 706.

This amendment provides notice that the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS PITTSBURGH (SSN 720) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provision of 72 COLREGS without interfering with its special function as a naval ship: Rule 21 (a) pertaining to the centerline position of the masthead light. The DAJAG (Admiralty and Maritime Law) has also certified that the light involved is located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), and Vessels.

For the reasons set forth in the preamble, the Navy amends part 706 of title 32 of the Code of Federal Regulations as follows:

PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

■ 1. The authority citation for part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

■ 2. Section 706.2 is amended in Table Two by amending, in alpha numerical order, by vessel number, an entry for USS PITTSBURGH (SSN 720) to read as follows:

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

* * * * *

TABLE TWO

Vessel	Number	Masthead lights, distance to stbd of keel in meters; Rule 21(a)	Forward anchor light, distance below flight dk in meters; § 2(K), Annex I	Forward anchor light, number of; Rule 30(a)(i)	Aft anchor light, distance below flight dk in meters; Rule 21(e), Rule 30(a)(ii)	Aft anchor light, number of; Rule 30(a)(ii)	Side lights, distance below flight dk in meters; § 2(g), Annex I	Side lights, distance forward of forward masthead light in meters; § 3(b), Annex I	Side lights, distance inboard of ship's sides in meters; § 3(b), Annex I
*	*	*		*	*		*	*	
USS PITTSBURG	SSN 720	0.41							
*	*	*		*	*		*	*	

* * * * *

Approved: June 29, 2011.

M. Robb Hyde,

Commander, JAGC, U.S. Navy, Deputy Assistant Judge Advocate, General (Admiralty and Maritime Law.

Dated: July 1, 2011.

D.J. Werner,

Lieutenant Commander, Office of the Judge Advocate General, U.S. Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 2011–17150 Filed 7–7–11; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–0509]

RIN 1625–AA09

Drawbridge Operation Regulations; Harlem River, New York City, NY

AGENCY: Coast Guard, DHS.

ACTION: Temporary interim rule with request for comments.

SUMMARY: The Coast Guard is temporarily changing the drawbridge operating regulations governing the operation of the 103rd Street (Wards Island) Pedestrian Bridge at mile 0.0, across the Harlem River at New York City, New York. This interim rule is necessary to facilitate the completion of a major bridge rehabilitation project at the 103rd Street (Wards Island) Pedestrian Bridge while soliciting comments from the public.

DATES: This rule is effective in the CFR from July 8, 2011 through September 30, 2011. This rule is effective with actual notice for purposes of enforcement on July 9, 2011 and is effective through September 30, 2011. Comments and related material must reach the Coast Guard on or before August 8, 2011.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2011–0509 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail:* 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.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

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

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail Mr. Gary Kassof, Project Officer, First Coast Guard District, (212) 668–7165, *Gary.kassof@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:

Public Participation and Request for Comments

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

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2011–0509), indicate the specific section of this document to which each comment applies, and give the reason for each suggestion or recommendation. You may submit your comments and material online, 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 delivery, 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 e-mail 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–2011–0509'' 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 this rule based on your comments.

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–2011–0509'' and click ''Search.'' Click the ''Open Docket Folder'' in the ''Actions'' column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200

New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of all 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, system of records notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one on or before August 8, 2011 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**.

Regulatory Information

The Coast Guard is issuing this temporary interim rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)).

This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule.

The Coast Guard previously issued two temporary deviations from the regulation governing the operation of the 103rd Street (Wards Island) Pedestrian Bridge to facilitate completion of a major rehabilitation project. The first temporary deviation was effective from January 10, 2011 through April 29, 2011. The second temporary deviation became effective on April 30, 2011 and will end on July 8, 2011.

The bridge owner, New York City Department of Transportation, advised the Coast Guard on May 27, 2011, that they recently discovered additional areas of the bridge that are in need of repair, and that the rehabilitation project will not be completed by July 8, 2011. The rehabilitation repairs must be completed before the bridge will be able to open again for the passage of vessel traffic.

It is impractical to issue a NPRM and take public comment before the current temporary deviation expires on July 8, 2011.

We are requesting public comment on the temporary change to the regulation governing the operation of the 103rd Street (Wards Island) Pedestrian Bridge. If we receive public input that indicates a need to revise the temporary change to the drawbridge's operating regulation, or the conditions it imposes, or raises any other significant public concerns, we will address those concerns prior to issuing any final rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard also finds good cause exists, for the same reasons discussed above, for making this rule effective less than 30 days after publication in the **Federal Register**.

Basis and Purpose

The 103rd Street (Wards Island) Pedestrian Bridge, across the Harlem River, mile 0.0, at New York City, New York, has a vertical clearance in the closed position of 55 feet at mean high water and 60 feet at mean low water. Most vessel traffic that uses this waterway can fit under the draw without requiring bridge openings. The drawbridge operation regulations are listed at 33 CFR 117.789(b)(1).

The bridge has remained in the closed position since January 10, 2011, in order to complete its rehabilitation. The owner of the bridge, New York City Department of Transportation, has requested an extension of the bridge closure to complete unforeseen additional repairs.

The Coast Guard published a temporary deviation from the regulation governing the operation of the 103rd Street (Wards Island) Pedestrian Bridge on January 20, 2011, (76 FR 3516), authorizing the bridge to remain in the closed position effective from January 10, 2011 through April 29, 2011. The bridge owner requested a second temporary deviation on March 21, 2011, to complete the rehabilitation repairs at the bridge. As a result, the Coast Guard published a second temporary deviation on April 11, 2011, (76 FR 19910), effective from April 30, 2011 through July 8, 2011.

On May 27, 2011, the bridge owner requested an extension of the bridge closure through September 30, 2011. They advised the Coast Guard that work would not be completed before the second temporary deviation ended on July 8, 2011, because the bridge owner recently discovered additional areas of the bridge that are in need of repair.

Because the requested extension of the bridge closure would exceed 180 days, we are issuing a temporary interim rule requesting public comment in order to both facilitate completion of the bridge rehabilitation and to have the public participate in the rulemaking process.

Under this temporary interim rule, the 103rd Street (Wards Island) Pedestrian Bridge may remain in the closed position from July 9, 2011 through September 30, 2011.

Discussion of Rule

The Coast Guard is temporarily changing the drawbridge operation regulations listed at 33 CFR 117.789(b)(1).

This temporary interim rule for the 103rd Street (Wards Island) Pedestrian Bridge will allow the bridge to remain in the closed position from July 9, 2011 through September 30, 2011, to facilitate completion of bridge rehabilitation repairs.

Regulatory Analysis

We developed this interim rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analysis based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

The Coast Guard determined that this rule is not a significant regulatory action for the following reasons. The bridge presently can't open for vessel traffic due to the fact that rehabilitation repairs have not been completed. This action will facilitate completion of the bridge repairs. Most vessel traffic that uses this waterway can fit under the draw without requiring bridge openings. Vessels that cannot pass under the closed draw may take an alternate route on the Hudson River.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule will have a significant

economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under section 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit the bridge.

This action will not have a significant economic impact on a substantial number of small entities for the following reasons. The bridge presently cannot open for the passage of vessel traffic because the rehabilitation repairs are not completed. This action will facilitate completion of the bridge repairs. Most vessel traffic that uses this waterway can fit under the draw without requiring bridge openings. Vessels that cannot pass under the closed draw may take an alternate route using the Hudson River.

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 (Public Law 104–121), we offer to assist small entities in understanding the temporary interim rule so that they can better evaluate its effects on them and participate in the rulemaking. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

This 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.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order 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 Office 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

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

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 5100.1, and Commandant Instruction M16475.1D, 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 not likely to have a significant effect on the human environment because it simply promulgates the operating regulations or procedures for drawbridges. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

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.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard is amending 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(g); Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 117.789, paragraph (b)(1) is temporarily suspended from July 9, 2011 through September 30, 2011, and paragraph (b)(3) is temporarily added from July 9, 2011 through September 30, 2011, to read as follows:

§ 117.789 Harlem River.

* * * * *

(b)(3) The draws of the bridges at 103 Street, mile 0.0, need not open for the passage of vessel traffic from July 9, 2011, through September 30, 2011. The draws of the 125 Street (Triborough) bridge, mile 1.3, the Willis Avenue Bridge, mile 1.9, the Madison Avenue Bridge, mile 2.3, the 145 Street Bridge, mile 2.8, the Macombs Dam Bridge, mile 3.2, the 207 Street Bridge, mile 6.0, and the Broadway Bridge, mile 6.8, shall open on signal if at least a four hour advance notice is given to the New York City Highway Radio (Hotline) Room and the Triborough Bridge and Tunnel Authority (TBTA) for the 125 Street (Triborough) Bridge at mile 1.3. The draws of the above bridges, except the Broadway Bridge, need not open for the passage of vessel traffic from 6 a.m. to 9 a.m., and 5 p.m. to 7 p.m., Monday through Friday, except Federal holidays. The draw of the Broadway Bridge need not open for the passage of vessel traffic from 7 a.m. to 10 a.m. and 4 p.m. to 7 p.m., Monday through Friday, except Federal holidays.

* * * * *

Dated: June 22, 2011.

Daniel A. Neptun,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 2011–17115 Filed 7–7–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–0594]

Drawbridge Operation Regulation; Illinois Waterway, Near Morris, IL

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Elgin, Joliet, and Eastern Railroad Drawbridge across the Illinois Waterway, mile 270.6, near Morris, Illinois. The deviation is necessary to allow removal of the existing lift span and installation of the replacement lift span. This deviation allows the bridge to be maintained in the closed-to-navigation position for eighty-four hours.

DATES: This deviation is effective starting 7 a.m. on July 9, 2011 through 7 p.m. on July 12, 2011.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–0594 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–0594 in the ''Keyword'' box and then clicking ''Search''. They are also available for inspection or copying at the 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Eric A. Washburn, Bridge Administrator, Western Rivers, Coast Guard; telephone (314) 269–2378, e-mail *Eric.Washburn@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The Canadian National Railroad requested a temporary deviation for Elgin, Joliet, and Eastern Railroad Drawbridge, across the Illinois Waterway, mile 270.6, near Morris, Illinois to remain in the closed-to-navigation position for eighty-four hours while the existing lift span is removed and the replacement lift span is installed. The Elgin, Joliet, and Eastern Railroad Drawbridge currently operates in accordance with 33 CFR 117.5, which states the general requirement that drawbridges shall open promptly and fully for the passage of vessels when a request to open is given in accordance with the subpart.

There are no alternate routes for vessels transiting this section of the Illinois Waterway.

The Elgin, Joliet, and Eastern Railroad Drawbridge, in the closed-to-navigation position, provides a vertical clearance of 26.3 feet above flat pool. Due to construction activities, vessels will be unable to pass the bridge site during this 84-hour period. Navigation on the waterway consists primarily of commercial tows and recreational watercraft. This temporary deviation has been coordinated with waterway users. No objections were received.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: June 22, 2011.

Eric A. Washburn,

Bridge Administrator, Western Rivers.

[FR Doc. 2011–17111 Filed 7–7–11; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2006–0601; FRL–9223–4]

Approval and Disapproval and Promulgation of Air Quality Implementation Plans; Montana; Revisions to the Administrative Rules of Montana—Air Quality, Subchapter 7 and Other Subchapters

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is partially approving and partially disapproving State Implementation Plan (SIP) revisions submitted by the State of Montana on August 26, 1999, May 28, 2003, March 9, 2004, October 25, 2005, and October 16, 2006. The revisions contain new, amended, and repealed rules in Subchapter 7 (Permit, Construction, and Operation of Air Contaminant Sources) that pertain to the issuance of Montana air quality permits, in addition to other minor administrative changes to other subchapters of the Administrative Rules of Montana (ARM). In this action, EPA is approving those portions of the rules that are approvable and disapproving those portions of the rules that are

inconsistent with the Clean Air Act (CAA). This action is being taken under section 110 of the CAA.

DATES: *Effective Date:* This final rule is effective August 8, 2011.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2006–0601. All documents in the docket are listed in the *http://www.regulations.gov* Web site. 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 *http://www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Kevin Leone, Air Program, Mailcode 8P–AR, Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6227, or *leone.kevin@epa.gov*.

SUPPLEMENTARY INFORMATION:

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The initials *SIP* mean or refer to State Implementation Plan.

(iv) The words *State* or *Montana* mean the State of Montana, unless the context indicates otherwise.

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I. Background and Purpose

The CAA (section 110(a)(2)(C)) and 40 CFR 51.160 require states to have legally enforceable procedures to prevent construction or modification of a source if it would violate any SIP control strategies or interfere with attainment or maintenance of the National Ambient Air Quality Standards (NAAQS). Such minor New Source Review (NSR) programs are for pollutants from stationary sources that do not require Prevention of Significant Deterioration (PSD) or nonattainment NSR permits. States may customize the requirements of the minor NSR program as long as their program meets minimum requirements.

In a proposed rule action published on March 4, 2010, EPA proposed to partially approve and partially disapprove revisions to the State of Montana's State Implementation Plan (SIP) submitted on August 26, 1999, May 28, 2003, March 9, 2004, October 25, 2005, and October 16, 2006 (as described below). The revisions contain new, amended, and repealed rules in Subchapter 7 (Permit, Construction and Operation of Air Contaminant Sources) that pertain to the issuance of Montana air quality permits, and in addition other subchapters of the ARM.

A. August 26, 1999 Submittal

On August 26, 1999, the Governor of Montana submitted a SIP revision request. The revision contains amended and repealed rules to various subchapters in the ARM that were adopted by the Montana Board of Environmental Review (Board) on May 14, 1999. Specific to Subchapter 7 (Permit, Construction, and Operation of Air Contaminant Sources), the submittal revised ARM 17.8.705 and 17.8.733 and repealed ARM 17.8.708. However, as indicated below, a May 28, 2003 submittal rescinded the August 26, 1999 revisions to ARM 17.8.705 and 17.8.733.

B. May 28, 2003 Submittal

On May 28, 2003, the Governor of Montana submitted a SIP revision request. The revision contains new, amended, and repealed rules adopted by the Board on December 6, 2002. The new and repealed rules pertain to the issuance of Montana air quality permits and are in Subchapter 7 of the ARM. The amended rules contain references to the new and repealed rules.

The new rules include: ARM 17.8.740, 17.8.743, 17.8.744, 17.8.745, 17.8.748, 17.8.749, 17.8.752, 17.8.755, 17.8.756, 17.8.759, 17.8.760, 17.8.762, 17.8.763, 17.8.764, 17.8.765, 17.8.767, and 17.8.770.

The repealed SIP-approved rules include: ARM 17.8.701, 17.8.702, 17.8.704, 17.8.705, 17.8.706, 17.8.707, 17.8.710, 17.8.715, 17.8.716, 17.8.717, 17.8.720, 17.8.730, 17.8.731, 17.8.732, 17.8.733, and 17.8.734.

The amended SIP-approved rules include: ARM 17.8.101, 17.8.110, 17.8.309, 17.8.310, 17.8.818, 17.8.825, 17.8.826, 17.8.901, 17.8.904, 17.8.905, 17.8.906, 17.8.1004, 17.8.1005, 17.8.1106, and 17.8.1109.

The May 28, 2003 submittal also rescinded outstanding SIP submissions for rules that amended the following: ARM 17.8.702, adopted July 20, 2001 and submitted on December 20, 2001 [1]; and ARM 17.8.705 and 17.8.733, adopted on May 14, 1999 and submitted on August 26, 1999.

C. March 9, 2004 Submittal

On March 9, 2004, the Governor of Montana submitted a SIP revision request. The revision contains amended rules adopted by the Board on September 26, 2003. The amended rules pertain to the issuance of Montana air quality permits. The following rules were amended: ARM 17.8.749, 17.8.759, 17.8.763, and 17.8.764.

D. October 25, 2005 Submittal

On October 25, 2005, the Governor of Montana submitted a SIP revision request. The revision contains amended rules adopted by the Board on June 3, 2005. EPA approved all of the October 25, 2005 submittal on July 19, 2006 (71 FR 40922), except for ARM 17.8.767. We are addressing ARM 17.8.767 in this action.

E. October 16, 2006 Submittal

On October 16, 2006, the Governor of Montana submitted a SIP revision request. The revision contains an amended rule for ARM 17.8.743(1) and new rules codified as ARM 17.8.1601, 17.8.1602, 17.8.1603, 17.8.1604, 17.8.1605, and 17.8.1606, and ARM 17.8.759 adopted by the Board on December 2, 2005. The submittal also requested to withdraw ARM 17.8.743(1)(c) from being incorporated into the SIP. We are addressing ARM 17.8.759 in this action. The revision to ARM 17.8.743(1) and the new rules pertain to the regulation of oil and gas well facilities, and we will address this revision request in a separate action.

II. Response to Comments

EPA received one letter from WildEarth Guardians (WG) commenting on EPA's **Federal Register** action proposing approval and disapproval of the Montana SIP Provisions in Docket

[1] Note that the May 28, 2003 submittal requested rescinding revisions to ARM 17.8.702, adopted on July 20, 2001 and submitted on December 20, 2001. EPA had already approved the revisions to ARM 17.8.702 (see 67 FR 55125, 8/28/02, and 40 CFR 52.1370(c)(55)) by the time we had received the May 28, 2003 letter. However, the May 28, 2003 submittal also requests that all of ARM 17.8.702 be repealed. We are proposing to remove ARM 17.8.702 from the federally-approved SIP.

ID No. EPA–R08–OAR–2006–0601. In this section EPA responds to the significant adverse comments made by the commenter.

Comment No. 1—The commenter opposed EPA's approval of ARM 17.8.743(2) and (3). The commenter alleges that these rules directly contradict 40 CFR 51.160. To the extent the commenter makes this argument, EPA responds below.

EPA Response—EPA disagrees with the commenter's assessment. First, the commenter references 40 CFR 51.160(b) in particular, the requirement that a plan must set forth legally enforceable procedures which include a means for the State or local permitting agency to prevent construction or modification of a source if it will interfere with applicable portions of the control strategy or the attainment or maintenance of a national standard. The commenter asserts that ARM 17.8.743(2) allows a stationary source to initiate construction activities upon receipt of a ''completeness determination'' pursuant to ARM 17.8.759 and that the ''completeness determination'' requirements are insufficient to show compliance with 40 CFR 51.160(b).

EPA has determined the Montana rules are consistent with the CAA and EPA regulations, and therefore approvable as a SIP revision. Section 110(a)(2)(C) of the CAA requires that SIPs include a program for regulating the construction and modification of stationary sources as necessary to ensure that the NAAQS are achieved. The Montana regulations clearly regulate the construction and modification of stationary sources and ensure that the NAAQS will be met. In addition, as explained in the proposed rule, EPA's regulations at 40 CFR 51.160 do not require the issuance of a permit for the construction or modification of minor sources, but only that the SIP include legally enforceable procedures to prevent the construction of a source or modification that would violate the SIP control strategy or interfere with attainment or maintenance of the NAAQS. EPA-approved SIP minor NSR programs in several states do not require permits prior to construction, but instead contain other enforceable procedures. See 75 FR 54562 (Sept. 26, 2007) (Missouri), 68 FR 2217 (Jan. 16, 2003) (Idaho).

Montana's rules include enforceable procedures to prevent the construction of any source or modification that would violate SIP requirements. In determining whether or not the SIP includes these legally enforceable procedures, EPA does not look at a particular component of an implementation plan in isolation (such as ARM 17.8.743(2) and (3)). EPA must be able to determine that, with the revisions in place, the whole ''plan as revised'' meets the requirements of 51.160. In addition, Montana's rule contains sufficient safeguards to meet the requirements of 51.160. First, the State is not obligated to issue a permit where the owner or operator received a completeness determination. ARM 17.8.743(4). Second, the rule contains a provision indicating that if the owner or operator proceeds with the initial construction activities it accepts the regulatory risks of engaging in such activities. ARM 17.8.743(4). Third, Montana's rule contains safeguards regarding the type of activity allowed before permit issuance. The rule only allows installing concrete foundations work, below ground plumbing, installing ductwork, and other infrastructure and/or excavation work involving the same. ARM 17.8.743(2). Fourth, the rule specifically prohibits the construction or installation of emission units (without a permit or a State determination that the unit will not interfere with the NAAQS or a control strategy). ARM 17.8.743(2). Thus EPA disagrees with the commenter's suggestion that the rule does not state that construction or modification of the emission units subject to permitting cannot commence prior to issuance of the permit.

EPA has determined the addition of ARM 17.8.743(2) and (3) to the Montana Air Quality Program (MAQP) do not compromise the legally enforceable procedures in the MAQP and meet the requirements of 40 CFR 51.160.

The commenter also suggests that the phrase ''[a] true minor source is not subject to PSD requirements and is not subject to other federal requirements'' is confusing and appears to be a contradiction to the requirements of 40 CFR 51.160.

During the rulemaking process, EPA's intent was to make it explicitly clear that ARM 17.8.743(2) and (3) only apply to ''true'' minor sources in order to ensure that sources that are subject to federal requirements (*i.e.,* PSD and synthetic minors) do not begin any construction prior to permit issuance. 17.8.743(5) states: ''The provisions of (2) do not supersede any other local, State, or federal requirements associated with the activities set forth therein.'' EPA has interpreted ''federal requirements'' to mean synthetic minor permit limits. PSD provisions remain applicable until a proposed project legally obtains synthetic minor status (*i.e.,* obtains permitted limits which limit the source below the PSD thresholds). Therefore, EPA has concluded that the rule only applies to true minor sources.

Comment No. 2—The commenter opposed EPA's approval of ARM 17.8.752(1)(a)(i), alleging that this approval appears contrary to Section 110(l) of the CAA in that it would weaken current permitting requirements and will lead to more air pollution than would otherwise be allowed. The commenter states that the current minor source Best Available Control Technology (BACT) provision (triggered for an entire source) has been relied upon by Montana and EPA to ensure that the NAAQS will be attained and maintained pursuant to Section 110 of the CAA. The commenter acknowledges there is no federal requirement for minor source BACT. To the extent the commenter makes this argument, EPA responds below.

EPA Response—EPA disagrees with this comment. As the commenter points out, there is no federal requirement for BACT for minor sources and the inclusion of ARM 17.8.752(1)(a)(i) is a ''discretionary'' control measure. Measures not tied to an area's classification and not mandated by the CAA are often referred to as ''discretionary'' measures. States can remove discretionary measures from attainment, nonattainment or maintenance plans. In this instance, the State has not removed this discretionary control measure from its SIP, but has revised it. This revision results in minor source BACT applying only to the specific emissions unit being modified as opposed to the whole source. This revision will result in fewer sources postponing or foregoing modifying emission units, even those that would implement emission reductions, in order to avoid a comprehensive review and expensive upgrades to an entire facility.

EPA again notes that maintaining compliance with the NAAQS and Section 110 of the CAA is not dependent on a single component of the Montana ARM or a single revision of the SIP, but how the revisions as a whole affect attainment and maintenance of the NAAQS. ARM 17.8.752 has been used in addition to the remainder of the MAQP rules, individual control plans for nonattainment areas, generally applicable rules prohibiting certain emitting activities, open burning rules, *etc.* in order to ensure compliance with the NAAQS. ARM 17.8.752, as revised in this rule, does not weaken the MAQP program and thus a 110(l) analysis is not required before EPA can approve this provision.

Comment No. 3—The commenter states that the SIP revisions do not set

forth legally enforceable procedures that enable the State to determine how construction or modification of a stationary source impacts the ambient air quality standards and how these impacts will be assessed, in particular the ozone and $PM_{2.5}$ NAAQS, as required by 40 CFR 160(a)(2). The commenter further alleges that the SIP, in general, is not consistent with the procedures set forth in 40 CFR 160.

EPA Response—EPA disagrees with this comment. The revisions being approved in this action provide legally enforceable procedures for Montana's minor NSR to determine whether the construction of a new or modified source will result in interference with the NAAQS. ARM 17.8.743 requires sources to obtain a Montana air quality permit or a completeness determination before construction of a source may begin. ARM 17.8.743(3) states ''* * * the department may issue a letter instructing the owner or operator to immediately cease such activities pending a final determination on an application if it finds that the proposed project would result in a violation of the State Implementation Plan or would interfere with the attainment or maintenance of any federal or state ambient air quality standard.'' This satisfies the requirement of 40 CFR 51.160(a)(2) because it is a legally enforceable procedure that enables the State to prevent violations of the control strategy or interference with the NAAQS.

SIP revisions being approved in this action are not intended to determine the ability of the SIP as a whole to implement, maintain, and enforce each NAAQS promulgated by the EPA. For example, Montana submitted a SIP revision to demonstrate that the State meets the requirements of Section 110(a)(1) and (2) of the Clean Air Act for ozone and $PM_{2.5}$. This revision addresses basic SIP requirements, including emission inventories, monitoring, enforcement of emission limits and control measures, and modeling to assure attainment and maintenance of the standards. The evaluation of these ''infrastructure'' SIPs, as well as currently approved section 110 SIPs, need to be considered in determining whether the SIP as a whole provides appropriate legally enforceable procedures to ensure attainment and maintenance of the NAAQS.

III. Final Action

EPA is partially approving and partially disapproving SIP revisions submitted by the State of Montana on August 26, 1999, May 28, 2003, March 9, 2004, October 25, 2005, and October 16, 2006. First, in this action EPA is approving the removal of the following provisions from the federally-approved SIP: ARM 17.8.701, 17.8.702, 17.8.704, 17.8.705, 17.8.706, 17.8.707, 17.8.710, 17.8.715, 17.8.716, 17.8.717, 17.8.720, 17.8.730, 17.8.731, 17.8.732, 17.8.733, and 17.8.734.

Second, EPA is approving the following new Subchapter 7 provisions into the federally-approved SIP: ARM 17.8.740 (except 17.8.740(10) and (14) and the following phrases in 17.8.740(8)(a) and (c), respectively, (1) ''except when a permit is not required under ARM 17.8.745'' and (2) ''except as provided in ARM 17.8.745'' and the phrase ''reasonable period of time for startup and shutdown'' in ARM 17.8.740(2)), submitted on May 28, 2003; 17.8.743 (except the phrases ''asphalt concrete plants, mineral crushers'' in 17.8.743(1)(b) ''and 17.8.745'' in 17.8.743(1), and 17.8.743(1)(c)), submitted on May 28, 2003; 17.8.744 and 17.8.748, submitted on May 28, 2003; 17.8.749(1), (3), (4), (5), (6), and (8), submitted on May 28, 2003; 17.8.749(7), submitted on March 9, 2004; 17.8.752, 17.8.755, and 17.8.756, submitted on May 28, 2003; 17.8.759(1) through (3), submitted on May 28, 2003; 17.8.759(4) through (6), submitted on October 16, 2006; 17.8.760 and 17.8.762, submitted on May 28, 2003; 17.8.763(1) and (4), submitted on May 28, 2003; 17.8.763(2) and (3), submitted on March 9, 2004; 17.8.764(1) (except the phrase ''the emission increase meets the criteria in ARM 17.8.745 for a de minimis change not requiring a permit'' in 17.8.764(1)(b)) and (4), submitted on May 28, 2003; 17.8.764(2) and (3), submitted on March 9, 2004; 17.8.765, submitted on May 28, 2003; 17.8.767(1)(a) through (c), submitted on May 28, 2003; and 17.8.767(1)(d) through (g), (2), (3), and (4), submitted on October 25, 2005.

Third, EPA is disapproving the following new Subchapter 7 provisions: ARM 17.8.749(2), ARM 17.8.740(10), 17.8.740(14); and portions of 17.8.740(2).

Fourth, EPA is approving revisions to the following sections of other subchapters submitted on May 28, 2003: ARM 17.8.101(4); 17.8.110(7), (8), and (9); 17.8.818(1); 17.8.825(3); 17.8.826(1) and (2); 17.8.904(1) and (2); 17.8.905(1) and (4); 17.8.906; 17.8.1004; 17.8.1005(1), (2), and (5); 17.8.1106; and 17.8.1109.

Additionally, EPA is not acting, at the request of the State, on the following provisions in Subchapter 7: ARM 17.8.743(1)(c) and ARM 17.8.770, the phrase ''asphalt concrete plants, mineral crushers'' in ARM 17.8.743(1)(b) and ARM 17.8.745 submitted on May 28, 2003.

Note that, with respect to Montana's rules relating to new source review, EPA has determined that Montana's rules meet the requirements of 40 CFR part 51, subpart I, as currently in effect. And while EPA is approving the state's permit to construct rules, EPA recognizes that it has a responsibility to insure that all states properly implement their preconstruction permitting programs. Therefore, EPA's approval of Montana's rules in no way divests EPA of our continued oversight (as set forth in CAA sections 113, 167, and 505(b)) to insure that Montana's permits are consistent with the CAA, EPA regulations, and the SIP.

Consistent with EPA's proposal, this SIP approval does not extend to Indian country in Montana. See 75 FR 9843.

Finally, EPA is not acting on the following provisions of other subchapters because they were either disapproved in a previous action or they relate to a rule EPA is not taking action on: the following phrases in 17.8.740(8)(a) and (c), respectively, (1) ''except when a permit is not required under ARM 17.8.745'' and (2) ''except as provided in ARM 17.8.745,'' submitted on May 28, 2003; ARM 17.8.309(5)(b), 17.8.310(3)(e), 17.8.316(6), and 17.8.901(14)(e)(iii), submitted on May 28, 2003; the phrase ''and 17.8.745'' in ARM 17.8.743(1), submitted on May 28, 2003; ARM 17.8.749(2) submitted on May 28, 2003; the phrase ''the emission increase meets the criteria in ARM 17.8.745 for a de minimis change not requiring a permit,'' in ARM 17.8.764(1)(b), submitted on May 28, 2003; and ARM 17.8.743(1), 17.8.1601, 17.8.1602, 17.8.1603, 17.8.1604, 17.8.1605, and 17.8.1606, submitted on October 16, 2006.

IV. 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 approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under

Executive Order 12866 (58 FR 51735, October 4, 1993);

• Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

• Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 6, 2011. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: September 24, 2010.

James B. Martin,

Regional Administrator, Region 8.

PART 52—[AMENDED]

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

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

Subpart BB—Montana

■ 2. Amend § 52.1370 by adding paragraphs (c)(49)(i)(F), (c)(55)(i)(B), and (c)(70) to read as follows:

§ 52.1370 Identification of plan.

* * * * *

(c) * * *

(49) * * *

(i) * * *

(F) Previously approved in paragraph (c)(49)(i)(A) under Subchapter 7: *Permit, Construction, and Operation of Air Contaminant Sources.* These sections are now deleted without replacement: ARM 17.8.701, *Definitions;* ARM 17.8.702, *Incorporation by Reference* (excluding 17.8.702(1)(f)); ARM 17.8.704, *General Procedures for Air Quality Preconstruction Permitting;* 17.8.705, *When Permit Required-Exclusions;* 17.8.706, *New or Altered Sources and Stacks-Permit Application Requirements;* 17.8.707 *Waivers;* 17.8.710, *Conditions for Issuance of Permit;* 17.8.715, *Emission Control Requirements;* 17.8.716, *Inspection of Permit;* 17.8.717, *Compliance with Other Statutes and Rules;* 17.8.720, *Public Review of Permit Applications;* 17.8.730, *Denial of Permit;* 17.8.731, *Duration of Permit;* 17.8.732, *Revocation of Permit;* 17.8.733, *Modification of Permit;* 17.8.734, *Transfer of Permit,* as adopted by Montana on 12/9/1996 and effective 12/27/2002.

* * * * *

(55) * * *

(i) * * *

(B) Previously approved in paragraph (c)(55)(i)(A) under *Subchapter 7: Permit Construction and Operation of Air Contaminant Sources.* This section is now deleted without replacement: ARM 17.8.702(1)(g), *Incorporation by Reference,* as adopted by Montana on 7/20/2001 and effective 12/27/2002.

* * * * *

(70) On May 28, 2003, March 9, 2004, October 25, 2005 and October 16, 2006, the State of Montana submitted revisions to its State Implementation Plan (SIP) that contained new, revised, amended and repealed rules pertaining to the issuance of Montana air quality permits in addition to minor administrative changes to other subchapters of the Administrative Rules of Montana (ARM).

(i) Incorporation by reference.

(A) Letter from David L. Klemp, Montana State Air Director, to Deborah Lebow Aal, Acting Air Program Director, dated April 29, 2011. For certain sections, the following incorporates by reference official State of Montana publications of the Administrative Rules of Montana that are dated after the effective date shown in the incorporation by reference for each section. In these instances, the official publication provides a history for the section showing the last effective date of a change. For each of these sections, the last effective date of a change matches the effective date of the section, showing that the official publication reflects the text of the section as of the effective date shown in the following incorporation by reference. The sections, their effective dates, and the date of the publication are as follows: ARM 17.8.825, effective 12/27/2002, publication 9/30/2006; ARM 17.8.826, effective 12/27/2002, publication 9/30/2006; ARM 17.8.906, effective 12/27/2002, publication 6/30/2003; ARM 17.8.740, effective 12/27/2002, publication 9/30/2006; ARM 17.8.744, effective 12/27/2002, publication 12/31/2005; ARM 17.8.752, effective 12/27/2002, publication 6/30/2006; ARM 17.8.755, effective 12/27/2002, publication 6/30/2006; ARM 17.8.756, effective 12/27/2002, publication 6/30/2006; ARM 17.8.767, effective 12/27/2002, publication 3/31/

2004; ARM 17.8.749, effective 10/17/2003, publication 6/30/2006; ARM 17.8.759, effective 10/17/2003, publication 12/31/2003; ARM 17.8.763, effective 10/17/2003, publication 6/30/2006; ARM 17.8.764, effective 10/17/2003, publication 6/30/2006; ARM 17.8.602, effective 6/17/2005, publication 3/31/2007; ARM 17.8.767, effective 6/17/2005, publication 6/30/2006; ARM 17.8.802, effective 6/17/2005, publication 12/31/2005; ARM 17.8.1102, effective 6/17/2005, publication 3/31/2007; ARM 17.8.759, effective 12/23/2005, publication 9/30/2006.

(B) ARM submission dated May 28, 2003.

(*1*) The following provisions of the ARM are amended effective 12/27/2002: 17.8.101, *Definitions,* (4) ''*Air quality preconstruction permit,'';* 17.8.110, *Malfunctions,* (7), (8), and (9); 17.8.818, *Review of Major Stationary Sources and Major Modifications—Source Applicability and Exemptions,* (1); 17.8.825, *Sources Impacting Federal Class I Areas—Additional Requirements,* (3); 17.8.826, *Public Participation;* 17.8.904, *When Montana Air Quality Permit Required;* 17.8.905, *Additional Conditions of Montana Air Quality Permit,* (1) and (4); 17.8.906, *Baseline for Determining Credit for Emissions and Air Quality Offsets;* 17.8.1004, *When Montana Air Quality Permit Required;* 17.8.1005, *Additional Conditions of Montana Air Quality Permit,* (1), (2) and (5); 17.8.1106, *Visibility Impact Analysis;* 17.8.1109, *Adverse Impact and Federal Land Manager.*

(*2*) The following new provisions of the ARM are effective 12/27/2002: 17.8.740, *Definitions,* (except for the phrase in 17.8.740(2) ''includes a reasonable period of time for startup and shakedown and''; the phrase in 17.8.740(8)(a) '', except when a permit is not required under ARM 17.8.745''; the phrase in 17.8.740(8)(c) '', except as provided in ARM 17.8.745''; 17.8.740(10) ''Negligible risk to the public health, safety, and welfare and to the environment''; and 17.8.740(14) ''Routine Maintenance, repair, or replacement''); 17.8.743, *Montana Air Quality Permits—When Required,* (except the phrase in 17.8.743(1) ''and 17.8.745,'', the phrase in 17.8.743(1)(b) ''asphalt concrete plants, mineral crushers, and'', and 17.8.743(1)(c)); 17.8.744, *Montana Air Quality Permits—General Exclusions;* 17.8.748, *New or Modified Emitting Units—Permit Application Requirements;* 17.8.749, *Conditions For Issuance or Denial of Permit,* (1), (3), (4), (5), (6), and (8); 17.8.752, *Emission Control Requirements;* 17.8.755, *Inspection of Permit;* 17.8.756, *Compliance with Other Requirements;* 17.8.759, *Review of Permit Applications,* (1) through (3); 17.8.760, *Additional Review of Permit Applications;* 17.8.762, *Duration of Permit;* 17.8.763, *Revocation of Permit,* (1) and (4); 17.8.764, *Administrative Amendment to Permit,* (1) (except for the phrase in 17.8.764(1)(b) ''unless the increase meets the criteria in ARM 17.8.745 for a de minimis change not requiring a permit, or''), (2) and (3); 17.8.765, *Transfer of Permit;* 17.8.767, *Incorporation by Reference,* (1)(a) through (c).

(C) ARM submission dated March 09, 2004.

(*1*) The following provisions of the ARM are amended effective 10/17/2003: 17.8.749, *Conditions For Issuance or Denial of Permit,* (7); 17.8.759, *Review of Permit Applications;* 17.8.763, *Revocation of Permit,* (2) and (3); 17.8.764, *Administrative Amendment to Permit,* (2) and (3).

(D) ARM submission dated October 25, 2005.

(*1*) The following provisions of the ARM are amended effective 6/17/2005: 17.8.102, *Incorporation by Reference—Publication Dates;* 17.8.103, *Incorporation by Reference and Availability of Referenced Documents;* 17.8.302, *Incorporation by Reference;* 17.8.602, *Incorporation by Reference;* 17.8.767, *Incorporation by Reference,* (1)(d) through (g), (2), (3), and (4); 17.8.802, *Incorporation by Reference;* 17.8.902, *Incorporation by Reference;* 17.8.1002, *Incorporation by Reference;* 17.8.1102, *Incorporation by Reference.*

(E) ARM submission dated October 16, 2006.

(*1*) The following provisions of the ARM are amended effective 12/23/2005: 17.8.759, *Review of Permit Applications,* (4) through (6).

* * * * *

Editorial Note: This document was received in the Office of the Federal Register on June 30, 2011.

[FR Doc. 2011–16935 Filed 7–7–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2010–1002; FRL–9430–7]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Modifications to Indiana Prevention of Significant Deterioration and Nonattainment New Source Review Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving Indiana's modifications to its Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) rules. The amendments include grammatical changes, corrections to numbering, addition of definitions consistent with Federal PSD and NNSR regulations, and removal of references to provisions which were vacated in the Federal rules. Indiana submitted these rule revisions to EPA for approval on November 24, 2010. They are consistent with the current Federal PSD and NNSR regulations.

DATES: This direct final rule will be effective September 6, 2011, unless EPA receives adverse comments by August 8, 2011. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2010–1002, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *E-mail: pamela.blakley@epa.gov.*
3. *Fax:* (312) 692–2450.
4. *Mail:* Pamela Blakley, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* Pamela Blakley, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2010–

1002. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://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 *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *http://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 *http://www.regulations.gov* or in hard copy at the U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 AM to 4:30 PM, Monday through Friday, excluding Federal holidays. We recommend that you telephone Charmagne Ackerman, Environmental Engineer, at (312) 886–0448 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Charmagne Ackerman, Environmental Engineer, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–0448, *ackerman.charmagne@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This supplementary information section is arranged as follows:

I. What is being addressed in this document?
II. What are the changes that EPA is approving?
III. What action is EPA taking?
IV. Statutory and Executive Order Reviews.

I. What is being addressed in this document?

We are approving amendments to Indiana's PSD and Emission Offset regulations. Previously, EPA approved revisions to these regulations into the State Implementation Plan (SIP) on June 18, 2007 (72 FR 33395). On November 24, 2010, the Indiana Department of Environmental Management (IDEM) requested that EPA approve PSD and Emission Offset rule amendments to the SIP. The rule amendments include grammatical changes, corrections to numbering notation, the addition of definitions consistent with Federal PSD and NNSR regulations, and removal of references to provisions which were vacated in the New Source Review (NSR) Reform Rules. These amendments are contained in Indiana's PSD rules at 326 IAC 2–2–1, 326 IAC 2–2–2, 326 IAC 2–2–4, 326 IAC 2–2–5, 326 IAC 2–2–7, 326 IAC 2–2–8 and 326 IAC 2–2–10, and Emission Offset rules at 326 IAC 2–3–1, 326 IAC 2–3–2, and 326 IAC 2–3–3.

II. What are the changes that EPA is approving?

On December 31, 2002, EPA published final rule changes to the PSD and NSR programs (67 FR 80186) (2002 NSR Reform Rules), and on November 7, 2003, EPA published a notice of final action on the reconsideration of the December 31, 2002 final rule changes (68 FR 63021). After the 2002 NSR Reform Rules were finalized and effective (March 3, 2003), various petitioners challenged numerous aspects, along with portions of EPA's 1980 PSD and NNSR Rules (45 FR 5276, August 7, 1980). On June 24, 2005, the United States Circuit Court of Appeals for the DC Circuit Court issued a decision on the challenges to the 2002 NSR Reform Rules. *See New York* v. *United States,* 413 F.3d 3 (DC Cir. 2005). In summary, the DC Circuit Court vacated portions of the 2002 NSR Reform Rules pertaining to ''clean units'' and ''pollution control projects'' (PCPs), remanded a portion of the ''reasonable possibility'' provisions (40 CFR 52.21(r)(6) and 40 CFR 51.166(r)(6)), and either upheld or did not comment on the other provisions included as part of the 2002 NSR Reform Rules.

On June 13, 2007 (72 FR 32526), EPA took final action to revise the 2002 NSR Reform Rules to remove from Federal law all provisions pertaining to clean units and the PCP exemption that were vacated by the DC Circuit Court. In the final partial approval of the NSR Reform rules into the Indiana SIP (72 FR 33395), EPA did not take action on the clean unit and PCP portions of the rules at IDEM's request. Although today's action is proposing to approve Indiana's removal of these provisions, EPA never approved them into the SIP. Indiana has removed the following rules due to references to clean units and PCPs: 326 IAC 2–2–1(m), (dd)(2)(H), (ii)(6)(D), and (ll); 326 IAC 2–2–2 (d)(5) and (f); 2–2–4(a)(3); 2–2–5(b); 2–3–1(j), (y)(2)(H), (cc)(3)(B)(iii), and (cc)(3)(B)(iv)(EE),(gg); 326 IAC 2–3–2(c)(5) and (l); and 326 IAC 2–3–3(b)(12). Additionally, IDEM has removed references to clean units and PCPs in 326 IAC 2–2–4(a) and (b); 2–2–7(a); 2–2–8(b); and 2–2–10; 2–3–2(m), but the remainder of those subsections remain intact.

In *New York* v. *United States,* the DC Circuit also remanded EPA's ''reasonable possibility'' provision, which identifies for sources and reviewing authorities the circumstances under which a major stationary source undergoing a modification that does not trigger major NSR must keep records. On December 21, 2007, EPA addressed the Court's remand, and took final action to establish that a ''reasonable possibility'' applies where source emissions equal or exceed 50 percent of the Clean Air Act (CAA) NSR significance levels for any pollutant (72 FR 72607). See 40 CFR 52.21(r)(b). IDEM added 326 IAC 2–2–8(b)(6) and 326 IAC 2–3–2(l)(6) to include provisions that are consistent with EPA's reasonable possibility language.

The November 7, 2003, reconsideration rule added the definition for ''replacement unit'' at 40 CFR 52.21 (b)(33), which means an emissions unit for which all the criteria listed in paragraphs (b)(33)(i) through (iv) of this section are met. No creditable emission reductions shall be generated from shutting down the existing emissions unit that is replaced. The definition has been added to Indiana's regulations at 326 IAC 2–2–1(tt) and 326 IAC 2–3–1(nn).

IDEM has also added ''oxides of nitrogen'' (unless a NO_X waiver is in effect) to the following sections of the Emission Offset rules: 326 IAC 2–3–1(p), (y), (z), (pp); 326 IAC 2–3–2(b) and (g); and 326 IAC 2–3–3(a)(5)(B). Oxides of

nitrogen were added pursuant to section 182(f) of the CAA as it is a known precursor to the formation of ozone.

IDEM's revisions in 326 IAC 2–2–1 through 2–2–5, 326 IAC 2–2–7, 326 IAC 2–2–8, 326 IAC 2–2–10, and 326 IAC 2–3–1 through 2–3–3 also include corrections to grammatical errors, use of acronyms and corrections to numbering notations due to several subsections being added and removed.

III. What action is EPA taking?

EPA is approving the revisions to the PSD rules at 326–IAC 2–2–1, 326 IAC 2–2–2, 326 IAC 2–2–4, 326 IAC 2–2–5, 326 IAC 2–2–7, 326 IAC 2–2–8 and 326 IAC 2–2–10, and Emission Offset rules at 326 IAC 2–3–1, 326 IAC 2–3–2, and 326 IAC 2–3–3.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan if relevant adverse written comments are filed. This rule will be effective September 6, 2011 without further notice unless we receive relevant adverse written comments by August 8, 2011. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. If we do not receive any comments, this action will be effective September 6, 2011.

IV. Statutory and executive order reviews.

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

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

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 6, 2011. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: June 28, 2011.

Susan Hedman,

Regional Administrator, Region 5.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart P—Indiana

■ 2. In § 52.770 the table in paragraph (c) is amended by revising the entry for ''Article 2. Permit Review Rules'' to read as follows:

§ 52.770 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED INDIANA REGULATIONS

Indiana citation	Subject	Indiana effective date	EPA approval date	Notes
*	*	*	*	*
	Article 2. Permit Review Rules			
	Rule 1.1. General Provisions			
2–1.1–6	Public notice	6/26/1999	6/27/2003, 68 FR 38197.	
2–1.1–7	Fees	9/10/2004	6/18/2007, 72 FR 33395.	
2–1.1–8	Time periods for determination on permit applications.	6/26/1999	6/27/2003, 68 FR 38197.	
2–1.1–9.5	General provisions; term of permit	12/16/2007	10/6/2009, 74 FR 51240.	
	Rule 2. Prevention of Significant Deterioration (PSD) Requirements			
2–2–1	Definitions	10/31/2010	7/8/2011, [Insert page number where the document begins].	
2–2–2	Applicability	10/31/2010	7/8/2011, [Insert page number where the document begins].	
2–2–3	Control technology review; requirements	9/10/2004	6/18/2007, 72 FR 33395.	
2–2–4	Air quality analysis; requirements	10/31/2010	7/8/2011, [Insert page number where the document begins].	
2–2–5	Air quality impact; requirements	10/31/2010	7/8/2011, [Insert page number where the document begins].	
2–2–6	Increment consumption; requirements	9/10/2004	6/18/2007, 72 FR 33395.	
2–2–8	Source obligation	10/31/2010	7/8/2011, [Insert page number where the document begins].	
2–2–10	Source information	10/31/2010	7/8/2011, [Insert page number where the document begins].	
2–2–11	Stack height provisions	4/22/2001	6/27/2003, 68 FR 38197.	
2–2–12	Permit rescission	4/8/2004	5/20/2004, 69 FR 29071.	
2–2–13	Area designation and redesignation	4/22/2001	6/27/2003, 68 FR 38197.	
2–2–15	Public participation	4/22/2001	6/27/2003, 68 FR 38197.	
2–2–16	Ambient air ceilings	4/22/2001	6/27/2003, 68 FR 38197.	
	Rule 2.4. Actuals Plantwide Applicability Limitations in Attainment Areas			
2–2.4–1	Applicability	9/10/2004	6/18/2007, 72 FR 33395.	
2–2.4–2	Definitions	9/10/2004	6/18/2007, 72 FR 33395.	
2–2.4–3	Permit application requirements	9/10/2004	6/18/2007, 72 FR 33395.	
2–2.4–4	General requirements for establishing PALs	9/10/2004	6/18/2007, 72 FR 33395.	
2–2.4–5	Public participation requirements for PALs	9/10/2004	6/18/2007, 72 FR 33395.	
2–2.4–6	Establishing a 10 year actuals PAL level	9/10/2004	6/18/2007, 72 FR 33395.	
2–2.4–7	Contents of the PAL permit	9/10/2004	6/18/2007, 72 FR 33395.	
2–2.4–8	PAL effective period and reopening of the PAL permit.	9/10/2004	6/18/2007, 72 FR 33395.	
2–2.4–9	Expiration of a PAL	9/10/2004	6/18/2007, 72 FR 33395.	
2–2.4–10	Renewal of a PAL	9/10/2004	6/18/2007, 72 FR 33395.	
2–2.4–11	Increasing a PAL during the PAL effective period.	9/10/2004	6/18/2007, 72 FR 33395.	
2–2.4–12	Monitoring requirements for PALs	9/10/2004	6/18/2007, 72 FR 33395.	
2–2.4–13	Record keeping requirements	9/10/2004	6/18/2007, 72 FR 33395.	
2–2.4–14	Reporting and notification requirements	9/10/2004	6/18/2007, 72 FR 33395.	
2–2.4–15	Termination and revocation of a PAL	9/10/2004	6/18/2007, 72 FR 33395.	
	Rule 3. Emission Offset			
2–3–1	Definitions	10/31/2010	7/8/2011, [Insert page number where the document begins].	
2–3–2	Applicability	10/31/2010	7/8/2011, [Insert page number where the document begins].	
2–3–3	Applicable requirements	10/31/2010	7/8/2011, [Insert page number where the document begins].	
2–3–4	Banking of emission offsets	12/13/1993	10/7/1994, 59 FR 51108.	
2–3–5	Location of offsetting emissions	12/13/1993	10/7/1994, 59 FR 51108.	
	Rule 3.4. Actuals Plantwide Applicability Limitations in Nonattainment Areas			
2–3.4–1	Applicability	9/10/2004	6/18/2007, 72 FR 33395.	
2–3.4–2	Definitions	9/10/2004	6/18/2007, 72 FR 33395.	
2–3.4–3	Permit application requirements	9/10/2004	6/18/2007, 72 FR 33395.	
2–3.4–4	Establishing PALs; general requirements	9/10/2004	6/18/2007, 72 FR 33395.	
2–3.4–5	Public participation requirements for PALs	9/10/2004	6/18/2007, 72 FR 33395.	

EPA-APPROVED INDIANA REGULATIONS—Continued

Indiana citation	Subject	Indiana effective date	EPA approval date	Notes
2–3.4–6	Establishing a 10 year actuals PAL level	9/10/2004	6/18/2007, 72 FR 33395.	
2–3.4–7	Contents of the PAL permit	9/10/2004	6/18/2007, 72 FR 33395.	
2–3.4–8	PAL effective period and reopening of the PAL permit.	9/10/2004	6/18/2007, 72 FR 33395.	
2–3.4–9	Expiration of a PAL	9/10/2004	6/18/2007, 72 FR 33395.	
2–3.4–10	Renewal of a PAL	9/10/2004	6/18/2007, 72 FR 33395.	
2–3.4–11	Increasing a PAL during the PAL effective period.	9/10/2004	6/18/2007, 72 FR 33395.	
2–3.4–12	Monitoring requirements for PALs	9/10/2004	6/18/2007, 72 FR 33395.	
2–3.4–13	Record keeping requirements	9/10/2004	6/18/2007, 72 FR 33395.	
2–3.4–14	Reporting and notification requirements	9/10/2004	6/18/2007, 72 FR 33395.	
2–3.4–15	Termination and revocation of a PAL	9/10/2004	6/18/2007, 72 FR 33395.	
	Rule 5.1. Construction of New Sources			
2–5.1–4	Transition procedures	9/10/2004	6/18/2007, 72 FR 33395.	
	Rule 6. Emission Reporting			
2–6–1	Applicability	8/13/2006	3/29/2007, 72 FR 14678.	
2–6–2	Definitions	3/27/2004	10/29/2004, 69 FR 63069.	
2–6–3	Compliance schedule	8/13/2006	3/29/2007, 72 FR 14678.	
2–6–4	Requirements	8/13/2006	3/29/2007, 72 FR 14678.	
2–6–5	Additional information requests	3/27/2004	10/29/2004, 69 FR 63069.	
	Rule 8. Federally Enforceable State Operating Permit Program			
2–8–1	Definitions	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–2	Applicability	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–3	Permit application	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–4	Permit content	12/16/2007	10/6/2009, 74 FR 51240.	
2–8–5	Compliance requirements for FESOPs	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–6	Federally enforceable requirements	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–7	Permit issuance, renewal, and revisions	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–8	Permit reopening	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–9	Permit expiration	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–10	Administrative permit amendments	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–11	Permit modification (Repealed)	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–11.1	Permit revisions	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–12	Emergency provision	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–13	Public notice	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–14	Review by U.S. EPA	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–15	Operational flexibility	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–16	Fees	6/24/1994	8/18/1995, 60 FR 43008.	
2–8–17	Local agencies	6/24/1994	8/18/1995, 60 FR 43008.	
	Rule 9. Source Specific Operating Agreement Program			
2–9–1	General provisions	6/24/1994	4/2/1996, 61 FR 14487.	
2–9–2	Source specific restrictions and conditions (Repealed).	6/24/1994	4/2/1996, 61 FR 14487	Sec. 2(a), 2(b), and 2(e)

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[FR Doc. 2011–17036 Filed 7–7–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2006–0976; FRL–9430–5]

Approval and Promulgation of Air Quality Implementation Plans; Ohio; Control of Gasoline Volatility; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correcting amendment.

SUMMARY: This document corrects an error in the codification in a May 25, 2007, final rule under the Clean Air Act pertaining to a request for the use of low Reid Vapor Pressure (RVP) fuel in the Cincinnati and Dayton areas. Clinton County, Ohio is actually not part of the area affected by the rulemaking.

DATES: *Effective Date:* This final rule is effective on July 8, 2011.

FOR FURTHER INFORMATION CONTACT: Carolyn Persoon, Environmental Engineer, Control Strategies Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–8290, *persoon.carolyn@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. EPA published a final approval of Ohio rules that request use of low RVP fuel in the Cincinnati and Dayton areas on May 25, 2007 (72 FR 29269). Thecodification of this approval states that the Ohio rules require that low-RVP fuel of 7.8 pounds per square inch (psi) be sold in Hamilton, Butler, Clinton, Warren, Clermont, Clark, Greene, Miami, and Montgomery counties. However, the addition of Clinton County in the final rule and the codification was a clerical error. The Ohio rules submitted to EPA for action do not apply to Clinton County, Ohio. The error has resulted in a discrepancy between 40 CFR 52.1870 and the state rules of Ohio. This document corrects the erroneous amendatory language.

Correction

In the codification published in the **Federal Register** on May 25, 2007 (72 FR 29269), on page 29273 in the second column, paragraph numbered (138): ''Areas which includes Hamilton, Butler, Clinton, Warren and Clermont, Clark, Greene, Miami, and Montgomery counties.'' is corrected to read: ''Areas which include Hamilton, Butler, Warren and Clermont, Clark, Greene, Miami, and Montgomery Counties.''

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. We have determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because we are merely correcting an incorrect citation in a previous action. The underlying state rule is not affected. Thus, notice and public procedure are unnecessary. We find that this constitutes good cause under 5 U.S.C. 553(b)(B).

Statutory and Executive Order Reviews

Under Executive Order (E.O.) 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)). Because the agency has made a ''good cause'' finding that this action is not subject to notice-and-comment requirements under the Administrative Procedures Act or any other statute as indicated in the Supplementary Information section above, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. This rule also does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of governments, as specified by Executive Order 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

This technical correction action does not involve technical standards; thus the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. The rule also does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996). EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1998) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 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. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA had made such a good cause finding, including the reasons therefore, and established an effective date of July 8, 2011. 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 correction to 40 CFR part 52 for Ohio is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Dated: June 24, 2011.

Susan Hedman,

Regional Administrator, Region 5.

List of Subjects in 40 CFR Part 52

Air pollution control, Carbon monoxide, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart KK—Ohio

■ 2. Section 52.1870 is amended by revising paragraph (c)(138) to read as follows:

§ 52.1870 Identification of plan.

* * * * *

(c) * * *

(138) On February 14, 2006, and October 6, 2006, the State of Ohio submitted a revision to the Ohio State Implementation Plan. This revision is for the purpose of establishing a gasoline Reid Vapor Pressure (RVP) limit of 7.8 pounds per square inch (psi) for gasoline sold in the Cincinnati and

Dayton areas which include Hamilton, Butler, Warren, Clermont, Clark, Greene, Miami, and Montgomery Counties.

* * * * *

[FR Doc. 2011–17049 Filed 7–7–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2008–0639; EPA–R01–OAR–2008–0641; EPA–R01–OAR–2008–00642; EPA–R01–OAR–2008–0643; A–1–FRL–9431–2]

Approval and Promulgation of Implementation Plans; Connecticut, Maine, New Hampshire and Rhode Island; Infrastructure SIPs for the 1997 8-Hour Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving submittals from the States of Connecticut, Maine, New Hampshire and Rhode Island. These submittals outline how each state's State Implementation Plan (SIP) meets the requirements of the Clean Air Act (CAA) for the 1997 8-hour ozone national ambient air quality standards (NAAQS). Section 110(a) of the CAA requires that each state adopt and submit a SIP for the implementation, maintenance and enforcement of each NAAQS promulgated by the EPA. This SIP is commonly referred to as an infrastructure SIP. Specifically, EPA is taking final action to fully approve the submittals from Connecticut, Maine, New Hampshire and Rhode Island, with one exception. EPA is taking direct final action to conditionally approve one element of Connecticut's submittal. These actions are being taken under the Clean Air Act.

DATES: *Effective Dates:* This rule will be effective August 8, 2011, with one exception. The conditional approval of one element of Connecticut's SIP is a direct final rule which will be effective September 6, 2011, unless EPA receives adverse comments on that action by August 8, 2011.

If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, if any, on EPA's direct final conditional approval for Connecticut, identified by Docket ID Number EPA–R01–OAR–200–0639 by one of the following methods:

1. *http://www.regulations.gov*: Follow the on-line instructions for submitting comments.

2. *E-mail: arnold.anne@epa.gov* Fax: (617) 918–0047. Mail: ''Docket Identification Number EPA–R01–OAR–2008–0639'', Anne Arnold, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912

3. *Hand Delivery or Courier.* Deliver your comments to: Anne Arnold, Manager, Air Quality Planning Unit, Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding legal holidays.

Instructions: Direct your comments for Connecticut to Docket ID No. EPA–R01–OAR–2008–0639. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *http://www.regulations.gov*, or e-mail, information that you consider to be CBI or otherwise protected. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100, Boston, MA. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Richard P. Burkhart, Air Quality Planning Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, 5 Post Office Square, Suite 100, Boston, MA 02109–3912, telephone number (617) 918–1664, fax number (617) 918–0664, e-mail *Burkhart.Richard@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background

Section 110(a) of the Clean Air Act imposes the obligation upon states to make a SIP submission to EPA for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the SIP for a new or revised NAAQS affects the content of the submission. The contents of such SIP submissions may also vary depending upon what provisions the state's existing SIP already contains. In the case of the 1997 8-hour ozone NAAQS, states typically have met the basic program elements required in section 110(a)(2) through earlier SIP submissions in connection with previous ozone standards.

On October 2, 2007, EPA issued a guidance document entitled, ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 1997

8-hour Ozone and fine particle ($PM_{2.5}$) National Ambient Air Quality Standards.'' This guidance noted that to the extent an existing SIP already meets the section 110(a)(2) requirements, states need only certify that fact via a letter to EPA.

The States of Connecticut, Maine, New Hampshire, and Rhode Island each submitted such certification letters to EPA on December 28, 2007, January 3, 2008, December 14, 2007 and December 14, 2007, respectively. All four submittals were deemed complete, effective April 28, 2008. (See 73 FR 16205; March 27, 2008.)

On March 23, 2011, EPA proposed to approve the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions for the 1997 8-hour ozone NAAQS. *See* 76 FR 16358. A summary of the background for today's final actions is provided below. See EPA's March 23, 2011, proposed rulemaking at 76 FR 16358 for more detail.

More specifically, section 110(a)(1) provides the procedural and timing requirements for SIPs. Section 110(a)(2) lists specific elements that states must meet for ''infrastructure'' SIP requirements related to a newly established or revised NAAQS. As mentioned above, these requirements include SIP infrastructure elements such as modeling, monitoring, and emissions inventories that are designed to assure attainment and maintenance of the NAAQS. The requirements that are the subject of this proposed rulemaking are listed below: [1]

- 110(a)(2)(A): Emission limits and other control measures.
- 110(a)(2)(B): Ambient air quality monitoring/data system.
- 110(a)(2)(C): Program for enforcement of control measures.[2]
- 110(a)(2)(D)(ii): Interstate transport.
- 110(a)(2)(E): Adequate resources.
- 110(a)(2)(F): Stationary source monitoring system.
- 110(a)(2)(G): Emergency power.
- 110(a)(2)(H): Future SIP revisions.
- 110(a)(2)(J): Consultation with government officials; public notification; and PSD and visibility protection.
- 110(a)(2)(K): Air quality modeling/data.
- 110(a)(2)(L): Permitting fees.
- 110(a)(2)(M): Consultation/participation by affected local entities.

II. Scope of Action on Infrastructure Submissions

EPA is taking final action to approve the Connecticut, Maine, New Hampshire and Rhode Island SIPs as demonstrating that the respective States meet the requirements of sections 110(a)(1) and (2) of the CAA for the 1997 8-hour ozone NAAQS. Section 110(a) of the CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by the EPA, which is commonly referred to as an ''infrastructure'' SIP. Connecticut, Maine, New Hampshire and Rhode Island certified that the Connecticut, Maine, New Hampshire and Rhode Island SIPs contain provisions that ensure the 1997 8-hour ozone NAAQS is implemented, enforced, and maintained in Connecticut, Maine, New Hampshire and Rhode Island, respectively. The Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions address all the required infrastructure elements for the 1997 8-hour ozone NAAQS. EPA has determined that the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions are consistent with section 110 of the CAA, with the exception of the Connecticut submission with respect to section 110(a)(2)(D)(ii). Therefore, EPA is taking final action to fully approve the submittals from Connecticut, Maine, New Hampshire and Rhode Island, with one exception. EPA is taking direct final action to conditionally approve Connecticut's submittal with respect to section 110(2)(D)(ii), as discussed further in Section III below. Additionally, EPA is responding to comments received on EPA's March 23, 2011 proposed approval of the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions.

EPA is currently acting upon SIPs that address the infrastructure requirements of CAA section 110(a)(1) and (2) for ozone and $PM_{2.5}$ NAAQS for various states across the country. Commenters on EPA's recent proposals for some states raised concerns about EPA statements that it was not addressing certain substantive issues in the context of acting on the infrastructure SIP submissions.[3] The commenters specifically raised concerns involving provisions in existing SIPs and with EPA's statements that it would address two issues separately and not as part of actions on the infrastructure SIP submissions: (i) existing provisions related to excess emissions during periods of start-up, shutdown, or malfunction at sources, that may be contrary to the CAA and EPA's policies addressing such excess emissions (''SSM''); and (ii) existing provisions related to ''director's variance'' or ''director's discretion'' that purport to permit revisions to SIP approved emissions limits with limited public process or without requiring further approval by EPA, that may be contrary to the CAA (''director's discretion''). EPA notes that there are two other substantive issues for which EPA likewise stated that it would address the issues separately: (i) existing provisions for minor source new source review programs that may be inconsistent with the requirements of the CAA and EPA's regulations that pertain to such programs (''minor source NSR''); and (ii) existing provisions for Prevention of Significant Deterioration programs that may be inconsistent with current requirements of EPA's ''Final NSR Improvement Rule,'' 67 FR 80,186 (December 31, 2002), as amended by 72 FR 32,526 (June 13, 2007) (''NSR Reform''). In light of the comments, EPA now believes that its statements in various proposed actions on infrastructure SIPs with respect to these four individual issues should be explained in greater depth with respect to these issues.

EPA intended the statements in the proposals concerning these four issues merely to be informational, and to provide general notice of the potential existence of provisions within the existing SIPs of some states that might require future corrective action. EPA did not want states, regulated entities, or members of the public to be under the misconception that the Agency's approval of the infrastructure SIP

[1] Two elements identified in section 110(a)(2) are not governed by the three year submission deadline of section 110(a)(1) because SIPs incorporating necessary local nonattainment area controls are not due within three years after promulgation of a new or revised NAAQS, but rather due at the time the nonattainment area plan requirements are due pursuant to section 172. These requirements are: (1) Submissions required by section 110(a)(2)(C) to the extent that subsection refers to a permit program as required in part D Title I of the CAA; and (2) submissions required by section 110(a)(2)(I) which pertain to the nonattainment planning requirements of part D, Title I of the CAA. Today's final rulemaking does not address infrastructure elements related to section 110(a)(2)(I) but does provide detail, as explained in the notice of proposed rulemaking, on how the respective states' SIP addresses the requirements of section 110(a)(2)(C) not related to the part D permit program for nonattainment areas.

[2] This rulemaking only addresses requirements for this element as they relate to attainment areas, if any.

[3] See, Comments of Midwest Environmental Defense Center, dated May 31, 2011. Docket # EPA–R05–OAR–2007–1179 (adverse comments on proposals for three states in Region 5). EPA notes that these public comments on another proposal are not relevant to this rulemaking and do not have to be directly addressed in this rulemaking. EPA will respond to these comments in the appropriate rulemaking action to which they apply.

submission of a given state should be interpreted as a reapproval of certain types of provisions that might exist buried in the larger existing SIP for such state. Thus, for example, EPA explicitly noted that the Agency believes that some states may have existing SIP approved SSM provisions that are contrary to the CAA and EPA policy, but that ''in this rulemaking, EPA is not proposing to approve or disapprove any existing State provisions with regard to excess emissions during SSM of operations at facilities.'' EPA further explained, for informational purposes, that ''EPA plans to address such State regulations in the future.'' EPA made similar statements, for similar reasons, with respect to the director's discretion, minor source NSR, and NSR Reform issues. EPA's objective was to make clear that approval of an infrastructure SIP for these ozone and $PM_{2.5}$ NAAQS should not be construed as explicit or implicit reapproval of any existing provisions that relate to these four substantive issues.

Unfortunately, the commenters and others evidently interpreted these statements to mean that EPA considered action upon the SSM provisions and the other three substantive issues to be integral parts of acting on an infrastructure SIP submission, and therefore that EPA was merely postponing taking final action on the issue in the context of the infrastructure SIPs. This was not EPA's intention. To the contrary, EPA only meant to convey its awareness of the potential for certain types of deficiencies in existing SIPs, and to prevent any misunderstanding that it was reapproving any such existing provisions. EPA's intention was to convey its position that the statute does not require that infrastructure SIPs address these specific substantive issues in existing SIPs and that these issues may be dealt with separately, outside the context of acting on the infrastructure SIP submission of a state. To be clear, EPA did not mean to imply that it was not taking a full final agency action on the infrastructure SIP submission with respect to any substantive issue that EPA considers to be a required part of acting on such submissions under section 110(k) or under section 110(c). Given the confusion evidently resulting from EPA's statements, however, we want to explain more fully the Agency's reasons for concluding that these four potential substantive issues in existing SIPs may be addressed separately.

The requirement for the SIP submissions at issue arises out of CAA section 110(a)(1). That provision requires that states must make a SIP submission ''within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof)'' and that these SIPs are to provide for the ''implementation, maintenance, and enforcement'' of such NAAQS. Section 110(a)(2) includes a list of specific elements that ''[e]ach such plan'' submission must meet. EPA has historically referred to these particular submissions that states must make after the promulgation of a new or revised NAAQS as ''infrastructure SIPs.'' This specific term does not appear in the statute, but EPA uses the term to distinguish this particular type of SIP submission designed to address basic structural requirements of a SIP from other types of SIP submissions designed to address other different requirements, such as ''nonattainment SIP'' submissions required to address the nonattainment planning requirements of part D, ''regional haze SIP'' submissions required to address the visibility protection requirements of CAA section 169A, new source review permitting program submissions required to address the requirements of part D, and a host of other specific types of SIP submissions that address other specific matters.

Although section 110(a)(1) addresses the timing and general requirements for these infrastructure SIPs, and section 110(a)(2) provides more details concerning the required contents of these infrastructure SIPs, EPA believes that many of the specific statutory provisions are facially ambiguous. In particular, the list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive provisions, and some of which pertain to requirements for both authority and substantive provisions.[4] Some of the elements of section 110(a)(2) are relatively straightforward, but others clearly require interpretation by EPA through rulemaking, or recommendations through guidance, in order to give specific meaning for a particular NAAQS.[5]

Notwithstanding that section 110(a)(2) states that ''each'' SIP submission must meet the list of requirements therein, EPA has long noted that this literal reading of the statute is internally inconsistent, insofar as section 110(a)(2)(I) pertains to nonattainment SIP requirements that could not be met on the schedule provided for these SIP submissions in section 110(a)(1).[6] This illustrates that EPA must determine which provisions of section 110(a)(2) may be applicable for a given infrastructure SIP submission. Similarly, EPA has previously decided that it could take action on different parts of the larger, general ''infrastructure SIP'' for a given NAAQS without concurrent action on all subsections, such as section 110(a)(2)(D)(i), because the Agency bifurcated the action on these latter ''interstate transport'' provisions within section 110(a)(2) and worked with states to address each of the four prongs of section 110(a)(2)(D)(i) with substantive administrative actions proceeding on different tracks with different schedules.[7] This illustrates that EPA may conclude that subdividing the applicable requirements of section 110(a)(2) into separate SIP actions may sometimes be appropriate for a given NAAQS where a specific substantive action is necessitated, beyond a mere submission addressing basic structural aspects of the state's SIP. Finally, EPA notes that not every element of section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAQS and the attendant infrastructure SIP submission for that NAAQS. For example, the monitoring requirements that might be necessary for purposes of section 110(a)(2)(B) for one NAAQS could be

[4] For example, section 110(a)(2)(E) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; section 110(a)(2)(C) provides that states must have a substantive program to address certain sources as required by part C of the CAA; section 110(a)(2)(G) provides that states must have both legal authority to address emergencies and substantive contingency plans in the event of such an emergency.

[5] For example, section 110(a)(2)(D)(i) requires EPA to be sure that each state's SIP contains adequate provisions to prevent significant contribution to nonattainment of the NAAQS in other states. This provision contains numerous terms that require substantial rulemaking by EPA in order to determine such basic points as what constitutes significant contribution. See, *e.g.,* ''Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NOx SIP Call; Final Rule,'' 70 FR 25,162 (May 12, 2005)(defining, among other things, the phrase ''contribute significantly to nonattainment'').

[6] See, *e.g., Id.,* 70 FR 25,162, at 63–65 (May 12, 2005)(explaining relationship between timing requirement of section 110(a)(2)(D) versus section 110(a)(2)(I)).

[7] EPA issued separate guidance to states with respect to SIP submissions to meet section 110(a)(2)(D)(i) for the 1997 ozone and 1997 $PM_{2.5}$ NAAQS. See, ''Guidance for State Implementation Plan (SIP) Submissions to Meet Current Outstanding Obligations Under Section 110(a)(2)(D)(i) for the 8-Hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards,'' from William T. Harnett, Director Air Quality Policy Division OAQPS, to Regional Air Division Director, Regions I–X, dated August 15, 2006.

very different than what might be necessary for a different pollutant. Thus, the content of an infrastructure SIP submission to meet this element from a state might be very different for an entirely new NAAQS, versus a minor revision to an existing NAAQS.[8]

Similarly, EPA notes that other types of SIP submissions required under the statute also must meet the requirements of section 110(a)(2), and this also demonstrates the need to identify the applicable elements for other SIP submissions. For example, nonattainment SIPs required by part D likewise have to meet the relevant subsections of section 110(a)(2) such as section 110(a)(2)(A) or (E). By contrast, it is clear that nonattainment SIPs would not need to meet the portion of section 110(a)(2)(C) that pertains to part C, *i.e.,* the PSD requirement applicable in attainment areas. Nonattainment SIPs required by part D also would not need to address the requirements of section 110(a)(2)(G) with respect to emergency episodes, as such requirements would not be limited to nonattainment areas. As this example illustrates, each type of SIP submission may implicate some subsections of section 110(a)(2) and not others.

Given the potential for ambiguity of the statutory language of section 110(a)(1) and (2), EPA believes that it is appropriate for EPA to interpret that language in the context of acting on the infrastructure SIPs for a given NAAQS. Because of the inherent ambiguity of the list of requirements in section 110(a)(2), EPA has adopted an approach in which it reviews infrastructure SIPs against this list of elements ''as applicable.'' In other words, EPA assumes that Congress could not have intended that each and every SIP submission, regardless of the purpose of the submission or the NAAQS in question, would meet each of the requirements, or meet each of them in the same way. EPA elected to use guidance to make recommendations for infrastructure SIPs for these NAAQS.

On October 2, 2007, EPA issued guidance making recommendations for the infrastructure SIP submissions for both the 1997 8-hour ozone NAAQS and the 1997 $PM_{2.5}$ NAAQS. [9] Within this guidance document, EPA described the duty of states to make these submissions to meet what the Agency characterized as the ''infrastructure'' elements for SIPs, which it further described as the ''basic SIP requirements, including emissions inventories, monitoring, and modeling to assure attainment and maintenance of the standards.'' [10] As further identification of these basic structural SIP requirements, ''attachment A'' to the guidance document included a short description of the various elements of section 110(a)(2) and additional information about the types of issues that EPA considered germane in the context of such infrastructure SIPs. EPA emphasized that the description of the basic requirements listed on attachment A was not intended ''to constitute an interpretation of'' the requirements, and was merely a ''brief description of the required elements.'' [11] EPA also stated its belief that with one exception, these requirements were ''relatively self explanatory, and past experience with SIPs for other NAAQS should enable States to meet these requirements with assistance from EPA Regions.'' [12] For the one exception to that general assumption, however, *i.e.,* how states should proceed with respect to the requirements of section 110(a)(2)(G) for the 1997 $PM_{2.5}$ NAAQS, EPA gave much more specific recommendations. But for other infrastructure SIP submittals, and for certain elements of the submittals for the 1997 $PM_{2.5}$ NAAQS, EPA assumed that each state would work with its corresponding EPA regional office to refine the scope of a state's submittal based on an assessment of how the requirements of section 110(a)(2) should reasonably apply to the basic structure of the state's SIP for the NAAQS in question.

Significantly, the 2007 Guidance did not explicitly refer to the SSM, director's discretion, minor source NSR, or NSR Reform issues as among specific substantive issues EPA expected states to address in the context of the infrastructure SIPs, nor did EPA give any more specific recommendations with respect to how states might address such issues even if they elected to do so. The SSM and director's discretion issues implicate section 110(a)(2)(A), and the minor source NSR and NSR Reform issues implicate section 110(a)(2)(C). In the 2007 Guidance, however, EPA did not indicate to states that it intended to interpret these provisions as requiring a substantive submission to address these specific issues in the context of the infrastructure SIPs for these NAAQS. Instead, EPA's 2007 Guidance merely indicated its belief that the states should make submissions in which they established that they have the basic SIP structure necessary to implement, maintain, and enforce the NAAQS. EPA believes that states can establish that they have the basic SIP structure, notwithstanding that there may be potential deficiencies within the existing SIP. Thus, EPA's proposals mentioned these issues not because the Agency considers them issues that must be addressed in the context of an infrastructure SIP as required by section 110(a)(1) and (2), but rather because EPA wanted to be clear that it considers these potential existing SIP problems as separate from the pending infrastructure SIP actions.

EPA believes that this approach to the infrastructure SIP requirement is reasonable, because it would not be feasible to read section 110(a)(1) and (2) to require a top to bottom, stem to stern, review of each and every provision of an existing SIP merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts that, while not fully up to date, nevertheless may not pose a significant problem for the purposes of ''implementation, maintenance, and enforcement'' of a new or revised NAAQS when EPA considers the overall effectiveness of the SIP. To the contrary, EPA believes that a better approach is for EPA to determine which specific SIP elements from section 110(a)(2) are applicable to an infrastructure SIP for a given NAAQS, and to focus attention on those elements that are most likely to need a specific SIP revision in light of the new or revised NAAQS. Thus, for example, EPA's 2007 Guidance specifically directed states to focus on the requirements of section 110(a)(2)(G) for the 1997 $PM_{2.5}$ NAAQS because of

[8] For example, implementation of the 1997 $PM_{2.5}$ NAAQS required the deployment of a system of new monitors to measure ambient levels of that new indicator species for the new NAAQS.

[9] See, ''Guidance on SIP Elements Required Under Section 110(a)(1) and (2) for the 1997 8-hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards,'' from William T. Harnett, Director Air Quality Policy Division, to Air Division Directors, Regions I–X, dated October 2, 2007 (the ''2007 Guidance''). EPA issued comparable guidance for the 2006 $PM_{2.5}$ NAAQS entitled ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 2006 24-Hour Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS),'' from William T, Harnett, Director Air Quality Policy Division, to Regional Air Division Directors, Regions I–X, dated September 25, 2009 (the ''2009 Guidance'').

[10] *Id.,* at page 2.

[11] *Id.,* at attachment A, page 1.

[12] *Id.,* at page 4. In retrospect, the concerns raised by commenters with respect to EPA's approach to some substantive issues indicates that the statute is not so ''self explanatory,'' and indeed is sufficiently ambiguous that EPA needs to interpret it in order to explain why these substantive issues do not need to be addressed in the context of infrastructure SIPs and may be addressed at other times and by other means.

the absence of underlying EPA regulations for emergency episodes for this NAAQS and an anticipated absence of relevant provisions in existing SIPs.

Finally, EPA believes that its approach is a reasonable reading of section 110(a)(1) and (2) because the statute provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow the Agency to take appropriate tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a ''SIP call'' whenever the Agency determines that a state's SIP is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or otherwise to comply with the CAA.[13] Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions.[14] Significantly, EPA's determination that an action on the infrastructure SIP is not the appropriate time and place to address all potential existing SIP problems does not preclude the Agency's subsequent reliance on provisions in section 110(a)(2) as part of the basis for action at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on the infrastructure SIP, EPA believes that section 110(a)(2)(A) may be among the statutory bases that the Agency cites in the course of addressing the issue in a subsequent action.[15]

[13] EPA has recently issued a SIP call to rectify a specific SIP deficiency related to the SSM issue. See, ''Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revision,'' 74 FR 21,639 (April 18, 2011).

[14] EPA has recently utilized this authority to correct errors in past actions on SIP submissions related to PSD programs. See, ''Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule,'' 75 FR 82,536 (Dec. 30, 2010). EPA has previously used its authority under CAA 110(k)(6) to remove numerous other SIP provisions that the Agency determined it had approved in error. See, *e.g.,* 61 FR 38,664 (July 25, 1996) and 62 FR 34,641 (June 27, 1997) (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); 69 FR 67,062 (November 16, 2004) (corrections to California SIP); and 74 FR 57,051 (November 3, 2009) (corrections to Arizona and Nevada SIPs).

[15] EPA has recently disapproved a SIP submission from Colorado on the grounds that it would have included a director's discretion provision inconsistent with CAA requirements, including section 110(a)(2)(A). See, *e.g.,* 75 FR 42,342 at 42,344 (July 21, 2010) (proposed disapproval of director's discretion provisions); 76 FR 4,540 (Jan. 26, 2011) (final disapproval of such provisions).

III. EPA's Response to Comments

EPA received one set of comments (from the Law Office of Robert Ukeiley, hereinafter referred to as ''the Commenter'') on the March 23, 2011, proposed rulemaking to approve revisions to the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions as meeting the requirements of sections 110(a)(1) and (2) of the CAA for the 1997 8-hour ozone NAAQS. Generally, the Commenter's concerns relate to whether EPA's approval of the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions are in compliance with section 110(l) of the CAA, and whether EPA's approval will interfere with the states' compliance with the CAA's prevention of significant deterioration (PSD) requirements. In addition, the commenter has concerns with how the Connecticut SIP addresses the element required by section 110(a)(2)(D)(ii). The comments are provided in the docket for today's final action. A summary of the comments and EPA's responses are provided below.

Comment 1: Under the header ''No Clean Air Act Section 110(l) analysis,'' the Commenter states ''Before providing the technical analysis for why finalizing this proposed rule would be contrary to the Clean Air Act, I wish to point out that it is 2011 and EPA has yet to ensure that these areas have plans to meet the 1997 National Ambient Air Quality Standard (NAAQS) for ozone.'' The Commenter goes on to state that ''EPA acknowledged that the science indicates that the 1997 NAAQS, which is effectively 85 parts per billion (ppb), does not protect people's health or welfare when in 2008, EPA set a new ozone NAAQS at 75 ppb.''

Response 1: As noted in EPA's proposed rulemaking on the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions and in today's final rulemaking, the very action that EPA is undertaking is a determination that Connecticut, Maine, New Hampshire and Rhode Island have plans to ensure compliance with the 1997 8-hour ozone NAAQS. The level of the 1997 ozone NAAQS is 0.08 parts per million (ppm) on an 8-hour average basis. The Connecticut, Maine, New Hampshire and Rhode Island submissions predate the release of the recent revision to the 8-hour ozone NAAQS on March 12, 2008, and are distinct from any plans that the States of Connecticut, Maine, New Hampshire and Rhode Island may provide to ensure compliance of the 2008 NAAQS. Our actions today are meant to address the 1997 ozone infrastructure requirements under Section 110 of the Act. EPA does not have before us the Section 110 infrastructure requirements for the 2008 ozone NAAQS. Nevertheless, EPA has considered the 2008 8-hour ozone NAAQS to the extent that section 110(l) applies to this action and will expound on this consideration in Response 2 below. Further, EPA agrees that the Agency has made the determination that the 1997 8-hour ozone NAAQS is not as protective as needed for public health and welfare, and as the Commenter mentioned, the Agency established a new ozone NAAQS at a level of 0.075 ppm on an 8-hour average basis. However, EPA notes that the Agency is currently reconsidering the 2008 8-hour ozone NAAQS, and has not yet designated areas for any subsequent NAAQS.

Finally, while it is not clear which areas the Commenter refers to in stating ''EPA has yet to ensure these areas have plans to meet'' the 1997 ozone NAAQS, the comment may refer to the requirements under section 172, Part D, Title I of the Act for states with nonattainment areas for the 1997 ozone NAAQS to submit nonattainment plans. As discussed in our notice proposing approval of the Connecticut, Maine, New Hampshire and Rhode Island infrastructure SIP, submissions required by section 110(a)(2)(I) which pertain to the nonattainment planning requirements of part D, Title I of the CAA are outside the scope of this action, as such plans are not due within three years after promulgation of a new or revised NAAQS, but rather are due at the time the nonattainment area plan requirements are due pursuant to section 172.

In addition, all of Rhode Island (see 75 FR 64949, Oct. 21, 2010), New Hampshire (see 76 FR 14865, March 18, 2011), and Maine (see 71 FR 71489, Dec. 11, 2006) meet the 1997 ozone NAAQS. The Greater Connecticut 8-hour ozone nonattainment area also meets the 1997 ozone NAAQS (see 75 FR 53219, August 31, 2011). The remainder of the State of Connecticut also meets the 1997 ozone NAAQS based on 2007–2009 ozone data, but EPA has not yet made the formal determination in the **Federal Register**. In summary, all four states have ozone air quality that meets the 1997 ozone NAAQS.

Comment 2: Also under the header ''No Clean Air Act Section 110(l) analysis,'' the Commenter cites the section 110(l) CAA requirement, and states ''Clean Air Act § 110(l) requires 'EPA to evaluate whether the plan as revised will achieve the pollution reductions required under the Act, and

the absence of exacerbation of the existing situation does not assure this result.' *Hall* v. *EPA,* 273 F.3d 1146, 1152 (9th Cir. 2001).'' The Commenter goes on to state that ''* * * the Federal Register notices are devoid of any analysis of how these rule makings will or will not interfere with attaining, making reasonable further progress on attaining and maintaining the 75 ppb ozone NAAQS as well as the 1-hour 100 ppb nitrogen oxides NAAQS.''

Response 2: EPA agrees with the Commenter's assertion that consideration of section 110(l) of the CAA is necessary for EPA's action with regard to approving the states' submissions. However, EPA disagrees with the Commenter's assertion that EPA did not consider 110(l) in terms of the March 23, 2011, proposed action. Further, EPA disagrees with the Commenter's assertion that EPA's proposed March 23, 2011 action does not comply with the requirements of section 110(l). Section 110(l) provides in part that: ''[t]he Administrator shall not approve a revision of a plan if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress * * *, or any other applicable requirement of this chapter.'' EPA has consistently interpreted section 110(l) as not requiring a new attainment demonstration for every SIP submission. EPA has further concluded that preservation of the status quo air quality during the time new attainment demonstrations are being prepared will not interfere with a state meeting its obligations to develop timely attainment demonstrations. The following actions are examples of where EPA has addressed 110(l) in previous rulemakings: See 70 FR 53, 57 (January 3, 2005); 70 FR 17029, 17033 (April 4, 2005); 70 FR 28429, 28431 (May 18, 2005); and 70 FR 58119, 58134 (October 5, 2005). The Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions do not revise or remove any existing emissions limit for any NAAQS or any other existing substantive SIP provisions relevant to the 1997 8-hour ozone NAAQS or the 2010 nitrogen dioxide (NO_2) NAAQS. Simply put, the submissions do not make any substantive revision that could result in any change in emissions. As a result, the submissions do not relax any existing requirements or alter the status quo air quality. Therefore, approval of the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions will not interfere with attainment or maintenance of any NAAQS.

Comment 3: Under the header ''No Clean Air Act Section 110(l) analysis,'' the Commenter states that ''We are not required to guess what EPA's Clean Air Act 110(l) analysis would be. Rather, EPA must approve in part and disapprove in part these action and re-propose to approve the disapproved part with a Clean Air Act § 110(l) analysis.'' Further, the Commenter states that ''EPA cannot include its analysis in its response to comments and approve the actions without providing the public with an opportunity to comment on EPA's Clean Air Act § 110(l) analysis.''

Response 3: Please see Response 2 for a fuller explanation regarding EPA's response to the Commenter's assertion that EPA's action is not in compliance with section 110(l) of the CAA. EPA does not agree with the Commenter's assertion that EPA's analysis did not somehow consider section 110(l) and so, therefore, ''EPA must approve in part and disapprove in part these action [sic] and re-propose to approve the disapproved part with a Clean Air Act § 110(l) analysis.'' Every action that EPA takes to approve a SIP revision is subject to 110(l) and thus EPA's consideration of whether a state's submission ''* * * would interfere with any applicable requirement concerning attainment and reasonable further progress * * *, or any other applicable requirement of this chapter'' is inherent in EPA's action to approve or disapprove a submission from a state. In the ''Proposed Action'' section of the March 23, 2010, rulemaking, EPA notes that EPA is proposing to approve the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions for the 1997 8-hour ozone NAAQS because these submissions are consistent with section 110 of the CAA. Section 110(l) is a component of section 110, so EPA believes that this provides sufficient notice that EPA considered section 110(l) for the proposed action and concluded that section 110(l) was not violated. Further, EPA does not agree with the Commenter's assertion that the Agency cannot provide additional clarification in response to a comment and take a final approval action without ''* * * providing the public with an opportunity to comment on EPA's Clean Air Act § 110(l) analysis.'' The Commenter does not cite any provision of the Act or other authority for the Commenter's assertion. In fact, the proposition that providing an analysis for the first time in response to a comment on a rulemaking somehow violates the public's opportunity to comment has been rejected by the DC Circuit Court of Appeals. *See Int'l Harvester Co.* v. *Ruckelshaus,* 478 F.2d 615, 632 n.51 (D.C. Cir. 1973). Furthermore, as mentioned above, EPA's approval of the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions does not make any substantive revision that could result in any change in emissions, so there is no further ''analysis'' beyond whether the state has adequate provisions in their SIPs to address the infrastructure requirements for the 1997 8-hour ozone NAAQS. EPA's March 23, 2011, proposed rulemaking goes through each of the relevant infrastructure requirements and provides detailed information on how the Connecticut, Maine, New Hampshire and Rhode Island SIPs address the relevant infrastructure requirements. Beyond making a general statement indicating that the Connecticut, Maine, New Hampshire and Rhode Island submissions are somehow not in compliance with section 110(l) of the CAA, the Commenter does not provide comments on EPA's detailed analysis of each infrastructure requirement to indicate that the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions for the 1997 8-hour ozone NAAQS are deficient in meeting these individual requirements. Therefore, EPA has no basis to question the Agency's determination that the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions meet the requirements for the infrastructure submission for the 1997 8-hour ozone NAAQS, including section 110(l) of the CAA.

Comment 4: Under the header ''No Clean Air Act Section 110(l) analysis,'' the Commenter further asserts that ''EPA's analysis must conclude that this proposed action would violation [sic] § 110(l) if finalized.'' An example given by the Commenter is as follows; ''For example, a 42 U.S.C. § 7502(a)(2)(J) public notification program based on a 85 [parts per billion (ppb)] ozone level interferes with a public notification program that should exist for a 75 ppb ozone level. At its worst, the public notification system would be notifying people that the air is safe when in reality, based on the latest science, the air is not safe. Thus, EPA would be condoning the states providing information that can physical[ly] hurt people.''

Response 4: EPA disagrees with the Commenter's statement that ''EPA's analysis must conclude that this proposed action would violation [sic] § 110(l) if finalized.'' As mentioned above, the Connecticut, Maine, New Hampshire and Rhode Island

infrastructure submissions do not revise or remove any existing emissions limit for any NAAQS, nor do they make any substantive revision that could result in any change in emissions. EPA has concluded that the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions do not relax any existing requirements or alter the status quo air quality. Therefore, approval of the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions will not interfere with attainment or maintenance of any NAAQS. See Response 2 and Response 3 above for a fuller discussion. Further, EPA disagrees with the Commenter's assertion that the section 110(a)(2)(J) requirement for public notification for the 1997 8-hour ozone NAAQS based on 85 ppb interferes with a public notification program that should exist for a 75 ppb ozone level, and * * * ''EPA would be condoning the states providing information that can physical[ly] hurt people.'' First, the 1997 8-hour ozone NAAQS is 0.08 ppm, which is effectively 0.084 ppm or 84 ppb due to the rounding convention, and not ''85 ppb'' as the Commenter mentioned. Second, EPA establishes the health-based NAAQS and provides extensive resources, technical analyses and support to the states to ensure compliance with the NAAQS to protect human health and the environment. As noted in Response 1, the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions were provided to address the 1997 8-hour ozone NAAQS and were submitted prior to EPA's promulgation of the 2008 8-hour ozone in March 2008. Thus, the States of Connecticut, Maine, New Hampshire and Rhode Island provided sufficient information at that time to meet the requirement for the 1997 8-hour ozone NAAQS which is the subject of this action.

As mentioned, in 2008, EPA issued revised 8-hour ozone NAAQS, which are currently under reconsideration. Infrastructure requirements for the 2008 (or a subsequent) NAAQS are distinct from these requirements for the 1997 8-hour ozone NAAQS. EPA continues to implement the 2008 ozone NAAQS for the purposes of health based air quality notification. When EPA promulgated the 2008 NAAQS (73 FR 16436, March 27, 2008), we revised the Air Quality Index (AQI) for ozone to show that at the level of the 2008 ozone NAAQS (0.075 ppm) the AQI is set to 100, which indicates ozone levels that are unhealthful for sensitive groups. It is this revised AQI that EPA uses to both forecast ozone levels and to provide notice to the public of current air quality. The EPA AIRNOW system uses the revised AQI as its basis for ozone. (See *http://www.airnow.gov.*) In addition when the States of Connecticut, Maine, New Hampshire and Rhode Island forecast ozone air quality and provide real-time ozone air quality information to the public, either through the AIRNOW system, or through their own (state-based) Internet system, the four states use the revised ozone AQI keyed to the 2008 revised ozone NAAQS.

Comment 5: Lastly, under the header ''No Clean Air Act Section 110(l) analysis,'' the Commenter asserts that ''if a SIP provides an ozone NAAQS of 85 ppb for PSD purposes, this interferes with the requirement that PSD programs require sources to demonstrate that they will not cause or contribute to a violation of a NAAQS because this requirement includes the current 75 ppb ozone NAAQS.''

Response 5: EPA believes that this comment gives no basis for concluding that EPA approval of the Connecticut, Maine, New Hampshire and Rhode Island infrastructure SIPs violate the requirements of section 110(l). EPA assumes that the comment refers to the requirement that owners and operators of sources subject to PSD demonstrate that the allowable emissions increases from the proposed source or modification, in conjunction with all other applicable emissions increases or reductions (including secondary emissions), will not cause or contribute to a violation of the NAAQS. 40 CFR 51.166(k)(1).

EPA further assumes that the Commenter's language ''if a SIP provides an ozone NAAQS of 85 ppb for PSD purposes'' refers to a hypothetical SIP-approved PSD program that only requires owners and operators of sources subject to PSD to make the demonstration discussed above for the 1997 ozone NAAQS, and not for the 2008 ozone NAAQS. However, the Commenter gives no indication that Connecticut, Maine, New Hampshire and Rhode Island's SIP-approved PSD program suffers from this alleged defect.

Furthermore, as discussed in detail above, the infrastructure SIP makes no substantive change to any provision of the Connecticut, Maine, New Hampshire and Rhode Island SIP-approved PSD programs, and therefore does not violate the requirements of section 110(l). Had these states submitted SIP revisions that substantively modified their PSD program to limit the required demonstration to just the 1997 ozone NAAQS, then the comment might have been relevant to a 110(l) analysis of that hypothetical SIP revision. However, in this case, the comment gives no basis for EPA to conclude that the four states' infrastructure SIPs would interfere with any applicable requirement of the Act.

In addition, all of Connecticut, Rhode Island, New Hampshire and Maine are in the Ozone Transport Region (OTR) (see CAA Section 184). For ozone and ozone precursors, all new or modified major sources in the OTR are covered by nonattainment new source review (NSR) regulations and must obtain offsets (at a greater than 1 to 1 ratio) for ozone precursors.[16] In summary, for OTR states, the PSD regulations for ozone do not apply and nonattainment NSR regulations require offsets consistent with the CAA's requirements to address the ambient impact of new source construction in these areas.

EPA concludes that approval of the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions will not make the status quo air quality worse and is in fact consistent with the development of an overall plan capable of meeting the Act's requirements. Accordingly, when applying section 110(l) to this submission, EPA finds that approval of Connecticut, Maine, New Hampshire and Rhode Island's infrastructure submissions is consistent with section 110 (including section 110(l)) of the CAA.

Comment 6: The Commenter provided comments on the lack of a designated air quality model to demonstrate that a PSD source will not cause or contribute to a violation of the ozone NAAQS. Specifically, the commenter stated:

> The SIP submittals do not comply with Clean Air Act 110(a)(2)(J), (K), and (D)(i)(II) because the SIP submittals do not identify a specific model to use in PSD permitting to demonstrate that a proposed source [or] modification will not cause or contribute to a violation of the ozone NAAQS. Many states abuse this lack of an explicitly named model by claiming that because no model is explicitly named, no modeling is required or use of completely irrelevant modeling (*e.g.* Kentucky using modeling from Georgia for the J.K. Smith proposed facility) is allowed.

To support the position as to the necessity of ''[w]hy and which model should be designated,'' the Commenter

[16] For portions of northern and downeast Maine EPA has granted a waiver for the ozone precursor oxides of nitrogen. (see 71 FR 5791, 2/3/06). This waiver was based on a finding that additional reductions in oxides of nitrogen in these areas would not produce net ozone air quality benefits in the ozone transport region. See 42 U.S.C. 7511a(f)(1)(B).

attached a petition [17] and incorporated this petition, and the exhibits to this petition, by reference in the submitted comments.

Response 6: The Commenter referred to the petition for rulemaking from Robert Ukeiley on behalf of the Sierra Club to designate air quality models to use for PSD permit applications with regard to ozone and $PM_{2.5}$. EPA is separately reviewing the July 28, 2010, ''Petition for Rulemaking to Designate Air Quality Models to Use for PSD Permit Applications with Regard to Ozone and $PM_{2.5}$,'' which requests that the EPA Administrator designate computer models to determine whether major sources of air pollution cause or contribute to violations of the ozone NAAQS and the $PM_{2.5}$ NAAQS and increments. Although the Commenter purports to incorporate the July 28, 2010 petition by reference, that petition arises in a different context, requests different relief, and raises distinct issues from those raised by the comment. EPA believes that the appropriate place to respond to the issues raised in the petition is in a direct response to the petition. Accordingly, this Response to the Comment is not a response to the July 28, 2010 petition, and the issues raised in that petition are being addressed under separate consideration.

Furthermore, the states included in this action are Connecticut, Maine, New Hampshire and Rhode Island. Since these states are in the Ozone Transport Region (OTR), they are required to, under Sections 182(f)(1) and 184(b) of the Clean Air Act, and in fact do, conduct nonattainment NSR for new major and modified major sources of ozone precursors.[18] Section 184(b)(2) requires major stationary sources of volatile organic compounds at the 50 ton per year level in the OTR to meet all ''the requirements which would be applicable to major stationary sources if the area were classified as a Moderate nonattainment area.'' Section 182(f)(1) has the effect of extending that requirement to major sources of nitrogen oxides at the 100 ton per year level in the OTR. Under the nonattainment NSR program, sources are not required to predict their ambient impacts using modeling. Rather, the program assumes the new or modified sources will contribute to nonattainment in the area. Accordingly, the program requires that these sources secure offsets for their new emissions at a ratio of at least 1.15 to 1 in the OTR. Thus, the offset requirement addresses the ambient impact element of NSR in these states for ozone precursors without reliance on any predictive modeling. Therefore, this comment regarding which model to use in the PSD modeling of single source's ozone precursors is not relevant to this action.

Comment 7: Under the heading ''CT's SIP must require notice to affected states,'' the Commenter states, ''CT's SIP is defective because its PSD regulations fail to require CT to give notice of PSD sources to affected states. 76 FR 16358, 16362 (Mar. 23, 2011). EPA must disapprove this defective provision. The fact that neighboring states have consistently obtained draft permits in the past does not justify approving an illegal SIP. It does not even make sense. To begin with, it is unlikely that EPA actually reviewed all PSD permits issued in the past to actually determine that proper notice was actually given by CT. In any event, CT could change its informal policy in the future, especially if there is a change in management in the agency or state.''

Response 7: Section 110(a)(2)(D)(ii) of the CAA requires SIPs to include provisions insuring compliance with the applicable requirements of sections 126 and 115 (relating to interstate and international pollution abatement). Specifically, section 126(a) requires new or modified major sources to notify neighboring states of potential impacts from the source. As noted in EPA's proposed approval (see 76 FR 16362), Connecticut's PSD regulations provide for notice to most of the parties consistent with the requirements in the EPA PSD program, although there is no specific mandate that affected states receive notice. As also noted in the proposed approval, Connecticut in fact issues extensive notice of its draft permits, and neighboring states consistently get copies on those drafts. However, EPA agrees with the commenter that the current Connecticut SIP does not explicitly require notice to affected states for some sources of air pollution. Subsequent to EPA's proposal, on May 2, 2011, EPA received a written commitment from the State of Connecticut to pursue regulatory revisions to Connecticut's PSD program to adopt a formal requirement to notify nearby states. Connecticut's letter also committed to continue to provide notice to nearby states while shepherding these regulatory revisions through the state process. Therefore, taking all of this information into consideration, EPA has decided to take direct final action to conditionally approve this element of the Connecticut SIP. Conditional approval is appropriate in this circumstance because the State has explicitly committed to continuing its practice of notifying affected states while it conforms its regulations to mandate that practice.

IV. Final Action

As described above, the Connecticut, Maine, New Hampshire and Rhode Island ozone infrastructure SIP submissions have addressed the elements of the CAA 110(a)(1) and (2) SIP requirements pursuant to EPA's October 2, 2007 guidance to ensure that the 1997 8-hour ozone NAAQS are implemented, enforced, and maintained in the respective state, except for one element in Connecticut. EPA is taking final action to approve the Connecticut, Maine, New Hampshire and Rhode Island infrastructure submissions for the 1997 8-hour ozone NAAQS because these submissions are consistent with section 110 of the CAA, except for the element required by section 110(a)(2)(D)(ii) in Connecticut.

EPA is conditionally approving the Connecticut submittal with respect to the requirement of CAA section 110(a)(2)(D)(ii). The State must submit to EPA by July 9, 2012 the revised PSD regulations requiring notification of nearby states. If the State fails to do so, this approval will become a disapproval on that date. EPA will notify the State by letter that this action has occurred. At that time, this commitment will no longer be a part of the approved Connecticut SIP. EPA subsequently will publish a notice in the notice section of the **Federal Register** notifying the public that the conditional approval automatically converted to a disapproval. If the State meets its commitment, within the applicable time frame, the conditionally approved submission will remain a part of the SIP until EPA takes final action approving or disapproving the new submittal. If EPA disapproves the new submittal, the conditionally approved submittal will also be disapproved at that time. If EPA approves the new submittal, Connecticut's infrastructure SIP will be fully approved in its entirety and

[17] The Commenter attached the July 28, 2010, ''Petition for Rulemaking to Designate Air Quality Models to use for PSD Permit Applications with Regard to Ozone and $PM_{2.5}$,'' from Robert Ukeiley on behalf of the Sierra Club. That petition and the attached exhibits are available in the docket supporting this action.

[18] Note that EPA has granted a waiver from the requirements of 182(f) for the northern-most counties in Maine. EPA granted this waiver based on the finding required under 182(f)(1)(B) that ''additional reductions of oxides of nitrogen would not produce net ozone air quality benefits in [the OTR].'' EPA has determined for northern Maine that NOx emissions reductions are not necessary to attain or maintain the ozone NAAQS in the OTR. Therefore, EPA does not believe that the absence of a specified model in the PSD program for predicting ozone impacts from a NOx source in this particular area of the OTR is problematic.

replace the conditionally approved element in the SIP.

If the conditional approval is converted to a disapproval, the final disapproval triggers the Federal Implementation Plan (FIP) requirement under section 110(c).

The EPA is publishing this conditional approval without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to conditionally approve the Connecticut submittal with respect to CAA section 110(a)(2)(D)(ii) should relevant adverse comments be filed. This rule will be effective September 6, 2011 without further notice unless the Agency receives relevant adverse comments by August 8, 2011.

If the EPA receives such comments, then EPA will publish a notice withdrawing the final conditional approval and informing the public that the conditional approval will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on the proposed rule. All parties interested in commenting on the proposed rule should do so at this time. If no such comments are received, the public is advised that the conditional approval will be effective on September 6, 2011 and no further action will be taken on the proposed rule. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

V. Statutory and Executive Order Reviews

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

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

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 6, 2011. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: June 28, 2011.

Ira W. Leighton,

Acting, Regional Administrator, EPA New England.

Part 52 of chapter I, title 40 of the Code of Federal Regulations, is amended as follows:

PART 52—[AMENDED]

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

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

Subpart H—Connecticut

■ 2. Section 52.377 is amended by adding paragraphs (g) and (h) to read as follows:

§ 52.377 Control strategy: Ozone.

* * * * *

(g) Approval—Submittal from the Connecticut Department of Environmental Protection, dated December 28, 2007, to address the Clean Air Act (CAA) infrastructure requirements for the 1997 ozone National Ambient Air Quality Standard (NAAQS). This submittal satisfies the requirements of CAA sections 110(a)(2)(A), (B), (C), (E), (F), (G), (H), (J), (K), (L), and (M).

(h) Conditional Approval—Submittal from the Connecticut Department of Environmental Protection, dated December 28, 2007, to address the Clean Air Act (CAA) infrastructure

requirements for the 1997 ozone National Ambient Air Quality Standard (NAAQS). On May 2, 2011, the State of Connecticut supplemented this submittal with a commitment to address the requirements of section 110(a)(2)(D)(ii) of the CAA that requires notification of affected states for Prevention of Significant Deterioration purposes. EPA is conditionally approving Connecticut's submittal with respect to CAA section 110(a)(2)(D)(ii).

Subpart U—Maine

■ 3. In § 52.1020, Table (e) is amended by adding a new entry at the end of the table to read as follows:

§ 52.1020 Identification of plan.

* * * * *

(e) * * *

MAINE NON REGULATORY

Name of non regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/ effective date	EPA approved date [3]	Explanations
*	*	*	*	*
Submittal to meet Clean Air Act Section 110(a)(2) Infrastructure Requirements for the 1997 8-Hour Ozone National Ambient Air Quality Standard.	State of Maine	January 3, 2008	July 8, 2011 [Insert **Federal Register** page number where the document begins].	This action addresses the following Clean Air Act requirements: 110(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M).

[3] In order to determine the EPA effective date for a specific provision listed in this table, consult the **Federal Register** notice cited in this column for the particular provision.

Subpart EE—New Hampshire

■ 4. In § 52.1520, Table (e) is amended by adding a new entry at the end of the table to read as follows:

§ 52.1520 Identification of plan.

* * * * *

(e) * * *

NEW HAMPSHIRE NON REGULATORY

Name of non regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/ effective date	EPA approved date [3]	Explanations
*	*	*	*	*
Submittal to meet Clean Air Act Section 110(a)(2) Infrastructure Requirements for the 1997 8-Hour Ozone National Ambient Air Quality Standard.	State of New Hampshire.	December 14, 2007	July 8, 2011 [Insert **Federal Register** page number where the document begins].	This action addresses the following Clean Air Act requirements: 110(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M).

[3] In order to determine the EPA effective date for a specific provision listed in this table, consult the **Federal Register** notice cited in this column for the particular provision.

Subpart OO—Rhode Island

■ 5. In § 52.2070, Table (e) is amended by adding a new entry at the end of the table to read as follows:

§ 52.2070 Identification of plan.

* * * * *

(e) * * *

RHODE ISLAND NON REGULATORY

Name of non regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/ effective date	EPA approved date	Explanations
*	*	*	*	*
Submittal to meet Clean Air Act Section 110(a)(2) Infrastructure Requirements for the 1997 8-Hour Ozone National Ambient Air Quality Standard.	State of Rhode Island	December 14, 2007	July 8, 2011 [Insert **Federal Register** page number where the document begins].	This action addresses the following Clean Air Act requirements: 110(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M).

[FR Doc. 2011–17021 Filed 7–7–11; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2011–0310; FRL–9434–4]

Approval and Promulgation of Implementation Plans; State of NE

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving the State Implementation Plan (SIP) submittal from the State of Nebraska addressing the requirements of Clean Air Act (CAA or Act) sections 110(a)(1) and (2) to implement, maintain, and enforce the 1997 revisions to the National Ambient Air Quality Standards (NAAQS) for ozone. The rationale for this action is explained in this notice and in more detail in the notice of proposed rulemaking for this action. EPA received no comments on the proposal.

DATES: *Effective Date:* This rule is effective August 8, 2011.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2011–0310. All documents in the docket are listed on the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the U.S. Environmental Protection Agency, Region 7, in the Air Planning and Development Branch of the Air and Waste Management Division, 901 North 5th Street, Kansas City, Kansas 66101. EPA requests that, if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance. The Regional Office official hours of business are Monday through Friday, 8:00 to 4:30, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth Kramer, Air Planning and Development Branch, U.S. Environmental Protection Agency, Region 7, 901 North 5th Street, Kansas City, Kansas 66101; *telephone number:* (913) 551–7186; *fax number:* (913) 551–7844; *e-mail address: kramer.elizabeth@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. These sections provide additional information on this final action:

Table of Contents

I. Background
II. Summary of Relevant Submissions
III. Scope of Infrastructure SIPs
IV. Final Action
V. Statutory and Executive Order Reviews

I. Background

On March 30, 2011 (76 FR 17592), EPA published a proposed rulemaking for the State of Nebraska. This rulemaking proposed approval of Nebraska's submittal dated December 7, 2007 as meeting the relevant and applicable requirements of CAA sections 110(a)(1) and (2) necessary to implement, maintain, and enforce the 1997 8-hour ozone NAAQS.

II. Summary of Relevant Submissions

The above referenced submittal addresses the infrastructure elements specified in CAA sections 110(a)(1) and (2). This submittal refers to the implementation, maintenance and enforcement of the 1997 8-hour ozone NAAQS. The rationale supporting EPA's proposed action is explained in the proposal and EPA incorporates by reference the rationale in the proposal, as supplemented by this notice, as its rationale for the final rule. No public comments were received on the proposed rulemaking.

III. Scope of Infrastructure SIPs

EPA is currently acting upon SIPs that address the infrastructure requirements of CAA section 110(a)(1) and (2) for ozone and PM2.5 NAAQS for various states across the country. Commenters on EPA's recent proposals for some states raised concerns about EPA statements that it was not addressing certain substantive issues in the context of acting on the infrastructure SIP submissions.[1] The commenters specifically raised concerns involving provisions in existing SIPs and with EPA's statements that it would address two issues separately and not as part of actions on the infrastructure SIP submissions: (i) existing provisions related to excess emissions during periods of start-up, shutdown, or malfunction at sources, that may be contrary to the CAA and EPA's policies addressing such excess emissions (''SSM''); and (ii) existing provisions related to ''director's variance'' or ''director's discretion'' that purport to permit revisions to SIP approved emissions limits with limited public process or without requiring further approval by EPA, that may be contrary to the CAA (''director's discretion''). EPA notes that there are two other substantive issues for which EPA likewise stated that it would address the issues separately: (i) existing provisions for minor source new source review programs that may be inconsistent with the requirements of the CAA and EPA's regulations that pertain to such programs (''minor source NSR''); and (ii) existing provisions for Prevention of Significant Deterioration (PSD) programs that may be inconsistent with current requirements of EPA's ''Final NSR Improvement Rule,'' 67 FR 80186 (December 31, 2002), as amended by 72 FR 32526 (June 13, 2007) (''NSR Reform''). In light of the comments, EPA now believes that its statements in various proposed actions on infrastructure SIPs with respect to these four individual issues should be explained in greater depth with respect to these issues.

EPA intended the statements in the proposals concerning these four issues merely to be informational, and to provide general notice of the potential existence of provisions within the existing SIPs of some states that might require future corrective action. EPA did not want states, regulated entities, or members of the public to be under the misconception that the Agency's approval of the infrastructure SIP submission of a given state should be interpreted as a reapproval of certain types of provisions that might exist buried in the larger existing SIP for such state. Thus, for example, EPA explicitly noted that the Agency believes that some states may have existing SIP approved SSM provisions that are contrary to the CAA and EPA policy, but that ''in this rulemaking, EPA is not proposing to approve or disapprove any existing State provisions with regard to excess emissions during SSM of operations at facilities.'' EPA further explained, for informational purposes, that ''EPA plans to address such State regulations in the future.'' EPA made

[1] See, Comments of Midwest Environmental Defense Center, dated May 31, 2011. Docket # EPA–R05–OAR–2007–1179 (adverse comments on proposals for three states in Region 5). EPA notes that these public comments on another proposal are not relevant to this rulemaking and do not have to be directly addressed in this rulemaking. EPA will respond to these comments in the appropriate rulemaking action to which they apply.

similar statements, for similar reasons, with respect to the director's discretion, minor source NSR, and NSR Reform issues. EPA's objective was to make clear that approval of an infrastructure SIP for these ozone and PM2.5 NAAQS should not be construed as explicit or implicit reapproval of any existing provisions that relate to these four substantive issues.

Unfortunately, the commenters and others evidently interpreted these statements to mean that EPA considered action upon the SSM provisions and the other three substantive issues to be integral parts of acting on an infrastructure SIP submission, and therefore that EPA was merely postponing taking final action on the issue in the context of the infrastructure SIPs. This was not EPA's intention. To the contrary, EPA only meant to convey its awareness of the potential for certain types of deficiencies in existing SIPs, and to prevent any misunderstanding that it was reapproving any such existing provisions. EPA's intention was to convey its position that the statute does not require that infrastructure SIPs address these specific substantive issues in existing SIPs and that these issues may be dealt with separately, outside the context of acting on the infrastructure SIP submission of a state. To be clear, EPA did not mean to imply that it was not taking a full final agency action on the infrastructure SIP submission with respect to any substantive issue that EPA considers to be a required part of acting on such submissions under section 110(k) or under section 110(c). Given the confusion evidently resulting from EPA's statements, however, we want to explain more fully the Agency's reasons for concluding that these four potential substantive issues in existing SIPs may be addressed separately.

The requirement for the SIP submissions at issue arises out of CAA section 110(a)(1). That provision requires that states must make a SIP submission ''within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof)'' and that these SIPS are to provide for the ''implementation, maintenance, and enforcement'' of such NAAQS. Section 110(a)(2) includes a list of specific elements that ''[e]ach such plan'' submission must meet. EPA has historically referred to these particular submissions that states must make after the promulgation of a new or revised NAAQS as ''infrastructure SIPs.'' This specific term does not appear in the statute, but EPA uses the term to distinguish this particular type of SIP submission designed to address basic structural requirements of a SIP from other types of SIP submissions designed to address other different requirements, such as ''nonattainment SIP'' submissions required to address the nonattainment planning requirements of part D, ''regional haze SIP'' submissions required to address the visibility protection requirements of CAA section 169A, new source review permitting program submissions required to address the requirements of part D, and a host of other specific types of SIP submissions that address other specific matters.

Although section 110(a)(1) addresses the timing and general requirements for these infrastructure SIPs, and section 110(a)(2) provides more details concerning the required contents of these infrastructure SIPs, EPA believes that many of the specific statutory provisions are facially ambiguous. In particular, the list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive provisions, and some of which pertain to requirements for both authority and substantive provisions.[2] Some of the elements of section 110(a)(2) are relatively straightforward, but others clearly require interpretation by EPA through rulemaking, or recommendations through guidance, in order to give specific meaning for a particular NAAQS.[3]

Notwithstanding that section 110(a)(2) states that ''each'' SIP submission must meet the list of requirements therein, EPA has long noted that this literal reading of the statute is internally inconsistent, insofar as section 110(a)(2)(I) pertains to nonattainment SIP requirements that could not be met on the schedule provided for these SIP submissions in section 110(a)(1).[4] This illustrates that EPA must determine which provisions of section 110(a)(2) may be applicable for a given infrastructure SIP submission. Similarly, EPA has previously decided that it could take action on different parts of the larger, general ''infrastructure SIP'' for a given NAAQS without concurrent action on all subsections, such as section 110(a)(2)(D)(i), because the Agency bifurcated the action on these latter ''interstate transport'' provisions within section 110(a)(2) and worked with states to address each of the four prongs of section 110(a)(2)(D)(i) with substantive administrative actions proceeding on different tracks with different schedules.[5] This illustrates that EPA may conclude that subdividing the applicable requirements of section 110(a)(2) into separate SIP actions may sometimes be appropriate for a given NAAQS where a specific substantive action is necessitated, beyond a mere submission addressing basic structural aspects of the State's implementation plan. Finally, EPA notes that not every element of section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAQS and the attendant infrastructure SIP submission for that NAAQS. For example, the monitoring requirements that might be necessary for purposes of section 110(a)(2)(B) for one NAAQS could be very different than what might be necessary for a different pollutant. Thus, the content of an infrastructure SIP submission to meet this element from a state might be very different for an entirely new NAAQS, versus a minor revision to an existing NAAQS.[6]

Similarly, EPA notes that other types of SIP submissions required under the statute also must meet the requirements of section 110(a)(2), and this also demonstrates the need to identify the applicable elements for other SIP

[2] For example, section 110(a)(2)(E) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; section 110(a)(2)(C) provides that states must have a substantive program to address certain sources as required by part C of the CAA; section 110(a)(2)(G) provides that states must have both legal authority to address emergencies and substantive contingency plans in the event of such an emergency.

[3] For example, section 110(a)(2)(D)(i) requires EPA to be sure that each state's SIP contains adequate provisions to prevent significant contribution to nonattainment of the NAAQS in other states. This provision contains numerous terms that require substantial rulemaking by EPA in order to determine such basic points as what constitutes significant contribution. See, *e.g.,* ''Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_x SIP Call; Final Rule,'' 70 FR 25162 (May 12, 2005) (defining, among other things, the phrase ''contribute significantly to nonattainment'').

[4] See, *e.g., Id.,* 70 FR 25162, at 63–65 (May 12, 2005) (explaining relationship between timing requirement of section 110(a)(2)(D) versus section 110(a)(2)(I)).

[5] EPA issued separate guidance to states with respect to SIP submissions to meet section 110(a)(2)(D)(i) for the 1997 ozone and 1997 PM2.5 NAAQS. See, ''Guidance for State Implementation Plan (SIP) Submissions to Meet Current Outstanding Obligations Under Section 110(a)(2)(D)(i) for the 8-Hour Ozone and PM2.5 National Ambient Air Quality Standards,'' from William T. Harnett, Director Air Quality Policy Division OAQPS, to Regional Air Division Director, Regions I–X, dated August 15, 2006.

[6] For example, implementation of the 1997 PM2.5 NAAQS required the deployment of a system of new monitors to measure ambient levels of that new indicator species for the new NAAQS.

submissions. For example, nonattainment SIPs required by part D likewise have to meet the relevant subsections of section 110(a)(2) such as section 110(a)(2)(A) or (E). By contrast, it is clear that nonattainment SIPs would not need to meet the portion of section 110(a)(2)(C) that pertains to part C, *i.e.,* the PSD requirement applicable in attainment areas. Nonattainment SIPs required by part D also would not need to address the requirements of section 110(a)(2)(G) with respect to emergency episodes, as such requirements would not be limited to nonattainment areas. As this example illustrates, each type of SIP submission may implicate some subsections of section 110(a)(2) and not others.

Given the potential for ambiguity of the statutory language of section 110(a)(1) and (2), EPA believes that it is appropriate for EPA to interpret that language in the context of acting on the infrastructure SIPs for a given NAAQS. Because of the inherent ambiguity of the list of requirements in section 110(a)(2), EPA has adopted an approach in which it reviews infrastructure SIPs against this list of elements ''as applicable.'' In other words, EPA assumes that Congress could not have intended that each and every SIP submission, regardless of the purpose of the submission or the NAAQS in question, would meet each of the requirements, or meet each of them in the same way. EPA elected to use guidance to make recommendations for infrastructure SIPs for these NAAQS.

On October 2, 2007, EPA issued guidance making recommendations for the infrastructure SIP submissions for both the 1997 8-hour ozone NAAQS and the 1997 PM2.5 NAAQS.[7] Within this guidance document, EPA described the duty of states to make these submissions to meet what the Agency characterized as the ''infrastructure'' elements for SIPs, which it further described as the ''basic SIP requirements, including emissions inventories, monitoring, and modeling to assure attainment and maintenance of the standards.''[8] As further identification of these basic structural SIP requirements, ''attachment A'' to the guidance document included a short description of the various elements of section 110(a)(2) and additional information about the types of issues that EPA considered germane in the context of such infrastructure SIPs. EPA emphasized that the description of the basic requirements listed on attachment A was not intended ''to constitute an interpretation of'' the requirements, and was merely a ''brief description of the required elements.''[9] EPA also stated its belief that with one exception, these requirements were ''relatively self explanatory, and past experience with SIPs for other NAAQS should enable States to meet these requirements with assistance from EPA Regions.''[10] For the one exception to that general assumption, however, *i.e.,* how states should proceed with respect to the requirements of section 110(a)(2)(G) for the 1997 PM2.5 NAAQS, EPA gave much more specific recommendations. But for other infrastructure SIP submittals, and for certain elements of the submittals for the 1997 PM2.5 NAAQS, EPA assumed that each State would work with its corresponding EPA regional office to refine the scope of a State's submittal based on an assessment of how the requirements of section 110(a)(2) should reasonably apply to the basic structure of the State's implementation plan for the NAAQS in question.

Significantly, the 2007 Guidance did not explicitly refer to the SSM, director's discretion, minor source NSR, or NSR Reform issues as among specific substantive issues EPA expected states to address in the context of the infrastructure SIPs, nor did EPA give any more specific recommendations with respect to how states might address such issues even if they elected to do so. The SSM and director's discretion issues implicate section 110(a)(2)(A), and the minor source NSR and NSR Reform issues implicate section 110(a)(2)(C). In the 2007 Guidance, however, EPA did not indicate to states that it intended to interpret these provisions as requiring a substantive submission to address these specific issues in the context of the infrastructure SIPs for these NAAQS. Instead, EPA's 2007 Guidance merely indicated its belief that the states should make submissions in which they established that they have the basic SIP structure necessary to implement, maintain, and enforce the NAAQS. EPA believes that states can establish that they have the basic SIP structure, notwithstanding that there may be potential deficiencies within the existing SIP. Thus, EPA's proposals mentioned these issues not because the Agency considers them issues that must be addressed in the context of an infrastructure SIP as required by section 110(a)(1) and (2), but rather because EPA wanted to be clear that it considers these potential existing SIP problems as separate from the pending infrastructure SIP actions.

EPA believes that this approach to the infrastructure SIP requirement is reasonable, because it would not be feasible to read section 110(a)(1) and (2) to require a top to bottom, stem to stern, review of each and every provision of an existing SIP merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts that, while not fully up to date, nevertheless may not pose a significant problem for the purposes of ''implementation, maintenance, and enforcement'' of a new or revised NAAQS when EPA considers the overall effectiveness of the SIP. To the contrary, EPA believes that a better approach is for EPA to determine which specific SIP elements from section 110(a)(2) are applicable to an infrastructure SIP for a given NAAQS, and to focus attention on those elements that are most likely to need a specific SIP revision in light of the new or revised NAAQS. Thus, for example, EPA's 2007 Guidance specifically directed states to focus on the requirements of section 110(a)(2)(G) for the 1997 PM2.5 NAAQS because of the absence of underlying EPA regulations for emergency episodes for this NAAQS and an anticipated absence of relevant provisions in existing SIPs.

Finally, EPA believes that its approach is a reasonable reading of section 110(a)(1) and (2) because the statute provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow the Agency to take appropriate tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a ''SIP Call'' whenever the Agency

[7] See, ''Guidance on SIP Elements Required Under Section 110(a)(1) and (2) for the 1997 8-hour Ozone and PM2.5 National Ambient Air Quality Standards,'' from William T. Harnett, Director, Air Quality Policy Division, to Air Division Directors, Regions I–X, dated October 2, 2007 (the ''2007 Guidance''). EPA issued comparable guidance for the 2006 PM2.5 NAAQS entitled ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 2006 24-Hour Fine Particle (PM2.5) National Ambient Air Quality Standards (NAAQS),'' from William T. Harnett, Director, Air Quality Policy Division, to Regional Air Division Directors, Regions I–X, dated September 25, 2009 (the ''2009 Guidance'').

[8] *Id.,* at page 2.

[9] *Id.,* at attachment A, page 1.

[10] *Id.,* at page 4. In retrospect, the concerns raised by commenters with respect to EPA's approach to some substantive issues indicates that the statute is not so ''self explanatory,'' and indeed is sufficiently ambiguous that EPA needs to interpret it in order to explain why these substantive issues do not need to be addressed in the context of infrastructure SIPs and may be addressed at other times and by other means.

determines that a State's implementation plan is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or otherwise to comply with the CAA.[11] Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions.[12] Significantly, EPA's determination that an action on the infrastructure SIP is not the appropriate time and place to address all potential existing SIP problems does not preclude the Agency's subsequent reliance on provisions in section 110(a)(2) as part of the basis for action at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on the infrastructure SIP, EPA believes that section 110(a)(2)(A) may be among the statutory bases that the Agency cites in the course of addressing the issue in a subsequent action.[13]

IV. Final Action

EPA is taking final action to approve Nebraska's submittal that provides the basic program elements to meet the applicable requirements in CAA sections 110(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M) necessary to implement, maintain, and enforce the 1997 8-hour ozone NAAQS.

As explained in the proposed rulemaking, this action does not address the requirements of section 110(a)(2)(D)(i) for the 1997 8-hour ozone NAAQS, because it has already been addressed in a separate rulemaking. *See* 72 FR 71245. The scope of this action is further discussed in section III, above.

V. Statutory and Executive Order Reviews

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

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

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 6, 2011. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review, nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone.

Dated: June 28, 2011.

Karl Brooks,

Regional Administrator, Region 7.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart CC—Nebraska

■ 2. In § 52.1420(e) the table is amended by adding an entry in numerical order to read as follows:

§ 52.1420 Identification of plan.

* * * * *

(e) * * *

[11] EPA has recently issued a SIP call to rectify a specific SIP deficiency related to the SSM issue. See, ''Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revision,'' 74 FR 21639 (April 18, 2011).

[12] EPA has recently utilized this authority to correct errors in past actions on SIP submissions related to PSD programs. See, ''Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule,'' 75 FR 82536 (December 30, 2010). EPA has previously used its authority under CAA 110(k)(6) to remove numerous other SIP provisions that the Agency determined it had approved in error. See, *e.g.,* 61 FR 38664 (July 25, 1996) and 62 FR 34641 (June 27, 1997) (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); 69 FR 67062 (November 16, 2004) (corrections to California SIP); and 74 FR 57051 (November 3, 2009) (corrections to Arizona and Nevada SIPs).

[13] EPA has recently disapproved a SIP submission from Colorado on the grounds that it would have included a director's discretion provision inconsistent with CAA requirements, including section 110(a)(2)(A). See, *e.g.,* 75 FR 42342 at 42344 (July 21, 2010) (proposed disapproval of director's discretion provisions); 76 FR 4540 (January 26, 2011) (final disapproval of such provisions).

EPA-APPROVED NEBRASKA NONREGULATORY PROVISIONS

Name of nonregulatory SIP provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanation
*	*	*	*	*
(24) Section 110(a)(2) .... Infrastructure Requirements for the 1997 8-Hour Ozone NAAQS.	Statewide	12/7/07	7/8/11 ..... [*insert FR page number where the document begins*].	This action addresses the following CAA elements, as applicable: 110(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M).

[FR Doc. 2011–17193 Filed 7–7–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2009–0512; FRL–9430–6]

Determination of Attainment, Approval and Promulgation of Air Quality Implementation Plans; Indiana; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: On March 12, 2010, EPA published a final rule making a determination that the entire Chicago-Gary-Lake County, Illinois-Indiana (IL-IN) 1997 eight-hour ozone nonattainment area has attained the 1997 eight-hour ozone National Ambient Air Quality Standard (NAAQS). This action corrects an omission in the regulatory text of the aforementioned **Federal Register** document.

DATES: *Effective Date:* This final rule is effective on July 8, 2011.

FOR FURTHER INFORMATION CONTACT: Edward Doty, Environmental Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6057, *doty.edward@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This action provides a technical correction to the regulatory language in the final rulemaking published at 75 FR 12088 on March 12, 2010. In that rulemaking, EPA made a determination that the entire Chicago-Gary-Lake County, IL-IN ozone nonattainment area has attained the 1997 eight-hour ozone NAAQS. The determination was based on complete, quality-assured ambient air quality monitoring data for the period of 2006–2008. Additional background on the applicable NAAQS and EPA's data are contained in the September 24, 2009 proposed rule at 74 FR 48703–48706.

As published on March 12, 2010, the regulatory language contained an omission which needs to be corrected. Our determination was properly codified for the Indiana portion of the area (Lake and Porter Counties) in the final rule at 75 FR 12089 with the addition of 40 CFR 52.777(mm)). However, an amendment to 40 CFR 52 codifying our determination for the Illinois portion of the area, Cook, DuPage, Kane, Lake, McHenry, and Will Counties, and portions of Grundy County (Aux Sable and Goose Lake Townships) and Kendall County (Oswego Township), was inadvertently omitted. Therefore, EPA is correcting this error by adding paragraph (jj) to 40 CFR 52.726 for Illinois.

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. We have determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because this rule is not substantive and imposes no regulatory requirements, but merely corrects an omitted citation in a previous action. Thus, notice and public procedure are unnecessary. We find that this constitutes good cause under 5 U.S.C. 553(b)(B).

Statutory and Executive Order Reviews

Under Executive Order (E.O.) 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)). Because the agency has made a ''good cause'' finding that this action is not subject to notice-and-comment requirements under the Administrative Procedures Act or any other statute as indicated in the Supplementary Information section above, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. This rule also does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of governments, as specified by Executive Order 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

This technical correction action does not involve technical standards; thus the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. The rule also does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996).

EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1998) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 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. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA had made such a good cause finding, including the reasons therefore, and established an effective date of July 8, 2011. 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 correction to 40 CFR part 52 for Illinois is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Dated: June 24, 2011.

Susan Hedman,

Regional Administrator, Region 5.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for 40 CFR part 52 continues to read as follows:

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

Subpart O—Illinois

■ 2. Section 52.726 is amended by adding paragraph (jj) to read as follows:

§ 52.726 Control strategy. Ozone.

* * * * *

(jj) *Determination of attainment.* On June 5, 2009, the state of Indiana requested that EPA find that the Indiana portion of the Chicago-Gary-Lake County, Illinois-Indiana (IL-IN) ozone nonattainment area has attained the 1997 8-hour ozone National Ambient Air Quality Standard (NAAQS). After review of Indiana's submission and 2006–2008 ozone air quality data for this ozone nonattainment area, EPA finds that the entire Chicago-Gary-Lake County, IL-IN area has attained the 1997 8-hour ozone NAAQS. Therefore, EPA has determined, as of March 12, 2010, that Cook, DuPage, Kane, Lake, McHenry, and Will Counties, and portions of Grundy County (Aux Sable and Goose Lake Townships) and Kendall County (Oswego Township) in Illinois have attained the 1997 8-hour ozone standard.

[FR Doc. 2011–17050 Filed 7–7–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 15 and 76

[CS Docket No. 97–80; PP Docket No. 00–67; FCC 10–181]

Implementation of Section 304 of the Telecommunications Act of 1996: Commercial Availability of Navigation Devices; Compatibility Between Cable Systems and Consumer Electronics Equipment

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, we adopt new rules designed to improve the operation of the CableCARD regime until a successor solution becomes effective. The Commission has not been fully successful in implementing the command of Section 629 of the Communications Act to ensure the commercial availability of navigation devices used by consumers to access the services of multichannel video programming distributors (''MVPDs''). The rules adopted in this order are intended to bolster support for retail CableCARD devices so that consumers may access cable services without leasing a set-top box from their cable operators.

DATES: Effective August 8, 2011, except for §§ 76.1205(b)(1), 76.1205(b)(1)(i), 76.1205(b)(2), 76.1205(b)(5), and 76.1602(b), which contain information collection requirements that have not been approved by OMB. The Federal Communications Commission will publish a document in the **Federal Register** announcing the effective date of §§ 76.1205(b)(1), 76.1205(b)(1)(i), 76.1205(b)(2), 76.1205(b)(5), and 76.1602(b).

The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of August 8, 2011.

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 or Alison Neplokh, *Alison.Neplokh@fcc.gov,* of the Media Bureau, (202) 418–1083.

For additional information concerning the information collection requirements contained in this document, send an e-mail to *PRA@fcc.gov* or contact Cathy Williams on (202) 418–2918.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *(Third Report and Order and Order on Reconsideration),* FCC 10–181, adopted and released on October 14, 2010. The full text of these documents 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. These documents 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 e-mail 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 and Order on Reconsideration

1. In this Third Report and Order (''*Order*''), we remedy shortcomings in our CableCARD rules in order to improve consumers' experience with retail navigation devices (such as set-top boxes and digital cable-ready television sets) and CableCARDs, the security devices used in conjunction with navigation devices to perform the conditional access functions necessary to access cable services. We believe these rule changes are necessary to discharge our responsibility under the Act to assure the development of a retail market for devices that can navigate cable services. We seek to remove the disparity in consumer experience between those who choose to buy a retail device and those who lease the cable provider's set-top box, as the

disparity is impeding the development of a retail market for navigation devices. Specifically, we adopt rules today to (1) require cable operators to support the reception of switched digital video services on retail devices to ensure that subscribers are able to access the services for which they pay regardless of whether they lease or purchase their devices; (2) prohibit price discrimination against retail devices to support a competitive marketplace for retail devices; (3) require cable operators to allow self-installation of CableCARDs where device manufacturers offer device-specific installation instructions to make the installation experience for retail devices comparable to the experience for leased devices; (4) require cable operators to provide multi-stream CableCARDs by default to ensure that cable operators are providing their subscribers with current CableCARD technology; and (5) clarify that CableCARD device certification rules are limited to certain technical features to make it easier for device manufacturers to get their products to market. We also modify our rules to encourage home-networking by simplifying our set-top box output requirements. In addition, we adopt a rule to promote the cable industry's transition to all-digital networks by exempting all one-way set-top boxes without recording functionality from the integration ban. Each of the rule changes adopted in this item are intended to meet the goals of Section 629 by further developing a retail market for navigation devices. Finally, we consider nine petitions for reconsideration of prior decisions in CS Docket No. 97–80, PP Docket No. 00–67, and the enforcement proceedings captioned above regarding changes to device certification procedures, the Commission's content encoding and protection rules, and access to switched digital video. Together, the changes we adopt today should benefit consumers who wish to buy navigation devices while at the same time removing unnecessary regulatory obligations on cable operators.

2. *Background.* In the Telecommunications Act of 1996, Congress added Section 629 to the Communications Act. That section directs the Commission to adopt regulations to assure the commercial availability of navigation devices used by consumers to access services from multichannel video programming distributors (''MVPDs''). Section 629 covers ''equipment used by consumers to access multichannel video programming and other services offered over multichannel video programming systems.'' Congress, in enacting the section, pointed to the vigorous retail market for customer premises equipment used with the public switched-telephone network and sought to create a similarly vigorous market for devices used with MVPD services.

3. In 1998, the Commission adopted the *First Report and Order* to implement Section 629. The order required MVPDs to make available a conditional access element separate from the basic navigation or host device, in order to permit unaffiliated manufacturers and retailers to manufacture and market host devices while allowing MVPDs to retain control over their system security. The technical details of this conditional access element were to be worked out in industry negotiations. In 2003, the Commission adopted, with certain modifications, standards on which the National Cable and Telecommunications Association (''NCTA'') and the Consumer Electronics Association (''CEA'') had agreed in a Memorandum of Understanding (''MOU''). The MOU prescribed the technical standards for one-way (from cable system to customer device) CableCARD compatibility. The CableCARD is a security device provided by an MVPD, which can be installed in a retail navigation device bought by a consumer in the retail market to allow the consumer's television to display MVPD-encrypted video programming. To ensure adequate support by MVPDs for CableCARDs, the Commission prohibited MVPDs from integrating the security function into set-top boxes they lease to consumers, thus forcing MVPDs to rely on CableCARDs as well. This ''integration ban'' was initially set to go into effect on January 1, 2005, but that date was later extended to July 1, 2007. Although the cable industry has challenged the lawfulness of the integration ban on three separate occasions, in each of those cases the DC Circuit denied those petitions.

4. Unfortunately, the Commission's efforts to date have not developed a vigorous competitive market for retail navigation devices that connect to subscription video services. Most cable subscribers continue to use the traditional set-top boxes leased from their cable operator; only 1 percent of the total navigation devices deployed are purchased at retail. Although following adoption of the CableCARD rules some television manufacturers sold unidirectional digital cable-ready products (''UDCPs''), most manufacturers have abandoned the technology. Indeed, since July 1, 2007, cable operators have deployed more than 22.75 million leased devices pre-equipped with CableCARDs, compared to only 531,000 CableCARDs installed in retail devices connected to their networks. Furthermore, while 605 UDCP models have been certified or verified for use with CableCARDs, only 37 of those certifications have occurred since the integration ban took effect in July 2007. This evidence indicates that many retail device manufacturers abandoned CableCARD before any substantial benefits of the integration ban could be realized.

5. Not only were very few retail devices manufactured and subsequently purchased in the retail market, but an additional complication with the installation process further depressed the retail market. The cable-operator leased devices come pre-equipped with a CableCARD, so that no subscriber premises installation of the card is required. But this is not the case with devices purchased at retail. CableCARDs for use in retail devices must be installed in the home, and many cable operators require professional installation by the cable operator. Unfortunately, the record reflects poor performance with regard to subscriber premise installations of CableCARDs in retail devices. This could be a consequence of the fact that only 1 percent of the total navigation devices deployed are purchased at retail and require an actual CableCARD installation, which may have made it difficult to train the cable installers properly. It could also reflect either indifference or reluctance by cable operators to support navigation devices purchased at retail in competition with their own set-top boxes. Regardless of the cause, these serious installation problems further undermine the development of a retail market.

6. A consumer using a unidirectional device cannot take advantage of two-way services offered by a cable operator. The Commission anticipated that the parties to the MOU would negotiate another agreement to achieve bidirectional compatibility, using either a software-based or hardware-based solution. Unlike one-way devices, which can only receive communication from cable headends, bidirectional devices can send requests to the cable headend, which enables those devices to receive services like cable operator-provided interactive programming guides, cable-operator provided video-on-demand and pay-per-view, and other interactive programming services. When the Commission realized in June 2007 that negotiations were not leading to an agreement for bidirectional

compatibility between consumer electronics devices and cable systems, it released a Third Further Notice of Proposed Rulemaking, seeking comment on competing proposals for bidirectional compatibility and other related issues. In the wake of the *Two-way FNPRM,* the six largest cable operators and numerous consumer electronics manufacturers negotiated an agreement for bidirectional compatibility that continues to rely and builds on CableCARDs by using a middleware-based solution called ''tru2way.''

7. The National Broadband Plan, released in March of this year, recommended changes in the CableCARD rules to provide benefits to consumers who use retail CableCARD devices without imposing unfair regulatory burdens on the cable industry. The plan suggested that these changes could serve as an interim solution that will benefit consumers while the Commission considers broader changes to develop a retail market for navigation devices. After considering those recommendations, on April 21, 2010 the Commission adopted a *Fourth Further Notice of Proposed Rulemaking* (''*FNPRM*'') seeking comment on proposed measures to remedy shortcomings in the existing CableCARD system. The Commission proposed five measures intended to remove the disparity between the treatment of consumers who choose to use a retail CableCARD-equipped video device and those who lease a cable provider's video navigation box. In the *FNPRM,* we sought comment on proposals to (1) Ensure that retail devices have comparable access to video programming that is prescheduled by the programming provider; (2) make CableCARD pricing and billing more transparent; (3) streamline CableCARD installations; (4) require cable operators to offer multi-stream CableCARDs; and (5) clarify certification requirements. In the *FNPRM,* we also proposed a rule change that would allow cable operators to substitute certain interfaces in lieu of the IEEE–1394 interface currently required on all high-definition set-top boxes, and proposed to define a baseline of functionality that such interfaces must meet. Finally, in order to encourage the cable industry's transition to digital technology, the Commission proposed an exemption to the integration ban for all one-way devices that do not have digital video recording capabilities.

8. *DISCUSSION. Reforming the CableCARD System.* Based on the record before us, we conclude that modifications to our rules are necessary to improve the CableCARD regime and advance the retail market for cable navigation devices. We are sympathetic to concerns that we are adopting these rules while we consider a successor regime, but we must keep in mind that CableCARD is a realized technology—consumer electronics manufacturers can build to and are building to the standard today. Until a successor technology is actually available, the Commission must strive to make the existing CableCARD standard work by adopting inexpensive, easily implemented changes that will significantly improve the user experience for retail CableCARD devices. Therefore, in this order we adopt rule changes that will (1) require cable operators to provide retail devices with access to switched-digital channels; (2) require cable operators to provide greater transparency in their CableCARD charges; (3) require cable operators to allow subscribers to self-install CableCARDs and require cable operators to inform their subscribers about this option; (4) require cable operators to provide multi-stream CableCARDs by default, unless a subscriber explicitly requests a single-stream CableCARD; and (5) clarify the testing requirements for CableCARD devices. Based on our examination of the record in this proceeding, we believe that these changes will be inexpensive to implement and will eliminate or reduce the disparity in the consumer experience between leased devices and retail devices, which has dampened enthusiasm for retail devices.

9. *Switched Digital Video.* Switched Digital Video (''SDV'') is a method of delivering linear programming that requires a set-top box to request specific channels from the cable head-end. SDV allows cable providers to offer their services more efficiently, as channels occupy capacity on the system only if subscribers are viewing or recording them. Unfortunately, this can affect one-way retail CableCARD devices adversely because one-way devices are not capable of requesting the switched channels, and therefore subscribers with retail devices are unable to access programming provided using SDV. Certain cable operators that have deployed SDV offer their subscribers free ''tuning adapters,'' which are repurposed set-top boxes that allow TiVo and Moxi retail set-top boxes and certain home-theater PCs to access switched digital content. These cable operators have provided the tuning adapters voluntarily, as the Commission's rules have not required cable operators to provide access to switched digital channels for one-way retail devices.

10. In the *FNPRM,* the Commission sought comment on whether this voluntary solution provides adequate support for retail navigation devices. The Commission also sought comment on TiVo's proposal to use an IP backchannel to request switched digital channels. There was vigorous disagreement between commenters on this issue—certain commenters strongly supported maintaining the *status quo,* while others zealously advocated a rule that would require cable operators who use SDV to support retail devices through the use of an IP backchannel.

11. Commenters who support maintaining the voluntary, market-based tuning adapter solution argue that SDV benefits consumers and that any changes to the *status quo* could stifle deployment of SDV and its associated benefits. They assert that the tuning adapter solution works adequately, and that there is no evidence that an IP backchannel would work better than the tuning adapter solution. They also argue that it does not make sense to require the industry to develop and deploy an IP backchannel solution, which could be costly and discourage deployment of SDV, particularly with the successor AllVid requirements on the horizon and the current availability of the cable industry's tru2way solution. They argue the additional development time and resources necessary to implement an IP backchannel would be better allocated to AllVid development. Certain commenters also assert that implementing a signaling backchannel over the public Internet would raise security and privacy concerns, including potential denial-of-service attacks, attacks that could provide unauthorized access to proprietary networks, and attacks that could result in theft of service and/or subscriber data. Therefore, these commenters argue, the tuning adapter solution that has developed in the marketplace is the most pragmatic, effective way to ensure that retail devices can access switched channels, and the Commission does not need to adopt rules.

12. While several commenters assert that the tuning adapter solution works adequately, others argue that consumers will not purchase retail CableCARD devices unless they are certain that they will be able to access all of the programming to which they subscribe. Because the Commission's rules do not require operators to provide access by retail CableCARD devices to switched digital video channels, TiVo is concerned that cable operators could withdraw their current willingness to

provide tuning adapters at no additional charge to the customer. Furthermore, a number of cable subscribers indicate that they have trouble obtaining tuning adapters that work. These commenters argue that the most effective way to provide retail CableCARD devices with access to switched-digital channels is through the use of an IP backchannel. They assert that the IP-backchannel solution would solve problems that consumers experience with tuning adapters because it would not require additional, potentially unreliable, customer-premises hardware. Furthermore, they argue, the tuning adapter takes up space, is not energy efficient, and limits the ability to use all of the tuners on multi-tuner devices, thereby limiting the ability of multi-tuner devices to record more than two channels at once. TiVo also expresses concern that cable operators are misinforming subscribers that certain channels are not available on retail devices. Finally, TiVo and CEA assert that the IP backchannel solution would be less expensive than tuning adapters in the long run.

13. We conclude that we should mandate SDV support for retail devices without specifying the technology that cable operators must use to ensure such compatibility. SDV is an innovative technology with a number of benefits, and we do not wish to discourage its deployment. The record is replete, however, with comments from consumers who have had negative experiences using tuning adapters to access switched digital channels on their retail CableCARD devices. Both of the proposed solutions have significant benefits and drawbacks, and the Commission believes that with appropriate direction, cable operators will find the most efficient means of effectively supporting SDV. For example, the Commission recognizes that the economics of deploying an IP backchannel solution are different between those operators who have already or will soon deploy SDV, and those operators who will deploy the next generation of SDV hardware. The Commission does not wish to foreclose the possibility of an IP backchannel for those operators to whom it will add *de minimis* costs as the result of being included in future headend equipment. Conversely, for those operators who currently use SDV and have significant deployments of tuning adapters, the cost to retrofit TiVo's IP backchannel proposal may be prohibitive. Further, the Commission does not presume that these are the only two means of supporting SDV, and expect that some operators may choose other options, such as in-home IP signaling, that provide additional benefits to consumers. We do not foreclose any of these options so long as appropriate documentation is available to enable UDCPs to access SDV channels.

14. Subscribers must be able to use the devices they purchase at retail to access all of the linear channels that comprise the cable package they purchase. Providing retail navigation devices and leased navigation devices with equivalent access to linear programming at an equivalent service price is essential to a retail market for navigation devices. We also want to avoid making deployment of SDV unnecessarily costly. While use of IP-backchannel would not require consumers to purchase additional equipment, we recognize that mandating this approach could be costly for some cable operators. Moreover, we note that operators currently provide tuning adapters at no charge to consumers. Accordingly, pursuant to our authority under Section 629 of the Communications Act, we require cable operators to ensure that cable subscribers who use retail CableCARD navigation devices have satisfactory access to all linear channels, but we will not mandate a specific method by which cable operators must provide such access. We believe that this rule change will address the security concerns raised about the IP-backchannel proposal, as our rule will not require a cable operator to adopt an approach that it believes is insecure. To address the problems with tuning adapters identified by commenters, the satisfactory access standard will require cable operators to ensure that retail devices are able to tune at least as many switched digital channels as that operator's most sophisticated operator-supplied set-top box or four simultaneous channels, whichever is greater. Further, the satisfactory access standard will require the ability to tune and maintain the desired channel as long as it is being watched or recorded, and to do so reliably. Furthermore, we prohibit cable operators from presenting their customers with misleading information regarding retail devices' ability to tune switched digital channels. We adopt these requirements pursuant to Section 629 because we conclude that SDV support for retail devices is necessary to assure a retail market for navigation devices. We will continue to monitor the development of SDV and the access afforded to cable customers who use, or wish to use, retail navigation devices. If we find that customers who want to use retail set-top boxes do not have satisfactory and equivalent access to all of the linear channels that comprise the cable package to which they subscribe, we will revisit our decision here.

15. *CableCARD Pricing and Billing.* In the *FNPRM,* the Commission sought comment on a proposal to require cable operators to list the fee for their CableCARDs as a line item on subscribers' bills separate from their host devices. The Commission proposed this rule change as a means to inform customers about retail navigation device options and to enable them to compare the price of a retail device to the price for leasing a set-top box from their cable operator. The proposed rule also was intended to ensure that the price that subscribers pay for CableCARDs in retail devices is the same as the price that subscribers pay for CableCARDs that are affixed to leased devices. Proponents of the Commission's proposed rule suggest that separate billing will facilitate fair choice and promote competition, as a viable retail market depends on transparency, while opponents argue that such billing would be difficult and expensive to implement, with no benefit to subscribers. Proponents of the rule assert that Section 629 requires separate billing and prohibits cross-subsidization. Opponents of the rule point to Section 629(f), which states that ''Nothing in this section shall be construed as expanding'' the Commission's authority under the Communications Act. Those commenters assert that the proposed rule would be an expansion of the Commission's authority under the statutory rate provision, Section 623, which allows cable operators to aggregate their equipment costs and charge a standard average rate across their footprints.

16. Public Knowledge argues that the proposed rule does not go far enough. Public Knowledge suggests that in addition to requiring cable operators to separate the monthly fee for a CableCARD from the set-top box on a subscriber's bill, the Commission should also require cable operators to provide each subscriber with the aggregate amount the subscriber has spent on set-top box lease fees. Additionally, Public Knowledge argues that cable operators should be required to notify subscribers about the retail options that are available to them. In a similar vein, Montgomery County, Maryland suggests that the Commission allow state legislatures to adopt legislation that would require cable operators to sell the devices that they lease to ensure that consumers have

more options to purchase navigation devices.

17. Opponents of the Commission's proposed billing rule assert that a separate billing requirement would only serve to confuse consumers and lead them to believe that their cable operators have added an extra fee to their bills. They also assert that this rule would arbitrarily burden subscribers who lease separated security devices as opposed to those who do not because currently all subscribers pay the same lease fee for a set-top box regardless of whether it has separated security. They argue that implementation of the billing rule would be costly for cable operators, as their billing systems are not designed to separate the cost of a CableCARD from the cost of the set-top box. NCTA and Arris assert that the availability of this information will not affect the retail market because the cost of CableCARDs has no effect on the retail market for set-top boxes.

18. Despite their opposition to the proposed rule as written, NCTA and others are not opposed to the purposes behind the rule, which are to treat retail and leased devices equivalently and encourage pricing transparency. As a compromise, NCTA has proposed that cable operators notify subscribers of the cost of CableCARDs on the operators' Web sites and yearly rate card notices. NCTA asserts that its proposal would serve the same purpose as the Commission's proposed rule without imposing expensive and confusing billing burdens on cable operators.

19. We conclude that NCTA's compromise solution will inform consumers about CableCARD costs and retail options adequately without imposing unnecessary burdens on cable operators. Therefore, we adopt a requirement that cable operators prominently list the fee for their CableCARDs as a line item on their Web sites (readily accessible to all members of the public) and annual rate cards separate from their host devices, and provide such information orally or in writing at a subscriber's request. These CableCARD lease fees must be uniform across a cable system regardless of whether the CableCARD is used in a leased set-top box or a navigation device purchased at retail. We are not convinced that NCTA's solution will ensure that cable operators are not subsidizing the costs of leased set-top boxes with service fees. Accordingly, we also adopt a rule that requires cable operators to reduce the price of packages that include set-top box rentals by the cost of a set-top box rental for customers who use retail devices, and prohibits cable operators from assessing service fees on consumer-owned devices that are not imposed on leased devices. These price reductions must reflect the portion of the package price that is reasonably allocable to the device lease fee. In the event that an interested party (including a consumer, local franchise authority, or device manufacturer) alleges a violation of this ''reasonably allocable'' standard, the Commission will consider in its evaluation whether the allocation is consistent with one or more of the following factors: (i) an allocation determination approved by a local, state, or Federal government entity; (ii) the monthly lease fee as stated on the cable system rate card for the navigation device when offered by the cable operator separately from a bundled offer; and (iii) the actual cost of the navigation device amortized over a period of no more than 60 months. These rule changes are well within our statutory authority under Section 629. Section 629 gives the Commission broad power to adopt regulations to assure the commercial availability of navigation devices and states that multichannel video programming distributors may lease their own devices, as long as ''the system operator's charges to consumers for such devices and equipment are separately stated and not subsidized by charges'' for multichannel video programming service. These minor rule changes will serve to ensure that cable operators are not subsidizing the costs of their set-top boxes via service charges and will serve to allow consumers to compare the costs involved in choosing between purchasing or leasing a navigation device. This prohibition on subsidies and increased transparency is vital to the continued development of a retail navigation device market, as it will allow subscribers to make informed economic decisions about whether they should purchase a navigation device at retail.

20. *CableCARD Installations.* In the *FNPRM,* the Commission expressed concern that CableCARD installation costs and policies may differ unjustifiably between retail devices and leased boxes. To address this situation, the Commission proposed requiring cable operators to allow subscribers to install CableCARDs in retail devices themselves if the cable operator allows its subscribers to self-install leased set-top boxes. Furthermore, the Commission proposed a rule with regard to professional installations that would require technicians to arrive with at least the number of CableCARDs requested by the customer.

21. Commenters who support adopting the proposed installation rule argue that individual users are more than capable of installing their own CableCARDs. According to these commenters, the installation consists of inserting a CableCARD and calling in to the cable operator to report a series of numbers that appear on an activation screen, which subscribers could easily do with basic instruction. Unfortunately, despite the apparent simplicity of installation, these individual subscribers comment that not all cable technicians are properly trained to install CableCARDs and they do not always arrive with functional CableCARDs; therefore it often takes several days and multiple installation appointments to get functional CableCARDs installed. According to TiVo, ''the premise of 'plug and play' was that a subscriber should be able to buy a device from a retailer, plug it into her cable connection, and have it work without the cable operator's intervention;'' therefore, TiVo argues, until individual subscribers have the option to self-install their own CableCARDs, subscribers will not be able to purchase devices that are truly ''plug and play.''

22. NCTA and CEA advocate a modification to the proposed rule that would require cable operators to allow self-installation of CableCARDs on any device for which the manufacturer provides detailed, step-by-step installation instructions. Several major cable operators, including Charter and Comcast, support the self-installation option so long as adequate installation instructions are provided by the manufacturer. Likewise, manufacturers such as Panasonic support the provision of Web-based installation walkthroughs as one means of fulfilling the goal of making step-by-step instructions available to consumers seeking to self-install CableCARDs. The few cable operator proponents do, however, request a four- to six-month phase-in period before this rule takes effect, during which time they will develop and implement necessary internal procedures and training that reflect the new policy.

23. Commenters including CEA/CERC and Panasonic suggest that cable operators should be required to permit retail outlets to sell CableCARDs and to assist in the installation at the point of sale. Commenters from the cable industry were not necessarily opposed to this option, but they did note that allowing retail stores to install CableCARDs at the point of sale would introduce certain business, technical, and operational hurdles, such as identifying the encryption technology that a cable operator uses in the specific subscriber's geographic location.

Therefore, they suggest that the Commission encourage industry negotiations to explore this option, but they oppose adoption of a rule that mandates retail installation. TiVo, however, supports this proposal as one of the few means of fulfilling the true purpose of the CableCARD requirement, which is to encourage a competitive market for retail devices that can be purchased, taken home, and installed without the cable operator's intervention.

24. In addition to its other proposals, CEA seeks better enforcement of the CableCARD rules, including the new proposed installation rule. CEA suggests that empowering local franchising authorities to enforce the CableCARD rules would encourage cable operators to comply with the rules.

25. Time Warner Cable and Verizon assert that cable operators are best equipped to determine whether customers should be allowed to install their own CableCARDs. They argue that the CableCARD installation process is not straightforward, that consumers may not be equipped to install such equipment, and that the installations are not overly expensive. Verizon further argues that customers have shown no real demand to perform self-installation. Similarly, Cox submits that the low number of interested consumers does not justify development of costly support mechanisms for those who wish to self-install, unless the customer support burden shifts entirely to retail device manufacturers. Verizon also expresses skepticism that the Commission has authority to adopt such a rule.

26. We conclude that the best means of assuring the development of a retail market for navigation devices is to require cable operators to allow subscribers to self-install CableCARDs. We believe cable operators should have time to train staff and develop more robust customer support infrastructures and procedures, and provide nine months to comply for any operators that allow subscribers on any of their systems to self-install any cable modems or leased set-top boxes. We are not persuaded by arguments that cable operators could not support activation of retail CableCARD devices within this reasonable transition period. However, we are concerned that a cable operator that does not permit self-installation of any equipment that attaches to its network may not have the customer support infrastructures in place to handle self-installations and may need a longer transition period. Therefore, we will allow cable operators that do not have any self-installation support in place twelve months to phase in this self-installation requirement. We also require cable operators to inform their subscribers about the self-installation option when they request CableCARDs.

27. With respect to professional installations, we adopt our proposed rule requiring technicians to arrive with at least the number of CableCARDs requested by the customer. We require cable operators to make good faith efforts to ensure that all CableCARDs delivered to customers or brought to professional installation appointments are in good working condition and compatible with their customers' devices, and to allow subscribers to request CableCARDs using the same methods that subscribers can use to request leased set-top boxes. These rules are intended to solve the complaints in the record that professional CableCARD installations often require multiple appointments. We believe that requiring cable technicians to have CableCARDs in good working condition on hand when they are requested and allowing subscribers to self-install CableCARDs will decrease the number of required appointments dramatically. To address Time Warner Cable and Verizon's concerns that subscribers may not be properly equipped to self-install a CableCARD, our self-installation rule will apply only where device manufacturers or vendors provide detailed, device-specific instructions on how to install a CableCARD and the manufacturer's or vendor's toll-free telephone number within the packaging of the device and on the manufacturer's or vendor's Web site. At this time we will not adopt a rule requiring retail installation of CableCARDs; however, since devices will now contain instructions from manufacturers or vendors on self-installation and because such an action will decrease the burden on the cable providers, we encourage cable operators and consumer electronics retailers to reach agreement through continued private negotiations to achieve this type of consumer-friendly retail option.

28. In addition to empowering cable subscribers to install CableCARDs, we will also make it easier for consumers to file complaints relating to cable customer premises equipment (including CableCARDs, tuning adapters, and set-top boxes) with the Commission by adding a specific reference to CableCARDs and other customer premises equipment to the process for filing complaints on our Web site. If a cable operator chooses to provide satisfactory access to SDV channels for retail devices by means of customer-premises equipment such as a tuning adapter, this process will encompass complaints relating to such equipment as well as complaints relating to CableCARDs. We will strictly enforce our navigation device rules in order to ensure proper support for CableCARD devices. We conclude that this streamlined complaint process makes CEA's suggestion that the Commission provide local franchising authorities with the authority to enforce the CableCARD rules unnecessary, and will allow for more consistent enforcement of our CableCARD rules nationwide. In addition, we will develop new consumer education materials specifically discussing the availability of cable boxes at retail as an alternative to leasing a cable box from the cable operator. Within the next few weeks, these materials will be available on our Web site and will be provided by our call center to those customers who lack Web access.

29. The changes we adopt herein will improve the consumer experience substantially, as cable subscribers will no longer have to schedule multiple installation appointments for CableCARD installations. Furthermore, these rule changes will place only a *de minimis* burden on cable operators, because the device manufacturer's or vendor's self-installation instructions will include the manufacturer's or vendor's toll-free telephone number directing customer questions to the manufacturer or vendor and not to the cable operator. We disagree with Verizon's assertion that the Commission does not have the authority to adopt such a rule, as we believe that this rule falls squarely within our authority under Section 629. The need to schedule multiple installation appointments unquestionably is an impediment to realizing a competitive retail market for navigation devices, and the record is replete with comments from frustrated consumers who have had to schedule multiple appointments with technicians due to CableCARD installation problems. We believe that Congress's intent in adopting Section 629 was to ensure that cable operators treat retail navigation devices in the same manner that they treat leased navigation devices. Accordingly, we believe that we have clear statutory authority under Section 629 to adopt this self-installation rule.

30. *Multi-stream CableCARDs.* A Multi-stream CableCARD is a single CableCARD that is capable of decrypting multiple channels, thereby allowing consumers to record one channel while simultaneously watching another channel. Original CableCARDs were only capable of decrypting a single

stream, therefore requiring devices with multiple tuners, such as most digital video recorders, to include two CableCARD slots. With the release of the Multi-stream CableCARD Interface Specification in 2005, device manufacturers obtained the ability to receive up to six program streams though a single CableCARD. Multi-stream CableCARDs, now called M–Cards, can also be used by older devices that had been designed for single-stream CableCARDs. Operators began deploying M–Cards shortly after the adoption of the Multi-stream CableCARD Interface Specification, and today retail devices often require them. In the *FNPRM,* the Commission proposed requiring cable operators to offer M–Cards upon request, to reduce the equipment fees paid by subscribers by enabling them to use only one CableCARD per device rather than two or more.

31. Commenters were generally supportive of the proposed rule, though numerous commenters suggested the Commission require the provisioning of M-Cards by default, rather than on request. TiVo, Public Knowledge, and CEA all explicitly suggested this approach. Arris and Tivo note that all leased set-top boxes include M-Cards, and that newer retail devices require M-Cards to function properly. They further claim that the record demonstrates that retail devices are left to use recycled single-stream cards that may not work, while leased set-top boxes are outfitted with new, functioning M-Cards. NCTA also states they do not object to requiring cable operators to provide an M-Card to any subscriber who requests one, though they assert that certain devices work better with single-stream CableCARDs, and therefore cable operators should also have the discretion to deploy them to their subscribers.

32. Only Verizon and John Staurulakis, Inc. assert that the Commission should not require cable operators to deploy M-Cards. They assert that such a requirement would be costly and unnecessary because so few subscribers actually use CableCARDs. Verizon further states that the marketplace is already working to increase the availability of M-Cards for those few subscribers. Comcast goes further, stating that M-Cards have been widely used since 2007, and cable operators have sufficient supplies of multi-stream CableCARDs to meet customer demand for them. NCTA also suggests that the Commission adopt the multi-stream CableCARD rules, which would test for compatibility between UDCPs and M-Cards, that NCTA and the CE industry proposed in 2006.

33. We conclude that the best step we can take in this regard to assure the development of a retail market for navigation devices is to require cable operators to provide multi-stream CableCARDs by default, unless a subscriber expressly requests a single-stream CableCARD. All new devices require multi-stream CableCARDs, and multi-stream CableCARDs have been standard equipment since 2007. Therefore, requiring cable operators to provide multi-stream CableCARDs by default will conform more closely to the concept of common reliance, provide improved customer experience, and impose little, if any, costs on the industry, as our examination of the record indicates that CableCARD manufacturers are no longer making single stream CableCARDs to sell to cable operators. We also adopt the multi-stream CableCARD rules that NCTA and the CE industry proposed in 2006, as they are necessary to update our rules to conform with the current state of CableCARD testing procedures.

34. *CableCARD Device Certification.* In the *FNPRM,* the Commission proposed a rule change intended to streamline the process of CableCARD device certification. The proposed rule would prohibit CableLabs or other qualified testing facilities from refusing to certify Unidirectional Digital Cable Products for any reason other than a failure to comply with a device conformance checklist referenced in the Commission's rules. The Commission proposed the rule change based on complaints regarding the cost, complexity, and restrictiveness of device certification. The Commission also committed to ''consider any other proposed solution to streamline the CableCARD certification process to facilitate the introduction of retail navigation devices.''

35. Comments regarding CableCARD device certification indicate that the proposed rule would simply codify the CableCARD certification process as it exists today. No commenter opposes the proposed rule, although certain commenters argue that the proposed rule would not do enough to protect device manufacturers. In addition, certain commenters argue that the proposed device certification rule is not rigorous enough to assure a competitive device market. Specifically, CEA and Public Knowledge each encourage the Commission to extend the device certification rule to apply to CableCARD-compatible computers and computer peripheral devices and to limit the terms that CableLabs may dictate in licensing agreements. They assert that these steps will allow start-up companies like SageTV to develop their devices, and that the proposed rule will not be effective without this extension. Indeed, NCTA and MPAA acknowledge that the Commission's proposed rule would have no effect on the SageTV certification problems that the Commission highlighted in the *FNPRM.*

36. In a similar vein, IPCO and Nagravision encourage the Commission to streamline the certification process for the CableCARD separated security modules, as the Commission does not have a rule that prescribes a certification process for the CableCARD itself. They assert that CableLabs has delayed certification of competitive separated security modules, which limits the companies' ability to develop affordable whole-system solutions to sell to cable operators. They reason that, if device manufacturers can manufacture and test their own CableCARDs in conjunction with their retail devices, they will be able to develop products more rapidly.

37. We conclude that the best step we can take in this regard to carry out our statutory mandate under Section 629 is to (i) modify our rules to reflect updated testing procedures, and (ii) adopt the proposed rule that prohibits CableLabs or other qualified testing facilities from refusing to certify UDCPs for any reason other than a failure to comply with the conformance checklists referenced in our current rules. These rule changes should encourage navigation device manufacturers to build competitive devices by eliminating unnecessary delays and costs associated with device testing, while continuing to recognize the importance of protecting cable networks and service. Based on the comments we have received about the certification process, we believe that these rule changes do little more than codify the certification process as it exists today. These changes require UDCP manufacturers and qualified test facilities to proceed in accordance with Uni-Dir-ATP-I02-040225: ''Uni-Directional Receiving Device Acceptance Test Plan,'' M–UDCP–PICS–I04–080225, and TP–ATP–M–UDCP–I05–20080304. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from Cable Television Laboratories, Inc., 858 Coal Creek Circle, Louisville, Colorado 80027, *www.cablelabs.com/opencable/udcp*, (303) 661–9100. You may inspect a copy at the Federal Communications Commission, 445 12th St., SW., Reference Information Center,

Room CY–A257, Washington, DC 20554, (202) 418–0270 or at the National Archives and Records Administration (NARA). For information of the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

38. Comments reflect that while the certification process is costly, CableLabs's device testing is conducted in a professional manner and is important to ensure that CableCARD devices work properly. CEA claims generally, however, that certain CableCARD licensing terms may go beyond what is allowed under Sections 76.1201 and 76.1204 of our rules. They assert that these licensing terms limit innovation. To the extent that any interested party has concerns that an aspect of the CableCard licensing regime violates Sections 76.1201 through 76.1204 of the Commission's rules, that party may allege a specific violation of the Commission's rules pursuant to Section 76.7 of our rules.

39. We decline to adopt IPCO and Nagravision's proposal to extend certification rules to the CableCARD security modules by dictating the specific testing procedures that CableLabs must use to certify CableCARD security modules. CableCARDs are an important part of protecting signal theft and protecting cable networks. Section 629(b) prohibits the Commission from adopting regulations that would jeopardize the security of cable systems or interfere with a cable operator's right to prevent theft of service. Therefore, we believe that it would be prudent to defer to CableLabs's policies on certifying whether the CableCARDs themselves, which are the lynchpins of the conditional access scheme, are robust enough to protect cable systems and prevent theft of service.

40. *Interface Requirements.* The Commission's rules require cable operators to include an IEEE 1394 interface on all high-definition set-top boxes that they acquire for distribution to customers. IEEE 1394, also known as Firewire, is an external serial data connection that allows for audio and video data transfers. The Commission adopted a requirement from the MOU to provide an IEEE 1394 interface on all high-definition set-top boxes as a means of enabling a market for devices which interact with the operator-supplied set-top box. In the *FNPRM,* the Commission proposed to give cable operators greater flexibility in deciding which type of interface to include on the set-top boxes that they lease. Set-top box manufacturers and cable operators suggested that alternative interfaces could perform the same functions and have wider consumer adoption than the IEEE 1394 interface. The Commission also proposed to clarify that operators must enable bi-directional communication over these interfaces. The proposed clarification would require the interfaces to be able to receive remote-control commands from a connected device and deliver video in any industry-standard format to ensure that video made available over these interfaces can be received and displayed by devices manufactured by unaffiliated manufacturers (*i.e.,* manufacturers not owned by or under license of the leased set-top box vendor or cable operator) and sold at retail. The record generally supported replacing the IEEE 1394 interface requirement with a rule that would instead require cable operators to include an IP-based connection on all high-definition set-top boxes that they acquire for distribution to customers. The commenters also agreed that the Commission does not need to define the physical interface (*e.g.,* IEEE 1394, Ethernet, Wi-Fi, or MoCA) used to transfer the IP data. With respect to functionality, commenters disagreed on whether the Commission should set a baseline for functionality of that interface.

41. Certain commenters suggested that the Commission should adopt baseline standards to define a ''functional'' IP connection on a set-top box. Various industry associations have developed suites of standards that include functionality we might rely on. For example, Panasonic suggested that the Commission require that the IP connection pass through ''OpenCable Host Thin Chassis Device'' remote commands. OpenCable, branded for consumers as tru2way, was developed by CableLabs, is a set of standards defining a common interface for supporting interactive cable services. As the full implementation, branded for consumers as tru2way, has seen limited adoption in retail devices, the Host Thin Chassis Device standard was developed to provide reduced costs while simultaneously enabling two-way communication with CableCARDs. Among the component parts of the Host Thin Chassis Device standard are specifications for passing remote control commands entered with the TV remote control through to the set-top box.

42. CEA and the Digital Living Network Alliance (''DLNA'') each suggest that the Commission require that devices follow the DLNA guidelines. DLNA standards have been or are being developed to enable widespread network-based connectivity for a wide variety of devices, from handheld viewers to media servers. This focus on broad interoperability has resulted in standards which permit the addition or subtraction of various functional components, including remote control commands and content formats. Three consumers suggested that the Commission require that the interfaces pass through closed captioning data. The 1394 Trade Association and Texas Instruments commented that each leased set-top box should be required to play back any video that is sent to it over an IEEE 1394 interface.

43. Comcast, Verizon, and NCTA each argue that defining ''functional'' would put a large burden on cable operators. They assert that standards organizations are still working to define standards for functionality over IP-based connections, and that cable operators could not comply with a functionality requirement in the near future. They assure the Commission that the market will determine the specific type of functionality that consumers desire, and therefore urge the Commission not to lock operators into a certain defined set of functions, lest the Commission make the same mistakes it made with regard to the IEEE 1394 interface requirement.

44. We conclude that the best step we can take in this regard to fulfill our statutory mandate under Section 629 is to modify our interface rule to require cable operators to include an IP-based interface on all two-way high-definition set-top boxes that they acquire for distribution to customers without specifying a physical interface. IP has overwhelming marketplace support and serves the same purpose that our IEEE 1394 connection requirement was intended to serve. We agree with commenters that the method of physical transport (*e.g.,* Ethernet, Wi-Fi, MoCA, or IP implemented over IEEE 1394) is not relevant in this situation, as we predict based on our examination of the record in this proceeding that consumers will use network adapters to choose the physical transport method that they prefer for networking their devices, in furtherance of the goals of Section 629.

45. Contrary to Comcast, Verizon and NCTA's assertions, we believe that it is important to define a baseline of functionality to ensure that consumers who network their devices and device manufacturers can rely on networked devices' ability to communicate with leased set-top boxes. However, as with the physical interface itself, we find that it is appropriate, at this time, to refrain from specifying the exact manner in

which this baseline of functionality is to be implemented. Accordingly, we modify our rules to require that the IP-based connection deliver the video in a recordable format (*e.g.,* MPEG–2, MPEG–4, h.264), and pass through closed captioning data in a standard format. We also believe more advanced functionalities are necessary to provide a foundation for a retail market of navigation devices that are connected to leased set-top boxes with limited capabilities. Those functionalities include service discovery, video transport, and remote control command pass-through standards for home networking. While these functionalities may exist in some form today, there is considerable work ongoing in industry standard bodies to provide those functionalities in a manner designed for IP-based and home network solutions. We, therefore, do not mandate that these additional functionalities be supported by cable operators immediately. We do, however, wish to ensure that consumers benefit from these additional functionalities in a timely manner, and require operators to provide these additional functionalities by December 1, 2012, but do not mandate a particular means by which these functionalities are to be provided.

46. *Promoting Cable's Digital Transition.* The integration ban, which went into effect in 2007, is designed to support the market for retail navigation devices by creating an incentive for cable operators to fully support CableCARDs, drive costs down through economies of scale, and encourage cable operators to strive to improve and maintain the CableCARD system. In the *FNPRM,* the Commission proposed to allow operators to place into service new one-way navigation devices (including devices capable of processing a high-definition signal) that perform both conditional access and other functions in a single integrated device provided that the devices do not perform recording functions. The integration ban raises the cost of set-top boxes for cable operators, which discourages operators from transitioning their systems to all-digital. Transitioning to an all-digital cable system allows operators to make more efficient use of spectrum capacity, allowing the operators to dedicate more of their spectrum to broadband and other services. The impetus for this proposed rule change was to remove economic barriers that discourage cable operators from transitioning their systems to all-digital.

47. The rule proposed in the *FNPRM* would still require operators to offer CableCARDs to any subscribers who request them and to commonly rely on CableCARDs for any digital video recorder and bidirectional devices that they offer for lease or sale. In limiting the proposed rule's applicability to devices with less functionality, the Commission attempted to balance the goal of easing the financial burdens associated with transitioning to digital cable systems with the benefits that stem from common reliance. The Commission also sought comment on whether the potential effect on the retail market supports limiting any relief to smaller cable systems with activated capacity of 552 MHz or less. Some commenters additionally suggested that the integration ban should be eliminated entirely.

48. *Exempting Limited Capability High Definition Set-Top Boxes.* NCTA, ACA, Comcast, and Time Warner support the proposed rule and suggest that it will not impact the limited retail market for navigation devices that currently exists. Motorola adds that HD capability is commonplace rather than advanced and, therefore, the proposed rule would have no effect on the retail market for navigation devices, as the competitive devices available at retail have advanced functionality such as Internet connectivity and recording capability. Finally, proponents of the rule change assert that it will allow cable operators to deploy less expensive set-top boxes which will ease consumers' financial burden when cable operators transition to digital systems. BBT suggests that, for the sake of regulatory certainty, the Commission should not take a piecemeal approach in applying the integration ban suggesting that the Commission either abandon the integration ban altogether or not at all.

49. Public Knowledge and CEA argue that the proposed rule would undermine the goals of common reliance. They assert that the proposed rule would limit cable operators' incentives to support CableCARDs, and that the current state of CableCARD support suggests that cable operators need more, not fewer, incentives to support CableCARDs. They assert also that the Commission still does not have reliable data regarding the cost of relying on CableCARDs or the economic effect CableCARD exemptions have on the retail market. CEA and Public Knowledge argue that, without such data, the Commission cannot accurately balance the public interest benefits of the integration ban against the benefit of an exemption.

50. Based on our examination of the record, we will adopt the limited exemption to the integration ban proposed in the *FNPRM.* As the Commission explained in 2005, common reliance ensures that cable operators have incentives to make their services as accessible as possible to CableCARD devices. We find that even if cable operators are allowed to deploy integrated one-way devices they will still have incentives to ensure that CableCARD devices are able to receive their services because all two-way, digital video recorder (''DVR'') and Internet-connected devices deployed by cable operators will still be subject to the integration ban. Furthermore, as NCTA highlights, cable operators have deployed more than 40 times as many CableCARDs in their own separated security devices than in devices purchased at retail, and we believe that the former devices will remain in service for years to come. We conclude that this decision will not undermine the goal of common reliance, as we believe that the majority of operator-leased devices will continue to commonly rely on CableCARDs, and therefore cable operators will continue to have adequate incentives to support CableCARDs in retail devices. Allowing operators to deploy one-way devices with integrated security will help lower the costs of set-top box rentals to subscribers and allow operators to dedicate more of their spectrum to broadband without undermining the effectiveness of the integration ban. In this vein, while we recognize that the inclusion of an IP-based home-networking connection would provide additional functionality, we believe that the costs to consumers of imposing the interface requirement would outweigh the potential benefits. For these reasons, we exempt one-way set-top boxes from the Commission's integration ban and, correspondingly, our interface requirements.

51. *Limiting the Proposed Exemption to Small Systems.* We decline to put any limitation on the size or capacity of the systems to which the modified rule applies. While no commenter supports adopting an exemption limited to small cable operators as its preferred course of action, Public Knowledge, which encourages the Commission not to adopt any exemption to the integration ban, alternatively suggests that the Commission limit the rule's applicability to small cable systems. Public Knowledge reasons that such a limitation would mitigate the detrimental effects that such a rule would have on common reliance and the development of a retail market for navigation devices. Cable operators oppose such a limitation and assert that limiting the relief would be akin to not

offering relief at all. They argue that economies of scale are necessary to encourage manufacturers to develop inexpensive devices with integrated security. They argue that small system operators will not be able to achieve the economies of scale that are necessary to make this relief effective. They also assert that limiting the relief to small systems could unfairly harm subscribers who happen to live in areas with large systems because consumers would benefit if large systems were to transition to all-digital as well. For the same reasons that these commenters present, we agree that a small-system limitation would undermine the benefits of the rule change.

52. *Ending the Integration Ban.* We disagree with the arguments of NCTA and cable operators that the Commission should abandon the integration ban altogether. They assert that the integration ban is an expensive, discriminatory requirement with no consumer benefit. Cable operators reason that ending the integration ban would decrease the costs of transitioning to all-digital systems and would lead to increased availability of broadband. Finally, they argue that terminating the integration ban would reduce set-top box costs for all subscribers. In addition to the arguments summarized above, opponents of ending the integration ban assert that it would discourage cable operators from negotiating in good faith in developing a successor technology to CableCARD, as cable operators would have no economic incentive to work to develop such a technology in a timely fashion. We agree. The integration ban continues to serve several important purposes—better support for CableCARD devices, economies of scale for CableCARDs, and economic incentives to develop better solutions. Ending the integration ban before a successor standard is developed would undermine the market for retail navigation devices.

53. *Two-Way Negotiation Reporting.* As the Commission discussed in the *FNPRM,* in 2005 the Commission adopted a requirement that NCTA and CEA file reports every 60 days regarding the status of negotiations on a bidirectional CableCARD standard. As noted above, the six largest cable operators and numerous consumer electronics manufacturers negotiated an agreement for bidirectional compatibility that continues to rely on and builds on the standards for CableCARDs by using a middleware-based solution called ''tru2way.'' As the cable industry and the consumer electronics industry have concluded their negotiations on a bidirectional CableCARD standard, we do not believe it is necessary for those parties to continue to file status reports regarding those negotiations, and we therefore eliminate that requirement. As we will still require cable operators to commonly rely on CableCARDs in certain set-top boxes, we will retain the requirement that Comcast Corporation, Time Warner Cable, Cox Communications, Charter Communications, and Cablevision file quarterly reports detailing CableCARD deployment and support.

54. *Petitions for Reconsideration.* The Commission also has before it eight petitions for reconsideration in this docket. NCTA, DIRECTV, Genesis Microchip, Inc., MPAA, Broadcast Music, Inc. and the American Society of Composers, Authors and Publishers (''BMI and ASCAP''), and the National Music Publishers' Association *et al.* (''NMPA'') separately filed petitions for reconsideration of the *Plug and Play Order,* while NCTA and MPAA also petitioned for reconsideration of the Commission's *Sua Sponte Reconsideration Order.* As noted below, many of these petitioners seek reconsideration of the Commission's encoding rules. Our encoding rules prescribe whether and how MVPDs may mark different forms of content (*e.g.,* broadcast, non-premium subscription, pay television, video-on-demand, *etc.*) to limit the number of times the content may be copied. In addition to the petitions for reconsideration of orders adopted in the plug-and-play dockets, the Commission has before it a petition for reconsideration filed by TiVo, Inc., which is mooted by the rule changes adopted in this order.

55. *NCTA.* Our device certification rules allow device manufacturers to self-certify CableCARD devices once they have received CableLabs certification for any certified CableCARD device. NCTA urges the Commission to reconsider the rule that a manufacturer's certified first ''product'' eliminates the need for its first television set to be tested if the manufacturer has already received certification for a set-top box. NCTA asserts that digital televisions (''DTVs'') are more complex than DVR devices or other products, and that a manufacturer's first television should be tested in order to ensure that consumers' televisions are able to receive digital cable programming. We agree. As NCTA explains in its petition for reconsideration, ''unless the first tested UDCP is a DTV, there will be no real test that the UDCP actually and clearly displays encrypted programming, [emergency alert system] messages, [Program and System Information Protocol] information, and closed captions so there is no assured compliance with all of the relevant standards in the agreed-upon Joint Test Suite.'' We conclude that making such testing a part of our rules is necessary to ensure that new devices are built to comply with the Commission's rules. Accordingly, we grant NCTA's petition for reconsideration with respect to this issue, and modify our rules to clarify that a manufacturer may not self-certify its first DTV.

56. Next, NCTA asserts that the Commission's rules permit too much flexibility in defining a qualified testing facility, and would allow unqualified organizations to test plug and play products because our rules do not require test facilities to be impartial or have appropriate testing equipment. NCTA urges us to define ''qualified testing facility'' more precisely. CEA disagrees, asserting that NCTA bases its assertions on unfounded security concerns. We agree with NCTA's assertions that it is important for our rules to require that qualified testing facilities are impartial organizations whose employees have a detailed understanding of the Joint Test Suite for CableCARD products. We do not believe that NCTA's security concerns are unfounded, nor do we believe that NCTA's suggested rule change will hinder independent testing facilities from becoming ''qualified testing facilities.'' Therefore, we adopt NCTA's recommendation by modifying our rules to specifically require testing facilities to be impartial and have appropriate testing equipment. To the extent that there are disagreements regarding whether specific testing facilities meet the standards set forth in our modified rule, we will consider such disagreements on a case-by-case basis.

57. In its final critique of the *Plug and Play Order,* NCTA takes issue with the language of certain Commission rules. NCTA asserts that the Commission's rules should unequivocally state that digital cable ready products must ''pass'' applicable tests, rather than the current requirement which merely requires that the devices be subject to testing. NCTA also requests that we amend our rules to clarify that a cable operator may carry more than 12 hours of programming metadata (Program and System Information Protocol or ''PSIP'' data) if it so chooses, and shall only be required to carry PSIP data that conforms to the standards adopted by the Advanced Television Systems Committee for transmission of that data. As these requests will clarify the Commission's intent in the *Plug and*

Play Order, we adopt them without exception.

58. NCTA's petition for reconsideration of the *Sua Sponte Reconsideration Order* requests that the Commission clarify that programming that is not retransmitted ''substantially simultaneously'' to the time it is broadcast is not considered ''Unencrypted Broadcast Television'' under our encoding rules. Currently, our rules define ''Unencrypted Broadcast Television'' as the retransmission of any service, program, or schedule or group of programs that is made by a terrestrial television broadcast station in the clear (*i.e.,* without any encryption). NCTA asserts that it is likely that this definition is broader than the Commission intended. NCTA states, as an example, that the omission of the term ''substantially simultaneously'' prevents it from placing copy protections on VOD content that was originally delivered over the air because it is a retransmission of a program that was initially made by a terrestrial television broadcast station. With our encoding rules, we intend to reflect consumer expectations that they may freely copy unencrypted broadcast programming as it airs. We also intend to reflect that consumers do not have the expectation that they may freely copy all content simply because it was available over the air at one point during the history of television broadcasting. Therefore, we agree with NCTA's assertion that we should add the phrase ''substantially simultaneously'' back into the definition of ''Unencrypted Broadcast Television,'' for the reason that NCTA provides.

59. *DIRECTV.* DIRECTV urges the Commission to close what it calls the ''broadband loophole'' in the encoding rules. According to DIRECTV, cable operators and telcos will be able to subvert the Commission's encoding rules by delivering their video offerings over the Internet, which are specifically exempt from our encoding rules. We understand DIRECTV's concern, but there is no evidence that any MVPD is using Internet-based delivery to subvert our encoding rules. If DIRECTV has evidence that this concern is more than hypothetical and is harming consumers, we urge the company to file a petition for declaratory ruling or a petition for rulemaking. Therefore, we deny this portion of DIRECTV's petition for reconsideration.

60. DIRECTV next argues that the Commission should define minimum standards that include an IEEE 1394 interface. DIRECTV is concerned that television manufacturers could build sets with IEEE 1394 connections that support a cable-only version of IEEE 1394, and prevent consumers from connecting satellite boxes to their television sets. Given the rule change that we adopted in Section III.B above to remove the IEEE 1394 output requirement, and the limited consumer adoption of IEEE 1394 outputs on television sets, we dismiss DIRECTV's petition for reconsideration as moot on this point.

61. DIRECTV also takes issue with the Commission's decision to provide CableLabs with the authority to approve and reject content protection technologies for set-top box outputs and to license DFAST technology, which is the content protection scheme used between CableCARDs and UDCPs. DIRECTV's objections are based on a concern that CableLabs could use its licensing power for anti-competitive purposes against DIRECTV's services and devices by preventing DIRECTV devices from using DFAST or rejecting DIRECTV's preferred content protection technologies. The intervening years since the adoption of the *Plug and Play Order* have demonstrated that these concerns are without merit. Indeed, as of June 30, 2003, 20.4 million households in the U.S. subscribed to DBS service; as of June 2010, that number increased to over 33 million, and DIRECTV has not established that CableLabs has rejected any content protection technology to DIRECTV's detriment. Furthermore, we have invited DIRECTV and others to cooperate with the Commission as we seek to develop a successor technology to CableCARD that would apply to all MVPDs. Accordingly, we deny DIRECTV's petition for reconsideration.

62. *Genesis Microchip.* Genesis Microchip takes issue with the Commission's requirement that a DVI or HDMI interface be included on a digital cable ready device. Genesis Microchip asserts that DVI and HDMI were not developed by standards development organizations such as IEEE and ANSI, and are not available on a non-discriminatory basis. Genesis Microchip also asserts that the Commission's requirement violates the Administrative Procedure Act. Opponents to Genesis Microchip's petition for reconsideration point out correctly that the Commission addressed Genesis Microchip's arguments in the *Plug and Play Order,* stating that ''the technology underlying these specifications is widely available in the marketplace today'' and that ''the adopter agreements for these technologies are freely offered on non-discriminatory terms.'' Furthermore, HDMI is a ubiquitous output, available on an estimated one billion devices, and we are convinced that Genesis Microchip's objections are not supported by marketplace reality. Therefore, we deny Genesis Microchip's petition for reconsideration.

63. *MPAA.* MPAA seeks reconsideration of four points in the *Plug and Play Order.* First, MPAA asserts that the Commission should mandate that all digital cable ready devices be built with the capability to recognize and honor video programming that is encoded with a request to remotely disable selected audio/video outputs, also known as ''selectable output control.'' MPAA believes that selectable output control functionality is essential to protect content and facilitate future business models that take advantage of selectable output control functionality. We do not believe that such a mandate is necessary. In May 2010, the Commission's Media Bureau released an order granting in part MPAA's request for waiver of the prohibition on the use of selectable output control for certain high-value films in order to support a new business model of delivering early-release films over MVPD systems to consumers. As MPAA argued in support of that waiver, ''the use of SOC would have no impact whatsoever on the ability of existing [consumer electronics equipment] to work in exactly the same fashion that such devices work today.'' While it is possible that consumer electronics manufacturers may want to build devices with SOC in order to be compatible with future business models like the early-release film model, as they are free to do under our rules, we do not believe that it is necessary to require such functionality to protect high-value content or ensure the success of such future business models. Therefore, we do not believe that it is necessary to mandate that such functionality be built into consumer electronics devices, and we deny MPAA's petition for reconsideration with respect to this issue.

64. Second, MPAA would like Subscription VOD designated as a defined business model. Subscription VOD is a video-on-demand service that requires customers to subscribe to a service to gain access to the on-demand programming. In the *Plug and Play Order,* the Commission classified Subscription VOD as an Undefined Business Model, in order to ''allow [* * *] SVOD to more fully develop as a program offering in the marketplace.'' MPAA asserts that because the Commission did not explicitly adopt a rule that allows cable operators to prohibit their subscribers from copying Subscription VOD, the Commission will

stifle the development of the service. Starz Encore Group originally opposed this petition, arguing that the Commission's flexible rules would encourage SVOD to flourish, but later withdrew its opposition based on its new position that the ''Undefined Business Model'' public notification process is ''difficult and cumbersome * * * for cable operators to navigate.'' We conclude that MPAA's concerns were unfounded, and that the procedures agreed upon in the MOU are sufficient to meet the needs of content owners, MVPDs, and their subscribers. As contemplated in the *Plug and Play Order,* Subscription VOD services have thrived in the marketplace, as Starz On-Demand, HBO On-Demand, Cinemax On-Demand, and Showtime On-Demand are all popular services available to consumers. Subject to the review process for Undefined Business Models set forth in Section 76.1906 of our rules, content providers and MVPDs are free to negotiate the terms for how such business models are encoded. To the extent that any interested party has specific problems with the current state of the encoding of any SVOD service, our rules set forth procedures for filing complaints regarding how such content is encoded. Accordingly, we deny MPAA's petition for reconsideration with respect to this issue.

65. Third, MPAA seeks simplified procedures for announcing and challenging the launch of an Undefined Business Model for content encoding purposes. When an entity launches a new video programming service that is not defined in our encoding rules, that entity must announce its launch publicly, describe the service, and explain how it will be encoded for recording purposes. Interested parties may then challenge the encoding terms for up to two years after the announcement of the service. MPAA's challenge stems from a concern that Undefined Business Model announcements will lead to regulatory uncertainty because numerous MVPDs will be required to make announcements regarding these new business models, and that the window for accepting such challenges is too long. We disagree. This rule has been in effect for over six years, and the Commission has not received a single challenge regarding the encoding rules for an undefined business model. Accordingly, we conclude that MPAA's speculative challenge is unfounded.

66. Fourth, MPAA seeks clarification that Section 76.1908(a), which allows MVPDs to maintain undistributed copies of audio-visual content that is encoded in any way the MVPD chooses, does not nullify contractual obligations between MVPDs and content providers. MPAA is correct in its assertion that the Commission did not intend that MVPDs be allowed to use Section 76.1908(a) of the Commission's rules to make copies of ''Copy Never'' content on a PVR in a consumer's home. Therefore, we clarify that Section 76.1908(a) does not permit MVPDs to make copies of content that would violate agreements between content owners and MVPDs.

67. Finally, MPAA seeks review of the Commission's *Sua Sponte Reconsideration Order* on the same grounds that NCTA does. For the same reasons provided in our consideration of NCTA's petition above in paragraph 57, MPAA's petition is granted with respect to this issue.

68. *BMI and ASCAP.* BMI and ASCAP have filed a petition for reconsideration seeking a declaration that performance rights organizations are allowed to decrypt content that has been encrypted, when used solely for the purpose of monitoring and tracking transmissions of audiovisual works for royalty purposes. We do not believe that a rule change is necessary for such a narrow exception of our rules, and we agree with the Home Recording Rights Coalition that the Commission does not have the authority to grant a waiver of the Digital Millennium Copyright Act's prohibition on circumventing content encryption. Accordingly, we deny BMI and ASCAP's petition for reconsideration.

69. *NMPA.* The National Music Publishers Association seeks reconsideration of the Commission's decision not to require output controls on digital audio outputs. NMPA asserts that unprotected digital audio outputs will contribute to illegal copying, and that the Commission's decision not to require content protections on digital audio outputs violates copyright concerns. We continue to believe that our existing treatment of audio outputs is necessary to protect legacy devices that do not have protected digital connections. Moreover, NMPA provides no evidence that illegal copying of the audio channel of cable television programming is anything more than a speculative problem. Accordingly, we deny NMPA's petition for reconsideration.

70. *TiVo.* On July 27, 2009, TiVo filed a petition for reconsideration of the Commission's decision that our then existing rules did not require cable operators to provide UDCPs with access to switched digital channels. Due to the rule change that we adopt in Section III.A.1 above, which requires cable operators to provide UDCPs with access to switched digital channels, we dismiss TiVo's petition as moot.

71. *Conclusion.* The steps we take in this order represent inexpensive reforms that will remove the disparity in the subscriber experience for those customers who choose to purchase a retail navigation device as opposed to leasing the cable provider's set-top box. These steps will help to develop a retail market for navigation devices during the interim period before a successor solution is developed and implemented for all MVPDs. While we are optimistic about the prospects of a successor technology, we must also be pragmatic about harnessing realized solutions. Therefore, until a successor technology is actually available, the Commission must strive to make the existing CableCARD standard work effectively.

72. *Procedural Matters. Paperwork Reduction Act Analysis.* This *Order* adopts new or revised information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. The requirements will be submitted to the Office of Management and Budget (OMB) for review under section 3507 of the PRA. The Commission will publish a separate notice in the **Federal Register** inviting comment on the new or revised information collection requirement(s) adopted in this document. The requirement(s) will not go into effect until OMB has approved it and the Commission has published a notice announcing the effective date of the information collection requirement(s). In addition, we note that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), we previously sought specific comment on how the Commission might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.'' We find that the modified information collection requirements must apply fully to small entities (as well as to others) to ensure compliance with our CableCARD rules, as described in the *Order.*

73. *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 in Appendix A.

74. *Congressional Review Act.* The Commission will send a copy of this *Third Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

75. *Additional Information.* For additional information on this proceeding, contact Steven Broeckaert, *Steven.Broeckaert@fcc.gov,* or Brendan Murray, *Brendan.Murray@fcc.gov,* of the Media Bureau, Policy Division, (202) 418–2120.

76. For additional information concerning the information collection(s) contained in this document, contact Cathy Williams at (202) 418–2918, or via the Internet at *PRA@fcc.gov.*

Final Regulatory Flexibility Analysis

77. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Fourth Further Notice of Proposed Rule Making* (*FNPRM*). The Commission sought written public comment on the proposals in the *FNPRM,* including comment on the IRFA. No commenting parties specifically addressed the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

78. *Need for, and Objectives of, the Rules.* The need for FCC regulation in this area derives from deficiencies in our rules that prevent consumer electronics manufacturers from developing video navigation devices (such as televisions and set-top boxes) that can be connected directly to cable systems and access cable services without the need for a cable-operator provided navigation device. The objectives of the rules we adopt are to support a competitive market for navigation devices by increasing customer service and by improving audio-visual output functionality on cable-operator-leased devices.

79. Specifically, we adopt rules that (i) require cable operators to provide customer and technical support for retail devices to access switched digital channels; (ii) require that equivalent prices be charged for CableCARDs for use in cable-operator-provided set-top boxes and in retail devices, and that require the pricing information and billing of the CableCARD to be more transparent; (iii) simplify the CableCARD installation process; (iv) require cable operators to provide their subscribers with CableCARDs that can tune multiple streams of programming; and (v) streamline the CableCARD device certification process by modifying our rules to reflect updated testing procedures, and prohibiting a qualified testing facility from refusing to certify UDCPs for any reason other than a failure to comply with the conformance checklists referenced in our current rules.

80. *Legal Basis.* The authority for the action proposed in this rulemaking is contained in Sections 1, 4(i) and (j), 303, 403, 601, 624A and 629 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i) and (j), 303, 403, 521, 544a and 549.

81. *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'').

82. *Cable Television Distribution Services.* 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. To gauge small business prevalence for these cable services we must, however, use current census data that are based on the previous category of Cable and Other Program Distribution and its associated size standard; that size standard was: all such firms having $13.5 million or less in annual receipts. According to Census Bureau data for 2002, there were a total of 1,191 firms in this previous category that operated for the entire year. Of this total, 1,087 firms had annual receipts of under $10 million, and 43 firms had receipts of $10 million or more but less than $25 million. Thus, the majority of these firms can be considered small.

83. *Cable Companies and Systems.* 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. Industry data indicate that, of 1,076 cable operators nationwide, all but eleven are small under this size standard. In addition, under the Commission's rules, a ''small system'' is a cable system serving 15,000 or fewer subscribers. Industry data indicate that, of 6,635 systems nationwide, 5,802 systems have under 10,000 subscribers, and an additional 302 systems have 10,000–19,999 subscribers. Thus, under this second size standard, most cable systems are small.

84. *Cable System Operators.* 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.'' The Commission has determined that an operator serving fewer than 677,000 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. Industry data indicate that, of 1,076 cable operators nationwide, all but ten are small under this size standard. 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, and therefore we are unable to estimate more accurately the number of cable system operators that would qualify as small under this size standard. *Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing.* The Census Bureau defines this category as follows: ''This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.'' The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is: all such firms having 750 or fewer employees. According to Census Bureau data for 2002, there were a total of 1,041

establishments in this category that operated for the entire year. Of this total, 1,010 had employment of under 500, and an additional 13 had employment of 500 to 999. Thus, under this size standard, the majority of firms can be considered small.

85. *Other Communications Equipment Manufacturing.* The Census Bureau defines this category as follows: ''This industry comprises establishments primarily engaged in manufacturing communications equipment (except telephone apparatus, and radio and television broadcast, and wireless communications equipment).'' The SBA has developed a small business size standard for Other Communications Equipment Manufacturing, which is: all such firms having 750 or fewer employees. According to Census Bureau data for 2002, there were a total of 503 establishments in this category that operated for the entire year. Of this total, 493 had employment of under 500, and an additional 7 had employment of 500 to 999. Thus, under this size standard, the majority of firms can be considered small.

86. *Electronics Equipment Manufacturers.* The SBA has developed a small business size standard for manufacturers of audio and video equipment, which is: all such firms having 750 or fewer employees. Census Bureau data indicates that there are 571 U.S. establishments that manufacture audio and visual equipment, and that 560 of these establishments have fewer than 500 employees and would be classified as small entities. The remaining 11 establishments have 500 or more employees; however, we are unable to determine how many of those have fewer than 750 employees and therefore, also qualify as small entities under the SBA definition. We therefore conclude that there are no more than 560 small manufacturers of audio and visual electronics equipment for consumer/household use.

87. *Computer Manufacturers.* The Commission has not developed a definition of small entities applicable to computer manufacturers. Therefore, we will utilize the SBA definition of electronic computers manufacturing. According to SBA regulations, a computer manufacturer must have 1,000 or fewer employees in order to qualify as a small entity. Census Bureau data indicates that there are 485 firms that manufacture electronic computers and of those, 476 have fewer than 1,000 employees and qualify as small entities. The remaining 9 firms have 1,000 or more employees. We conclude that there are approximately 476 small computer manufacturers.

88. *Description of Projected Reporting, Recordkeeping and Other Compliance Requirements.* The rules adopted in the Order will impose additional reporting, recordkeeping, and compliance requirements on cable operators. The Order adopts a rule that requires cable operators to charge equivalent and transparent prices for CableCARDs. This rule change will require certain cable operators to change their billing practices by reporting CableCARD prices on their Web sites, annual rate cards, or monthly bills. The Order also adopts a rule that will require device manufacturers to include CableCARD installation instructions with their devices.

89. *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.

90. Four of the final rules did not require the Commission to consider alternatives. Based on our review of the record and analysis, a consideration of alternatives is unnecessary because adoption of these rules leads to far greater consumer and industry benefits that outweigh any de minimis burden that may be placed on small entities. The switched digital support rule places a minor burden on cable operators. This burden is offset because the rule will greatly benefit consumers by ensuring that subscribers are able to access all of the programming for which they pay. This rule ensures consumers will benefit regardless of whether they use retail or leased devices.

91. The installation rule decreases the burden on cable operators with respect to customer service calls. It requires cable technicians to arrive with the number of CableCARDs that a consumer requests, and allow for self-installation of CableCARDs. The effect will be to reduce the difficulties that consumers face when seeking to install a CableCARD in a retail device and to reduce the number of service calls that cable operators and subscribers need to schedule.

92. The rule regarding Multi-stream CableCARDs places a minimal burden on cable operators by requiring cable operators to provide subscribers with Multi-stream CableCARDs. However, the record indicates that Multi-stream CableCARDS have been the standard since 2007 and CableCARD manufacturers are no longer making single stream CableCARDs to sell to cable operators. Therefore, we believe the burden will be minimal and will be greatly outweighed by the benefits to consumers. This rule will reduce the cost that consumers face to use the picture-in-picture and ''watch one, record one'' functions of their video navigation devices, since fewer CableCARDs will be necessary.

93. The rule that streamlines the CableCARD device certification process will place no burden on qualified testing facilities. To the contrary, it will benefit consumer electronics manufacturers by reducing the cost of the certification process and limiting the influence that testing facilities have in the development of new consumer electronics equipment.

94. The Commission did consider alternatives to the pricing and billing rule. As proposed, the rule change would have required cable operators to separate and report the cost of a CableCARD on every monthly bill. As suggested in comments received in the proceeding, the Commission instead adopted a rule that will instead require cable operators to separate and report the cost on the annual rate card or on the operator's Web site. This new rule places a smaller burden on cable operators than the proposed rule. It will also greatly benefit consumers, resulting in fewer customer service calls, an increase in transparency of pricing, and provide consumers with pricing information prior to purchase, rather than after.

95. *Federal Rules Which Duplicate, Overlap, or Conflict with the Commission's Proposals.* None.

List of Subjects

47 CFR Part 15

Communications equipment, Computer technology, Labeling, Radio, Reporting and recordkeeping requirements, Security measures, Telephone, Wiretapping and electronic surveillance, Incorporation by reference.

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 parts 15 and 76 as follows:

PART 15—RADIO FREQUENCY DEVICES

■ 1. The authority citation for part 15 is revised to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, 304, 307, 336, 544a, and 549.

■ 2. Amend § 15.38 by revising paragraphs (a), (b) introductory text, and (c) to read as follows:

§ 15.38 Incorporation by reference.

(a) The materials listed in this section are incorporated by reference in this part. These incorporations by reference were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they exist on the date of the approval, and notice of any change in these materials will be published in the **Federal Register**. The materials are available for purchase at the corresponding addresses as noted, and all are available for inspection at the Federal Communications Commission, 445 12th St., SW., Reference Information Center, Room CY–A257, Washington, DC 20554, (202) 418–0270, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(b) The following materials are available for purchase from at least one of the following addresses: Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112, (800) 854–7179, or at *http://global.ihs.com;* or American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, (212) 642–4900,or at *http://webstore.ansi.org/ansidocstore/default.asp.;* or Society of Cable Telecommunications Engineers, 140 Philips Road, Exton, PA 19341–1318, (800) 542–5040, or at *http://www.scte.org/standards/index.cfm.*

* * * * *

(c) The following materials are freely available from at least one of the following addresses: Cable Television Laboratories, Inc., 858 Coal Creek Circle, Louisville, Colorado, 80027, *http://www.cablelabs.com/opencable/udcp,* (303) 661–9100; or at Consumer Electronics Association, 1919 S. Eads St., Arlington; VA 22202, *http://www.ce.org/public_policy,* (703) 907–7634.

(1) Uni-Dir-PICS–I01–030903: ''Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma,'' September 3, 2003, IBR approved for § 15.123(c).

(2) Uni-Dir-ATP–I02–040225: ''Uni-Directional Receiving Device, Acceptance Test Plan,'' February 25, 2004, IBR approved for § 15.123(c).

(3) M–UDCP–PICS–I04–080225, ''Uni-Directional Cable Product Supporting M–Card: Multiple Profiles; Conformance Checklist: PICS,'' February 25, 2008, IBR approved for § 15.123(c).

(4) TP–ATP–M–UDCP–I05–20080304, ''Uni-Directional Digital Cable Products Supporting M–Card; M–UDCP Device Acceptance Test Plan,'' March 4, 2008, IBR approved for § 15.123(c).

■ 3. Revise § 15.123(c) to read as follows:

§ 15.123 Labeling of digital cable ready products.

* * * * *

(c) Before a manufacturer's or importer's first unidirectional digital cable product may be labeled or marketed as digital cable ready or with other terminology as described in paragraph (b) of this section, the manufacturer or importer shall verify the device as follows:

(1) The manufacturer or importer shall have a sample of its first model of a unidirectional digital cable product tested to show compliance with the procedures set forth in Uni-Dir-PICS–I01–030903: Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma (incorporated by reference, see § 15.38) at a qualified test facility. If the model fails to comply, the manufacturer or importer shall have any modifications to the product to correct failures of the procedures in Uni–Dir–PICS–I01–030903: ''Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma,'' September 3, 2003 (incorporated by reference, see § 15.38) retested at a qualified test facility and the product must comply with Uni-Dir-PICS–I01–030903: ''Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma,'' September 3, 2003 (incorporated by reference, see § 15.38) in accordance with the test procedures set forth in Uni–Dir–ATP–I02–040225: ''Uni-Directional Receiving Device, Acceptance Test Plan,'' February 25, 2004 (incorporated by reference, see § 15.38) or with M–UDCP–PICS–I04–080225, ''Uni-Directional Cable Product Supporting M–Card: Multiple Profiles; Conformance Checklist: PICS,'' February 25, 2008 (incorporated by reference, see § 15.38) in accordance with the test procedures set forth in TP–ATP–M–UDCP–I05–20080304, ''Uni-Directional Digital Cable Products Supporting M–Card; M–UDCP Device Acceptance Test Plan,'' March 4, 2008 (incorporated by reference, see § 15.38) before the product or any related model may be labeled or marketed. If the manufacturer or importer's first unidirectional digital cable product is not a television, then that manufacturer or importer's first model of a unidirectional digital cable product which is a television shall be tested pursuant to this subsection as though it were the first unidirectional digital cable product. A qualified test facility may only require compliance with the procedures set forth in Uni-Dir-PICS–I01–030903: Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma, September 3, 2003 (incorporated by reference, see § 15.38). Compliance testing beyond those procedures shall be at the discretion of the manufacturer or importer.

(2) A qualified test facility is a testing laboratory representing cable television system operators serving a majority of the cable television subscribers in the United States or an appropriately qualified independent laboratory with adequate equipment and competent personnel knowledgeable with respect to Uni-Dir-PICS–I01–030903: ''Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma,'' September 03, 2003 (incorporated by reference, see § 15.38); Uni–Dir–ATP–I02–040225: ''Uni-Directional Receiving Device, Acceptance Test Plan,'' February 25, 2004 (incorporated by reference, see § 15.38); M–UDCP–PICS–I04–080225, ''Uni-Directional Cable Product Supporting M–Card: Multiple Profiles; Conformance Checklist: PICS,'' February 25, 2008 (incorporated by reference, see § 15.38); and TP–ATP–M–UDCP–I05–20080304, ''Uni-Directional Digital Cable Products Supporting M–Card; M–UDCP Device Acceptance Test Plan,'' March 4, 2008 (incorporated by reference, see § 15.38). For any independent testing laboratory to be qualified hereunder such laboratory must ensure that all its decisions are impartial and have a documented structure which safeguards impartiality of the operations of the testing laboratory. In addition, any independent

testing laboratory qualified hereunder must not supply or design products of the type it tests, nor provide any other products or services that could compromise confidentiality, objectivity or impartiality of the testing laboratory's testing process and decisions.

(3) Subsequent to the testing of its initial unidirectional digital cable product model, a manufacturer or importer is not required to have other models of unidirectional digital cable products tested at a qualified test facility for compliance with the procedures of Uni-Dir-PICS–I01–030903: ''Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma,'' September 03, 2003 (incorporated by reference, see § 15.38) unless the first model tested was not a television, in which event the first television shall be tested as provided in § 15.123(c)(1). The manufacturer or importer shall ensure that all subsequent models of unidirectional digital cable products comply with the procedures in the Uni-Dir-PICS–I01–030903: ''Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma,'' September 03, 2003 (incorporated by reference, see § 15.38) and all other applicable rules and standards. The manufacturer or importer shall maintain records indicating such compliance in accordance with the verification procedure requirements in part 2, subpart J of this chapter. The manufacturer or importer shall further submit documentation verifying compliance with the procedures in the Uni-Dir-PICS–I01–030903: ''Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma,'' September 03, 2003 (incorporated by reference, see § 15.38) to the qualified test facility.

(4) Unidirectional digital cable product models must be tested for compliance with Uni-Dir-PICS–I01–030903: ''Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma,'' September 3, 2003 (incorporated by reference, see § 15.38) in accordance with Uni–Dir–ATP–I02–040225: ''Uni-Directional Receiving Device Acceptance Test Plan,'' February 25, 2004, (incorporated by reference, see § 15.38) or an equivalent test procedure that produces identical pass/fail test results. In the event of any dispute over the applicable results under an equivalent test procedure, the results under Uni–Dir–ATP–I02–040225: ''Uni-Directional Receiving Device Acceptance Test Plan,'' February 25, 2004 (incorporated by reference, see § 15.38) shall govern.

(5) This paragraph applies to unidirectional digital cable product models which utilize Point-of-Deployment modules (PODs) in multi-stream mode (M–UDCPs).

(i) The manufacturer or importer shall have a sample of its first model of a M–UDCP tested at a qualified test facility to show compliance with M–UDCP–PICS–I04–080225, ''Uni-Directional Cable Product Supporting M–Card: Multiple Profiles; Conformance Checklist: PICS,'' February 25, 2008 (incorporated by reference, see § 15.38) as specified in the procedures set forth in TP–ATP–M–UDCP–I05–20080304, ''Uni-Directional Digital Cable Products Supporting M–Card; M–UDCP Device Acceptance Test Plan,'' March 4, 2008 (both references incorporated by reference, see § 15.38). If the model fails to comply, the manufacturer or importer shall have retested, at a qualified test facility, a product that complies with Uni-Dir-PICS–I01–030903: ''Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma,'' September 03, 2003 (incorporated by reference, see § 15.38) in accordance with Uni–Dir–ATP–I02–040225: ''Uni-Directional Receiving Device Acceptance Test Plan,'' February 25, 2004, (incorporated by reference, see § 15.38) or an equivalent test procedure that produces identical pass/fail test results before any product or related model may be labeled or marketed. If the manufacturer or importer's first M–UDCP is not a television, then that manufacturer or importer's first model of a M–UDCP which is a television shall be tested pursuant to this subsection as though it were the first M–UDCP.

(ii) A qualified test facility is a testing laboratory representing cable television system operators serving a majority of the cable television subscribers in the United States or an appropriately qualified independent laboratory with adequate equipment and competent personnel knowledgeable with Uni-Dir-PICS–I01–030903: ''Uni-Directional Receiving Device: Conformance Checklist: PICS Proforma,'' September 03, 2003 (incorporated by reference, see § 15.38); Uni–Dir–ATP–I02–040225: ''Uni-Directional Receiving Device, Acceptance Test Plan,'' February 25, 2004 (incorporated by reference, see § 15.38); M–UDCP–PICS–I04–080225, ''Uni-Directional Cable Product Supporting M–Card: Multiple Profiles; Conformance Checklist: PICS,'' February 25, 2008 (incorporated by reference, see § 15.38); and TP–ATP–M–UDCP–I05–20080304, ''Uni-Directional Digital Cable Products Supporting M–Card; M–UDCP Device Acceptance Test Plan,'' March 4, 2008 (incorporated by reference, see § 15.38). For any independent testing laboratory to be qualified hereunder such laboratory must ensure that all its decisions are impartial and have a documented structure which safeguards impartiality of the operations of the testing laboratory. In addition, any independent testing laboratory qualified hereunder must not supply or design products of the type it tests, nor provide any other products or services that could compromise confidentiality, objectivity or impartiality of the testing laboratory's testing process and decisions.

(iii) Subsequent to the successful testing of its initial M–UDCP, a manufacturer or importer is not required to have other M–UDCP models tested at a qualified test facility for compliance with M–UDCP–PICS–I04–080225, ''Uni-Directional Cable Product Supporting M–Card: Multiple Profiles; Conformance Checklist: PICS,'' February 25, 2008 (incorporated by reference, see § 15.38) unless the first model tested was not a television, in which event the first television shall be tested as provided in § 15.123(c)(5)(i). The manufacturer or importer shall ensure that all subsequent models of M–UDCPs comply with M–UDCP–PICS–I04–080225, ''Uni-Directional Cable Product Supporting M–Card: Multiple Profiles; Conformance Checklist: PICS,'' February 25, 2008 (incorporated by reference, see § 15.38) and all other applicable rules and standards. The manufacturer or importer shall maintain records indicating such compliance in accordance with the verification procedure requirements in part 2, subpart J of this chapter. For each M–UDCP model, the manufacturer or importer shall further submit documentation verifying compliance with M–UDCP–PICS–I04–080225, ''Uni-Directional Cable Product Supporting M–Card: Multiple Profiles; Conformance Checklist: PICS,'' February 25, 2008 (incorporated by reference, see § 15.38) to the qualified test facility.

(iv) M–UDCPs must be in compliance with M–UDCP–PICS–I04–080225, ''Uni-Directional Cable Product Supporting M–Card: Multiple Profiles; Conformance Checklist: PICS,'' February 25, 2008 (incorporated by reference, see § 15.38) in accordance with the procedures set forth in TP–ATP–M–UDCP–I05–20080304, ''Uni-Directional Digital Cable Products Supporting M–Card; M–UDCP Device Acceptance Test Plan,'' March 4, 2008 (incorporated by reference, see § 15.38) or an equivalent test procedure that produces identical pass/fail test results. In the event of any dispute over the applicable results under an equivalent test procedure, the

results under TP–ATP–M–UDCP–I05–20080304, ''Uni-Directional Digital Cable Products Supporting M–Card; M–UDCP Device Acceptance Test Plan,'' March 4, 2008 (incorporated by reference, see § 15.38) shall govern.

* * * * *

PART 76—MULTICHANNEL VIDEO AND CABLE TELEVISION SERVICE

■ 4. 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.

■ 5. Revise § 76.640(b)(4)(ii) and (iii) to read as follows:

§ 76.640 Support for unidirectional digital cable products on digital cable systems.

* * * * *

(b)* * *

(4) * * *

(ii) Effective July 1, 2011, include both: (A) a DVI or HDMI interface and (B) a connection capable of delivering recordable high definition video and closed captioning data in an industry standard format on all high definition set-top boxes, except unidirectional set-top boxes without recording functionality, acquired by a cable operator for distribution to customers.

(iii) Effective December 1, 2012, ensure that the cable-operator-provided high definition set-top boxes, except unidirectional set-top boxes without recording functionality, shall comply with an open industry standard that provides for audiovisual communications including service discovery, video transport, and remote control command pass-through standards for home networking.

■ 6. Revise § 76.1204(a)(2) to read as follows:

§ 76.1204 Availability of equipment performing conditional access or security functions.

(a) * * *

(2) The foregoing requirement shall not apply:

(i) With respect to unidirectional navigation devices without recording functionality; or

(ii) To a multichannel video programming distributor that supports the active use by subscribers of navigation devices that:

(A) Operate throughout the continental United States, and

(B) Are available from retail outlets and other vendors throughout the United States that are not affiliated with the owner or operator of the multichannel video programming system.

* * * * *

■ 7. Revise § 76.1205 to read as follows:

§ 76.1205 CableCARD support.

(a) Technical information concerning interface parameters that are needed to permit navigation devices to operate with multichannel video programming systems shall be provided by the system operator upon request in a timely manner.

(b) A multichannel video programming provider that is subject to the requirements of § 76.1204(a)(1) must:

(1) Provide the means to allow subscribers to self-install the CableCARD in a CableCARD-reliant device purchased at retail and inform a subscriber of this option when the subscriber requests a CableCARD. This requirement shall be effective August 1, 2011, if the MVPD allows its subscribers to self-install any cable modems or operator-leased set-top boxes and November 1, 2011 if the MVPD does not allow its subscribers to self-install any cable modems or operator-leased set-top boxes;

(i) This requirement shall not apply to cases in which neither the manufacturer nor the vendor of the CableCARD-reliant device furnishes to purchasers appropriate instructions for self-installation of a CableCARD, and a manned toll-free telephone number to answer consumer questions regarding CableCARD installation but only for so long as such instructions are not furnished and the call center is not offered;

(ii) [Reserved].

(2) Effective August 1, 2011, provide multi-stream CableCARDs to subscribers, unless the subscriber requests a single-stream CableCARD;

(3) With respect to professional installations, ensure that the technician arrives with no fewer than the number of CableCARDS requested by the customer and ensure that all CableCARDs delivered to customers are in good working condition and compatible with the customer's device;

(4) Effective August 1, 2011, provide, through the use of a commonly used interface and published specifications for communication, CableCARD-reliant, firmware-upgradable navigation devices the ability to tune simultaneously as many switched-digital channels as the greatest number of streams supported by any set-top box provided by the cable operator, or four simultaneous channels, whichever is greater;

(5) Separately disclose to consumers in a conspicuous manner with written information provided to customers in accordance with § 76.1602, with written or oral information at consumer request, and on Web sites or billing inserts;

(i) Any assessed fees for the rental of single and additional CableCARDs and the rental of operator-supplied navigation devices; and,

(ii) If such provider includes equipment in the price of a bundled offer of one or more services, the fees reasonably allocable to:

(A) The rental of single and additional CableCARDs; and

(B) The rental of operator-supplied navigation devices.

(*1*) CableCARD rental fees shall be priced uniformly throughout a cable system by such provider without regard to the intended use in operator-supplied or consumer-owned equipment. No service fee shall be imposed on a subscriber for support of a subscriber-provided device that is not assessed on subscriber use of an operator-provided device.

(*2*) For any bundled offer combining service and an operator-supplied navigation device into a single fee, including any bundled offer providing a discount for the purchase of multiple services, such provider shall make such offer available without discrimination to any customer that owns a navigation device, and, to the extent the customer uses such navigation device in lieu of the operator-supplied equipment included in that bundled offer, shall further offer such customer a discount from such offer equal to an amount not less than the monthly rental fee reasonably allocable to the lease of the operator-supplied navigation device included with that offer. For purposes of this section, in determining what is ''reasonably allocable,'' the Commission will consider in its evaluation whether the allocation is consistent with one or more of the following factors:

(i) An allocation determination approved by a local, state, or Federal government entity;

(ii) The monthly lease fee as stated on the cable system rate card for the navigation device when offered by the cable operator separately from a bundled offer; and

(iii) The actual cost of the navigation device amortized over a period of no more than 60 months.

(c) A cable operator shall not provide misleading information regarding the ability of navigation devices to access switched digital channels.

■ 8. Amend 76.1602 by adding paragraphs (b)(7) and (8) read as follows:

§ 76.1602 Customer service—general information.

* * * * *

(b) * * *

(7) Effective May 1, 2011, any assessed fees for rental of navigation devices and single and additional CableCARDs; and,

(8) Effective May 1, 2011, if such provider includes equipment in the price of a bundled offer of one or more services, the fees reasonably allocable to:

(i) The rental of single and additional CableCARDs; and

(ii) The rental of operator-supplied navigation devices.

* * * * *

■ 9. Revise § 76.1902(s) to read as follows:

§ 76.1902 Definitions.

* * * * *

(s) *Unencrypted broadcast television* means any service, program, or schedule or group of programs, that is a substantially simultaneous retransmission of a broadcast transmission (*i.e.,* an over-the-air transmission for reception by the general public using radio frequencies allocated for that purpose) that is made by a terrestrial television broadcast station located within the country or territory in which the entity retransmitting such broadcast transmission also is located, where such broadcast transmission is not subject to a commercially-adopted access control method (*e.g.,* is broadcast in the clear to members of the public receiving such broadcasts), regardless of whether such entity subjects such retransmission to an access control method.

* * * * *

■ 10. Revise § 76.1908(a) to read as follows:

§ 76.1908 Certain practices not prohibited.

* * * * *

(a) Encoding, storing or managing commercial audiovisual content within its distribution system or within a covered product under the control of a covered entity's commercially adopted access control method, provided that the outcome for the consumer from the application of the encoding rules set out in § 76.1904(a) and (b) is unchanged thereby when such commercial audiovisual content is released to consumer control and provided that all other laws, regulations, or licenses applicable to such encoding, storage, or management shall be unaffected by this section, or

* * * * *

[FR Doc. 2011–16869 Filed 7–7–11; 8:45 am]

BILLING CODE 6712–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1834

RIN 2700–AD29

Major System Acquisition; Earned Value Management

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: NASA is issuing a final rule to delete the requirement in the NASA FAR Supplement (NFS) for contractors to establish and maintain an Earned Value Management System (EVMS) for firm-fixed-price (FFP) contracts. The final rule recognizes the reduction in risk associated with FFP contracts and intends to relieve contractors of an unnecessary reporting burden.

DATES: *Effective Date:* July 8, 2011.

FOR FURTHER INFORMATION CONTACT: Carl Weber, NASA, Office of Procurement, Contract Management Division (Suite 5K80); (202) 358–1784; *e-mail: carl.c.weber@nasa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

NASA published a proposed rule in the **Federal Register** at 76 FR 7526 on February 10, 2011. The sixty day comment period expired April 11, 2011. Three comments were received from two respondents. No changes are made to the proposed rule as a result of public comments.

II. Discussion and Analysis of the Public Comments

Comment: The respondent suggested that the policy should more clearly define in house and external Earned Value Management Requirements.

Response: The regulation in the NASA FAR Supplement, 1834.201, is only directed toward contractor external efforts. Internal Government requirements are included but are not regulatory and not a part of this rulemaking.

Comment: The respondent suggested including a statement requiring any additional reporting requirements for FFP contracts to be identified in the solicitation or subsequent contract modification.

Response: NASA will collect the necessary data for project management and oversight. The rule states: ''The contracting officer shall collaborate with the government's program/project manager to ensure the appropriate data can be obtained or generated to fulfill program management needs''. There are various methods to obtain the appropriate data, and the CO will include Data Requirements in the solicitation and/or contract as needed on a case-by-case basis.

Comment: The respondent stated that NASA should consider implementing the change to existing contracts providing additional cost savings to NASA and the industry.

Response: NASA will not require, but may consider, implementing the change on existing contracts, on a case-by-case basis.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

This final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* because it relaxes previous requirements in the NASA FAR Supplement and does not impose a significant economic impact beyond that previously required.

V. Paperwork Reduction Act

This final rule does not impose any new information collection requirements that require the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 1834

Government procurement.

William P. McNally,

Assistant Administrator for Procurement.

Accordingly, 48 CFR Part 1834 is amended as follows:

PART 1834—MAJOR SYSTEM ACQUISITION

■ 1. The authority citation for 48 CFR Part 1834 continues to read as follows:

Authority: 42 U.S.C. 2455(a), 2473(c)(1)

■ 2. Section 1834.201 is revised to read as follows:

1834.201 Policy.

(a) NASA requires use of an Earned Value Management System (EVMS) on acquisitions for development or production work, including development or production work for flight and ground support systems and components, prototypes, and institutional investments (facilities, IT infrastructure, etc.) as specified below:

(1) For cost or fixed-price incentive contracts and subcontracts valued at $50 Million or more the contractor shall have an EVMS that has been determined by the cognizant Federal agency to be in compliance with the guidelines in the American National Standards Institute/ Electronic Industries Alliance Standard 748, Earned Value Management Systems (ANSI/EIA–748).

(2) For cost or fixed-price incentive contracts and subcontracts valued at $20 Million or more but less than $50 Million, the contractor shall have an EVMS that complies with the guidelines in ANSI/EIA–748, as determined by the cognizant Contracting Officer.

(3) For cost or fixed-price incentive contracts and subcontracts valued at less than $20 Million the application of EVM is optional and is a risk-based decision at the discretion of the program/project manager.

(b) Requiring earned value management for firm-fixed-price (FFP) contracts and subcontracts of any dollar value is discouraged; however, a schedule management system and adequate reporting shall be required to plan and track schedule performance for development or production contracts valued at $20 Million or more. In addition, for FFP contracts that are part of a program/project of $50 Million or more, the contracting officer shall collaborate with the government's program/project manager to ensure the appropriate data can be obtained or generated to fulfill program management needs and comply with NASA Procedural Requirements (NPR) 7120.5.

(c) An EVMS is not required on non-developmental contracts for engineering support services, steady state operations, basic and applied research, and routine services such as janitorial services or grounds maintenance services.

(d) Contracting officers shall request the assistance of the cognizant Defense Contract Management Agency (DCMA) office in determining the adequacy of proposed EVMS plans and procedures and system compliance.

(e) Notwithstanding the EVMS requirements above, if an offeror proposes to use a system that has not been determined to be in compliance with the American National Standards Institute/Electronics Industries Alliance (ANSI/EIA) Standard–748, Earned Value Management Systems, the offeror shall submit a comprehensive plan for compliance with these EVMS standards, as specified in 1852.234–1, Notice of Earned Value Management System. Offerors shall not be eliminated from consideration for contract award because they do not have an EVMS that complies with these standards.

■ 3. In section 1834.203–70, the introductory text is revised to read as follows:

1834.203–70 NASA solicitation provision and contract clause.

Except for firm-fixed price contracts and the contracts identified in 1834.201(a)(3), the contracting officer shall insert—

* * * * *

[FR Doc. 2011–17116 Filed 7–7–11; 8:45 am]

BILLING CODE 7510–01–P

Proposed Rules

Federal Register
Vol. 76, No. 131
Friday, July 8, 2011

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 150

[NRC–2011–0146]

Proposed Generic Communications; Draft NRC Regulatory Issue Summary 2011–XX; NRC Regulation of Military Operational Radium-226

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability of draft Regulatory Issue Summary (RIS) for public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to issue a RIS that clarifies those discrete sources of radium-226 under military control that are subject to NRC regulation pursuant to the Energy Policy Act of 2005 (EPAct), as interpreted in the policy statement issued by the NRC in the final rule, ''Requirements for Expanded Definition of Byproduct Material'' (72 FR 55864; October 1, 2007), (hereinafter referred to as the NARM Rule). The clarification defines with greater specificity the term ''military operations'' as it is used to delineate that naturally-occurring and accelerator-produced radioactive material (NARM) subject to NRC jurisdiction. The RIS also describes acceptable regulatory approaches to adequately implement NRC's regulatory requirements for contamination and items and equipment containing NARM, and outlines a general plan of implementation for use with the military services. The NRC is seeking comment from interested parties on the clarity and utility of the proposed RIS.

DATES: Submit comments by September 6, 2011. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: Please include Docket ID NRC–2011–0146 in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site, *http://www.regulations.gov*. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed. You may submit comments by any one of the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2011–0146. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668; e-mail: *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.
- *Fax comments to:* RADB at 301–492–3446.

You can access publicly available documents related to this notice using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html*. From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr.resource@nrc.gov*. The draft RIS is available electronically under ADAMS Accession Number ML111510163.
- *Federal Rulemaking Web Site:* Public comments and supporting materials related to this notice can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2011–0146.

FOR FURTHER INFORMATION CONTACT: Robert L. Johnson, Office of Federal and State Materials and Environmental Management Programs, Division of Waste Management and Environmental Protection, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–3152, e-mail: *Robert.Johnson2@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Draft NRC Regulatory Issue Summary 2011–XXXX; NRC Regulation of Military Operational Radium-226

Addressees

All U.S. Air Force and U.S. Navy Masters Materials License (MML) contacts; all U.S. Army contacts with specific NRC licenses; all Agreement State Radiation Control Program Directors and State Liaison Officers.

Intent

The NRC is issuing this RIS to clarify which discrete sources of radium-226 under military control are subject to NRC regulation as byproduct material under the Atomic Energy Act of 1954, as amended (AEA) and as discussed in the NARM Rule. *See* ''Requirements for Expanded Definition of Byproduct Material'' (72 FR 55864; October 1, 2007). The RIS describes regulatory approaches to implement NRC's authority for military contamination and items and equipment containing NARM. The guidance also outlines a general plan of implementation for use with the military services.

Background

The EPAct expanded the AEA's definition of byproduct material to include discrete sources of radium-226, discrete sources of naturally occurring radioactive material, and accelerator-produced radioactive material for use for a commercial, medical, or research activity (collectively, these materials are referred to as NARM). The NRC has received recent inquiries from the military services regarding the scope of the NRC's jurisdiction over discrete

sources of radium-226 used by the military for military operations. Because it is necessary to distinguish between commercial, medical, and research uses covered by the EPAct and military uses not included in the expanded jurisdiction of the EPAct, the focus of this RIS is on how to categorize discrete sources used by the military. Specifically, Section 651(e)(3)(A) of the EPAct (§ 11e.(3) of the AEA; 42 U.S.C. 2014(e)) amended the definition of byproduct material to include ''any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after [August 8, 2005,] for use for a commercial, medical, or research activity.'' On November 30, 2007, NRC implemented this provision of the EPAct by amending the definition of byproduct material in 10 CFR parts 20, 30, 50, 72, 150, 170, and 171. *See* NARM Rule (72 FR 55864; October 1, 2007). Additionally, NRC established a definition for the term ''discrete source'' to be used for the purposes of the new definition of byproduct material as this term was not specifically defined by the EPAct. Accordingly, NRC's regulations in 10 CFR Parts 20, 30, 110, and 150 define a discrete source as ''a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.'' In addition, the Statement of Consideration (SOC) for the NARM Rule noted that ''once a discrete source meets the definition of *Byproduct material,* any contamination resulting from the use of such discrete sources of this byproduct material will also be considered byproduct material'' (72 FR 55871).

Under the EPAct the NRC has jurisdiction over discrete sources of radium-226 used by the military in medical or research activities, or in a manner similar to a commercial activity; however, the NRC does not have jurisdiction over radium-226 used by the military in military operations because, as the NRC noted in the NARM Rule, to do otherwise would ''vitiate any distinction that the EPAct intended to make for military use * * *'' (72 FR 55867). In the SOC, the NRC defined the term ''military operations'' to include that which is traditionally understood as the military's primary mission for national defense, i.e., warfare, combat, battlefield missions, and training for such missions, as well as ''material still under control of the military, i.e., in storage, or material that may be subject to decontamination and disposal.'' *Id.*

In accordance with the Commission's directives contained in the May 14, 2007, staff requirements memorandum for the NARM Rule (SRM–SECY–07–0062; M070514; ADAMS Accession No. ML071340237), the SOC provided that NRC would interact with the U.S. Department of Defense to obtain a common understanding of the uses of discrete sources of radium-226 and resolve any potential conflicts on a case-by-case basis. *See also* 72 FR 55867. Consequently, the staff has had numerous interactions with the military services on this matter discussing the historical uses, current military activities, and management of discrete sources of radium-226. Through these interactions it has become apparent to the staff that there is confusion over the precise meaning and scope of the phrase ''material still under control of the military, i.e., in storage, or material that may be subject to decontamination or disposal.'' This confusion and uncertainty has led staff to believe that a generic solution is required in order to assure that NRC regulations are appropriately implemented.

On February 16, 2011, the NRC staff prepared a Commission paper that discussed uses of military radium-226; identified issues; and recommended approaches to clarify and implement NRC's regulatory jurisdiction over certain types of radium-226 used by the military (SECY–11–0023; ADAMS Accession No. ML110110345). On March 24, 2001, the Commission responded to the staffs' recommendations in SECY–11–0023 by giving the following direction in SRM–SECY–11–0023 (ADAMS Accession No. ML110830952):

> The Commission has approved the staff's recommendation to prepare a guidance document and **Federal Register** notice that clarifies the radium-226 under military control that would be subject to NRC regulations, and describes the regulatory approaches to be used to implement NRC authority for radium-226 contamination and radium-226 in items and equipment.

Summary of Issue

This RIS describes: (1) Jurisdictional issues; (2) clarification of military radium-226 that is subject to NRC regulation; (3) acceptable regulatory approaches to implement NRC's jurisdiction for contamination and items and equipment; and (4) a general plan for implementing NRC's jurisdiction.

Jurisdictional Issues

As previously noted, the NRC expanded the category of radium-226 excluded from NRC jurisdiction by defining the term ''military operational'' material to include ''material still under control of the military, i.e., in storage, or material that may be subject to decontamination or disposal'' (72 FR 55867). This expanded definition led to questions from the military and the State of California about NRC's jurisdiction over some of the military's ongoing and planned remediation activities. In particular, new issues emerged from the staff's discussions about the military's ongoing remediation activities at the Navy's Hunters Point Shipyard (HPS) site and the Air Force's McClellan site in California. After remediation, these sites or portions of these sites are planned to be released to the public for redevelopment, similar to other Base Realignment and Closure (BRAC) sites. The following key issues have been identified by the staff based on interactions with the military and the State of California.

- Potential for unnecessary dual regulation under the AEA and Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and lack of finality of the military remediation if NRC is not involved during military remediation and before the transfer of remediated property to non-military owners;
- Potential for significant impacts to community redevelopment and reuse of remediated military property unless NRC is involved during remediation;
- Regulatory uncertainty and inconsistent understanding regarding NRC's jurisdiction unnecessarily complicates military remediation;
- Regulatory uncertainty regarding jurisdiction over storage and decontamination of equipment and items containing radium-226; and
- Potential implications for health and safety from the unregulated sites being remediated and the uncharacterized sites with suspected radium-226.

Clarification of Radium-226 Under Military Control That Should Be Subject to NRC Regulation

Discrete sources of radium-226 under military control that would be subject to NRC regulation under the NARM Rule as byproduct material include:

- Contamination. Examples include contamination in structures; soil; groundwater; sewers or storm drains; targets and associated contamination on firing ranges; and degraded devices and residue from radium paint shops buried in landfills. NRC's jurisdiction applies to radium-226 contamination that has been *confirmed* based on survey data or records documenting the actual existence of the contamination. Contamination that is only *suspected,* based on historical activities conducted

on a military base, should be tracked and appropriately controlled by the military. These suspected sites should come under NRC's jurisdiction when confirmed. Contamination can be on active military installations where remediation has either not started or where parcels are being remediated. The military's remediation activities associated with contamination can also be on BRAC sites that are planned for transfer to the public and redeveloped by local governments or others after remediation (*e.g.,* HPS and McClellan sites).

• Items or equipment not currently used in traditional military operations and no longer intended for future use in traditional military operations. Examples include vehicles, aircraft, or other equipment in storage that the military is no longer using and that is not intended to be used in the future and which could be decontaminated by removing radium-226 instruments, dials and/or components in preparation for release of the equipment or vehicles to the public. This could also be items such as dials or gauges that the military decides are no longer intended for future use in traditional military operations.

This RIS resolves an existing ambiguity by clarifying that military radium-226 that originated from a commercial supplier is byproduct material, except during its use by the military in traditional military operations. When the commercially-produced radium-226 is no longer being used for traditional military operations and is not intended for future traditional military operational use, it would revert to its initial classification as byproduct material. Under this clarification, the SOC discussion that contamination resulting from degradation of byproduct material would also be considered byproduct material would therefore apply to military radium-226 contamination. For example, degradation of buried markers can result in contamination of the surrounding soil or groundwater. In addition, the storage of material or equipment not intended for future military operations, removal of dials and gauges after their usable life, and remediation of radium-226 are similar to commercial activities and are consistent with the SOC statement ''that other military possession and uses of radium-226 in a manner similar to commercial use, e.g., military museums, are subject to NRC's regulatory authority.'' For the above reasons, the clarification is consistent with the definition of byproduct material in the EPAct and the NRC's regulations. Finally, as noted previously, the above clarifications are consistent with NRC's practice of regulating military radioactive material except when the material is used or useful in traditional military operations.

Regulatory Approaches for Contamination

The NRC staff would use the graded approach outlined below for implementing NRC regulation of confirmed radium-226 contamination. This approach provides levels of regulatory involvement taking into account the broad range of site-specific conditions expected, such as: the radionuclides present; the type and extent of contamination; the remediation status and types of remedies; and other Federal agency or State oversight. This approach provides a flexible yet consistent framework for the military services. The NRC staff also considered other implementation issues as noted below.

(1) *No ongoing or planned remediation.* Confirmed contamination on sites that are currently not being remediated or where remediation would be done in the future would be included as a possession-only permit under the existing Air Force or Navy MMLs or an Army possession-only license under the appropriate regulations for the radionuclides present.

(2) *Remediation of National Priorities List (NPL) sites.* For military remediation of sites listed on the NPL, NRC staff would use an approach similar to that approved by the Commission for the HPS site where NRC determined that it could rely on the CERCLA process and the Federal regulatory oversight by the U.S. Environmental Protection Agency (EPA) (SECY–08–0077; ADAMS Accession Nos. ML080800110 and ML081780111). These sites would not be actively regulated, although the Air Force and Navy sites would be permitted under the Air Force and Navy MMLs and the Army sites would be licensed. NRC would take a limited involvement approach to stay informed as it now does for the HPS site and the McClellan site. The Navy and Air Force would continue their existing role under CERCLA for these sites. However, NRC would reserve the option of providing comments to EPA on the military remediation, if necessary, to justify continued reliance on the CERCLA process and EPA oversight. If the NRC staff determines that the CERCLA process and EPA oversight is no longer sufficient, the NRC staff would more actively regulate the site as appropriate. The NRC staff considered the option of immediately regulating these sites, but prefers the approved approach for the HPS site because it would avoid or minimize dual regulation.

(3) *Remediation of non-NPL sites.* NRC would actively regulate sites not listed on the NPL that are remediated by the military. Because EPA generally does not provide regulatory oversight for these sites, there would be no other independent Federal oversight of the remediation activities occurring on the non-NPL sites. Regulation would be conducted under the existing Navy and Air Force MMLs and under existing Army licenses or another appropriate licensing approach that would be established. The Navy and Air Force would permit these sites under the MML. NRC would continue its existing oversight of the Navy and Air Force MML programs, but would also review and approve key remediation/decommissioning documents for more complex sites, such as sites with groundwater contamination or restricted use sites that use institutional controls and engineered barriers. Existing NRC oversight would continue for military contractors who have NRC service provider licenses and who conduct remediation activities. Furthermore, for those non-NPL sites where the military is required to remediate using the CERCLA process, NRC would coordinate its decommissioning process with the CERCLA process to minimize duplicative remedial activity. For those sites where remediation under the CERCLA process has already started, NRC would work with the military on a site-specific approach to ensure safety and minimize the impact on military schedules. Sites where remediation has been completed by the military would not be regulated unless newly acquired information indicates that additional remediation is needed to protect public health and safety and the environment.

(4) *Regulatory approaches for items and equipment.* NRC would regulate military equipment decontamination activities and items in storage where the military has determined that there is no future traditional military operational use for this material. Regulation would be under the Navy and Air Force MMLs and either existing Army commodity licenses or another appropriate licensing approach.

(5) *General plan for implementing NRC's jurisdiction.* The NRC staff intends to develop a Radium Implementation Plan to identify the specific actions and detailed guidance needed by NRC and the military to implement the jurisdiction and regulatory approach described above. The NRC staff is considering the

following general approaches for implementation:

- Work with each military service to customize actions and needs for guidance;
- Take a phased approach to implement NRC's jurisdiction, including an initial prelicensing/permitting phase to prepare for the licensing/permitting phase;
- Develop phased licensing/permitting jointly with the military services to minimize impact on the schedules for ongoing work;
- Select high priority sites identified by the military to serve as pilot sites to help develop detailed guidance. Also, identify high priority sites where NRC's attention is needed;
- Develop guidance to address questions and cases representative of each military service;
- Include guidance in the Air Force and Navy MML letters of understanding and guidance and similar documents developed for the Army;
- Interact with the Army to establish an appropriate licensing approach and guidance.

Topics where additional guidance could be developed include:

- Application of NRC's decommissioning timeliness requirements;
- Coordination of the military's use of the CERCLA process and NRC's decommissioning process in order to protect the public and the environment and minimize dual regulation; and
- Identification of responsibilities of NRC, Air Force, and Navy under each MML.

Backfit Discussion

This RIS requires no action or written response. Any action that addressees take to implement changes or procedures in accordance with the information contained in this RIS ensures compliance with current regulations, is strictly voluntary, and, therefore, is not a backfit under any of the backfitting provisions contained in 10 CFR 50.109, 70.76, 72.62, 76.76, or the issue finality provision of 10 CFR part 52. Consequently, the staff did not perform a backfit analysis.

Federal Register Notification

To be done after the public comment period.

Voluntary Response

All addresses and the public may voluntarily submit comments regarding the military radium policy presented in this RIS. To be of use to the NRC, responses should be submitted by September 6, 2011.

Congressional Review Act

This RIS is a rule as designated in the Congressional Review Act (5 U.S.C. 801–886) and, therefore, is subject to the Act.

Paperwork Reduction Act Statement

This RIS does not contain any information collection requirements and, therefore, is not subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

Contact

This RIS requires no specific action or written response. If you have any questions about this summary, please contact the technical contact.

Technical Contact: Robert L. Johnson, DWMEP/SPB, (301) 415–5143, e-mail: *robert.johnson2@nuc.gov.*

Note: The NRC's generic communications may be found on the NRC public Web site, *http://www.nrc.gov,* under Electonic Reading Room/Document Collections.

End of Draft Regulatory Issue Summary

Dated at Rockville, Maryland this 24th day of June 2011.

For the Nuclear Regulatory Commission.

Keith I. McConnell,

Deputy Director, Decommissioning and Uranium Recovery Licensing Directorate, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. 2011–17165 Filed 7–7–11; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE–2010–BT–DET–0040]

RIN 1904–AC52

Energy Conservation Program for Consumer Products and Certain Commercial and Industrial Equipment: Proposed Determination of Set-Top Boxes and Network Equipment as a Covered Consumer Product

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of extension of public comment period.

SUMMARY: This document announces that the period for submitting comments on the proposed determination for set-top boxes and network equipment is extended to September 30, 2011.

DATES: DOE will accept comments, data, and information regarding the proposed determination for set-top boxes and network equipment published June 15, 2011 (76 FR 34914) received no later than 5 p.m. on September 30, 2011.

ADDRESSES: Any comments submitted must identify the proposed determination for set-top boxes and network equipment and provide docket number EERE–2010–BT–DET–0040 and/or RIN number 1904–AC52. Comments may be submitted using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: Brenda.Edwards@ee.doe.gov.* Include docket number EERE–2010–BT–DET–0040 and/or RIN 1904–AC52 in the subject line of the message. Submit electronic comments in WordPerfect, Microsoft Word, PDF, or ASCII file format and avoid the use of special characters or any form of encryption.
- *Postal Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, 1000 Independence Avenue, SW., Washington, DC 20585–0121. Telephone: (202) 586–2945. Please submit one signed original paper copy.
- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza, SW., 6th Floor, Washington, DC 20024. Please submit one signed original paper copy.

Docket: For access to the docket to read background documents or comments received, visit the U.S. Department of Energy, Resource Room of the Building Technologies Program, 950 L'Enfant Plaza, SW., 6th Floor, Washington, DC 20024, (202) 586–2945, between 9 a.m. and 4 p.m. Monday through Friday, except Federal holidays. Please call Ms. Brenda Edwards at the above telephone number for additional information regarding visiting the Resource Room. Please note: DOE's Freedom of Information Reading Room (Room 1E–190 at the Forrestal Building) no longer houses rulemaking materials.

FOR FURTHER INFORMATION CONTACT: Mr. Wes Anderson, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue, SW., Washington, DC 20585–0121.

Telephone: (202) 586–7335. E-mail: *Wes.Anderson@ee.doe.gov.*

In the Office of General Counsel, contact Ms. Elizabeth Kohl, U.S. Department of Energy, Office of the General Counsel, GC–71, 1000 Independence Avenue, SW., Washington, DC 20585. Telephone: (202) 586–7796. E-mail: *Elizabeth.Kohl@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: On June 15, 2011, DOE published a notice of proposed determination (NOPD) in the **Federal Register** (76 FR 34914) to determine that set top boxes and network equipment meet the criteria for classification as a covered product under the Energy Policy and Conservation Act, as amended (EPCA, 42 U.S.C. 6291, *et seq.*). The NOPD provided for the submission of comments by July 15, 2011. Interested parties requested an extension of the comment period. One commenter stated that it represented over 2000 companies who manufacture set top boxes and similar products, as well as component suppliers and service providers for such products. This commenter stated that it had commissioned a revision of its 2007 energy use study examining power consumption data and trends for set-top boxes and other consumer electronics. The commenter indicated that the data in this study, due in late August 2011, would be helpful to DOE in determining how to proceed with its proposed determination, and that the study would also be helpful informing the comments submitted by the commenter on the proposal. Another commenter requested an extension of time to develop its comments, stating that additional time would allow them to provide better quality comments to DOE. DOE has determined that an extension of the public comment period is appropriate based on the foregoing reasons and is hereby extending the comment period. DOE will consider any comments received by 5 p.m. on September 30, 2011 and deems any comments received between July 15, 2011 and 5 p.m. on September 30, 2011 to be timely submitted.

Further Information on Submitting Comments

Under 10 CFR Part 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit two copies: One copy of the document including all the information believed to be confidential, and one copy of the document with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include (1) a description of the items, (2) whether and why such items are customarily treated as confidential within the industry, (3) whether the information is generally known by or available from other sources, (4) whether the information has previously been made available to others without obligation concerning its confidentiality, (5) an explanation of the competitive injury to the submitting person which would result from public disclosure, (6) when such information might lose its confidential character due to the passage of time, and (7) why disclosure of the information would be contrary to the public interest.

Issued in Washington, DC on July 5, 2011.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Office of Technology Development, Energy Efficiency and Renewable Energy.

[FR Doc. 2011–17215 Filed 7–7–11; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0713; Directorate Identifier 2011–CE–023–AD]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronáutica S.A. (EMBRAER) Model EMB–505 Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

It has been found the possibility of free-play between the mass balance weight and the elevator structure. This condition if not corrected could lead to elevator flutter and possible loss of airplane control.

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by August 22, 2011.

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

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

For service information identified in this proposed AD, contact EMBRAER S.A., Phenom Maintenance Support, Av. Brig. Faria Lima, 2170, Sao Jose dos Campos—SP, CEP: 12227–901—PO Box: 36/2, BRASIL; telephone: ++55 12 3927–5383; fax: ++55 12 3927–2619; E-mail: *phenom.reliability@embraer.com.br;* Internet: *http://www.embraer.com.br.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

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

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

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments

to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–0713; Directorate Identifier 2011–CE–023–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

The AGÊNCIA NACIONAL DE AVIAÇÃO CIVIL—BRAZIL (ANAC), which is the aviation authority for Brazil, has issued AD No.: 2011–05–05, effective date June 16, 2011 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> It has been found the possibility of free-play between the mass balance weight and the elevator structure. This condition if not corrected could lead to elevator flutter and possible loss of airplane control.
>
> Since this condition may occur in other airplanes of the same type and affects flight safety, a corrective action is required. Thus, sufficient reason exists to request compliance with this AD in the indicated time limit.

The MCAI requires replacement of the bolts that attach the balance mass weights to the elevator structure. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

EMBRAER S.A. has issued PHENOM Service Bulletin No.: 505–55–0002, dated January 14, 2011. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the Proposed AD

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

Differences Between This Proposed AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a Note within the proposed AD.

Costs of Compliance

We estimate that this proposed AD will affect 8 products of U.S. registry. We also estimate that it would take about 38 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $3,490 per product.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $53,760, or $6,720 per product.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Empresa Brasileira de Aeronáutica S.A. (EMBRAER): Docket No. FAA–2011–0713; Directorate Identifier 2011–CE–023–AD.

Comments Due Date

(a) We must receive comments by August 22, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Empresa Brasileira de Aeronáutica S.A. (EMBRAER) Model EMB–505 airplanes, all serial numbers (SN) through 50500023, certificated in any category.

Subject

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

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

It has been found the possibility of free-play between the mass balance weight and the elevator structure. This condition if not corrected could lead to elevator flutter and possible loss of airplane control.

Since this condition may occur in other airplanes of the same type and affects flight safety, a corrective action is required. Thus, sufficient reason exists to request compliance with this AD in the indicated time limit.

The MCAI requires replacement of the bolts that attach the balance mass weights to the elevator structure.

Actions and Compliance

(f) Unless already done, within 12 calendar months after the effective date of this AD, replace the bolts that attach the balance mass weights to the elevator structure following EMBRAER S.A. PHENOM Service Bulletin No.: 505–55–0002, dated January 14, 2011.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: The MCAI applies to SN 50500004 through 50500023. This AD applies to all SN through 50500023.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

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

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

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

Related Information

(h) Refer to MCAI AGÊNCIA NACIONAL DE AVIAÇÃO CIVIL—BRAZIL (ANAC) AD No.: 2011–05–05, effective date June 16, 2011; and EMBRAER S.A. PHENOM Service Bulletin No.: 505–55–0002, dated January 14, 2011, for related information. For service information related to this AD, contact EMBRAER S.A., Phenom Maintenance Support, Av. Brig. Faria Lima, 2170, Sao Jose dos Campos—SP, CEP: 12227–901—PO Box: 36/2, BRASIL; telephone: ++55 12 3927–5383; fax: ++55 12 3927–2619; E-mail: *phenom.reliability@embraer.com.br;* Internet: *http://www.embraer.com.br.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on July 1, 2011.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–17264 Filed 7–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0652; Directorate Identifier 2010–NM–045–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Model MD–90–30 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Model MD–90–30 airplanes. This proposed AD would require repetitive eddy current high frequency (ETHF) inspections for cracking on the aft side of the left and right wing rear spar lower caps at station Xrs = 164.000, further ETHF inspections if cracks are found, and repair if necessary. This proposed AD would also require repetitive post-repair inspections and repair if necessary. This proposed AD was prompted by reports of cracks of the wing rear spar lower cap at the outboard flap, inboard drive hinge at station Xrs = 164.000. We are proposing this AD to detect and correct cracking of the left and right rear spar lower caps, which could result in fuel leaks and damage to the wing skin or other structure, and consequent loss of the structural integrity of the wing.

DATES: We must receive comments on this proposed AD by August 22, 2011.

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

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

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, 3855 Lakewood Boulevard, MC D800–0019, Long Beach, California 90846–0001; telephone 206–544–5000, extension 2; fax 206–766–5683; e-mail *dse.boecom@boeing.com;* Internet *https://www.myboeingfleet.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 proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Roger Durbin, Airframe Branch, ANM–120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, California 90712–4137; phone (562) 627–5233; fax (562) 627–5210; e-mail: *roger.durbin@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–0652; Directorate Identifier 2010–NM–045–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We have received reports of cracks of the wing rear spar lower cap at the outboard flap, inboard drive hinge at station Xrs = 164.000, on Model MD–80 airplanes. It has been determined that these cracks are the result of material fatigue from normal flap operating loads. This condition, if not corrected, could result in fuel leaks and damage to the wing skin or other structure, and consequent loss of the structural integrity of the wing.

The subject area on Model MD–90–30 airplanes is almost identical to that on Model MD–80 airplanes. Therefore, Model MD–90–30 airplanes may be subject to the unsafe condition revealed on Model MD–80 airplanes.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. This service bulletin describes procedures for repetitive eddy current high frequency (ETHF) inspections for cracks on the left and right rear spar lower caps at station Xrs=164.000, further ETHF inspections if cracks are found, optional and non-optional repairs, and repetitive post-repair inspections.

FAA's Determination

We are proposing this AD because we evaluated all relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between the Proposed AD and the Service Information.''

Differences Between the Proposed AD and the Service Information

Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011, does not specify corrective actions if cracking is found during any inspection of repaired areas, but this proposed AD would require repairing those conditions in one of the following ways:

- In accordance with a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

Costs of Compliance

We estimate that this proposed AD would affect 17 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	4 work-hours × $85 per hour = $340 per inspection cycle.	N/A	$340 per inspection cycle	$5,780 per inspection cycle.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2011–0652; Directorate Identifier 2010–NM–045–AD.

Comments Due Date

(a) We must receive comments by August 22, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all The Boeing Company Model MD–90–30 airplanes, certificated in any category.

Subject

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

Unsafe Condition

(e) This AD was prompted by reports of cracks of the wing rear spar lower cap at the outboard flap, inboard drive hinge at station Xrs = 164.000. We are issuing this AD to detect and correct cracking of the left and right rear spar lower caps, which could result in fuel leaks and damage to the wing skin or other structure, and consequent loss of the structural integrity of the wing.

Compliance

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

Repetitive Inspections, Further Inspections if Cracking Found, Repair, and Repetitive Post-Repair Inspections

(g) Before the accumulation of 30,000 total flight cycles, or within 10,000 flight cycles after the effective date of this AD, whichever occurs later, do an eddy current high frequency (ETHF) inspection for cracking on the aft side of the left and right wing rear spar lower caps at station Xrs = 164.000, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. If no cracking is found on the left or right wing rear spar lower cap, repeat the inspection on the affected wing rear spar lower cap thereafter at intervals not to exceed 2,550 flight cycles. Doing a repair of the left or right wing rear spar lower cap required by this AD terminates the repetitive inspection required by this paragraph for that side only.

(h) If, during any inspection required by paragraph (g) of this AD, any crack is found that is two inches or less and not in the rear spar lower cap forward horizontal leg radius: Before further flight, do an ETHF inspection for cracking on the affected wing rear spar upper cap at station Xrs = 164.000, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011.

(1) If no crack is found in the rear spar upper cap during the inspection required in paragraph (h) of this AD, do the actions specified in paragraph (h)(1)(i) or (h)(1)(ii) of this AD.

(i) Option 1: Before further flight, do a doubler repair of the rear spar lower cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Within 13,500 flight cycles after doing the doubler repair, do an ETHF inspection for any cracking in the repaired area of the rear spar lower cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Repeat the inspection thereafter at intervals not to exceed 8,500 flight cycles. If any cracking is found during any inspection required by this paragraph, before further flight, repair in accordance with a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(ii) Option 2: Before further flight, do a splice repair of the rear spar lower cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Within 20,000 flight cycles after doing the splice repair, do an eddy current low frequency (ETLF) inspection and an ultrasonic (UT) inspection for cracking in the repaired area of the rear spar lower cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Repeat the inspections thereafter at intervals not to exceed 3,000 flight cycles. If any cracking is found during any inspection required by this paragraph, before further flight, repair in accordance with a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(2) If any crack that is two inches or less is found in the rear spar upper cap during the inspection required by paragraph (h) of this AD, do the actions specified in paragraph (h)(2)(i) or (h)(2)(ii) of this AD.

(i) Option 1: Before further flight, do a doubler repair of the rear spar upper and lower caps, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Within 13,500 flight cycles after doing the doubler repair, do an ETHF inspection for any cracking in the repaired area of the rear spar upper and lower caps, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Repeat the inspection thereafter at intervals not to exceed 8,500 flight cycles. If any cracking is found during any inspection required by this paragraph, before further flight, repair in accordance with a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(ii) Option 2: Before further flight, do a splice repair of the rear spar upper and lower caps, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Within 20,000 flight cycles after doing the splice repair, do an ETLF inspection and a UT inspection for any cracking in the repaired area of the rear spar lower cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Repeat the inspections thereafter at intervals not to exceed 3,000 flight cycles. If any cracking is found during any inspection required by this paragraph, before further flight, repair in accordance with a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(3) If any crack that is greater than two inches is found in the rear spar upper cap during the inspection required by paragraph (h) of this AD, do the actions specified in paragraph (h)(3)(i) or (h)(3)(ii) of this AD.

(i) Option 1: Before further flight, do a splice repair of the rear spar upper cap and a doubler repair of the rear spar lower cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Within 13,500 flight cycles after doing the doubler repair, do an ETHF inspection for any cracking in the repaired area of the rear spar lower cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Repeat the inspection thereafter at intervals not to exceed 8,500 flight cycles. If any cracking is found during any inspection required by this paragraph, before further flight, repair in accordance with a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(ii) Option 2: Before further flight, do a splice repair of the rear spar upper and lower caps, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Within 20,000 flight cycles after doing the splice repair, do an ETLF inspection and a UT inspection for any cracking in the repaired area of the rear spar lower cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Repeat the inspections thereafter at intervals not to exceed 3,000 flight cycles. If any cracking is found during any inspection required by this paragraph, before further flight, repair in accordance with a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(i) If any crack is found during any inspection required by paragraph (g) of this AD that is greater than two inches or is in the rear spar lower cap forward horizontal leg radius, before further flight, do an ETHF for cracking on the affected wing rear spar upper cap at station Xrs = 164.000, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011.

(1) If no crack is found in the rear spar upper cap, before further flight, do a splice repair of the rear spar lower cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Within 20,000 flight cycles after doing the splice repair, do an ETLF and a UT inspection for any cracking of the repaired area of the lower rear spar cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Repeat the inspection thereafter at intervals not to exceed 3,000 flight cycles. If any cracking is found during any inspection required by this

paragraph, before further flight, repair in accordance with a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(2) If any crack that is two inches or less is found in the rear spar upper cap, do the actions specified in paragraph (i)(2)(i) or (i)(2)(ii) of this AD.

(i) Option 1: Do the actions specified in paragraphs (i)(2)(i)(A), (i)(2)(i)(B), and (i)(2)(i)(C) of this AD.

(A) Before further flight, do a doubler repair of the rear spar upper cap and a splice repair of the rear spar lower cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011.

(B) Within 13,500 flight cycles after doing the doubler repair required by paragraph (i)(2)(i)(A) of this AD, do an ETHF inspection for any cracking in the repaired area of the rear spar upper cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Repeat the inspection thereafter at intervals not to exceed 8,500 flight cycles. If any cracking is found during any inspection required by this paragraph, before further flight, repair in accordance with a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(C) Within 20,000 flight cycles after doing the splice repair required by paragraph (i)(2)(i)(A) of this AD, do an ETLF and a UT inspection for cracking in the repaired area of the rear spar lower cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Repeat the inspections thereafter at intervals not to exceed 3,000 flight cycles. If any cracking is found during any inspection required by this paragraph, before further flight, repair in accordance with a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(ii) Option 2: Before further flight, do a splice repair of the rear spar upper and lower caps, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Within 20,000 flight cycles after doing the splice repair, do an ETLF and a UT inspection for cracking in the repaired area of the rear spar lower cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Repeat the inspections thereafter at intervals not to exceed 3,000 flight cycles. If any cracking is found during any inspection required by this paragraph, before further flight, repair in accordance with a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(3) If any crack that is greater than two inches is found in the rear spar upper cap, before further flight, do a splice repair of the rear spar upper and lower caps, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Within 20,000 flight cycles after doing the splice repair, do an ETLF and a UT inspection for cracking in the repaired area of the rear spar lower cap, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin MD90–57A026, Revision 1, dated February 23, 2011. Repeat the inspections thereafter at intervals not to exceed 3,000 flight cycles. If any cracking is found during any inspection required by this paragraph, before further flight, repair in accordance with a method approved in accordance with the procedures specified in paragraph (k) of this AD.

Credit for Actions Accomplished in Accordance With Previous Service Information

(j) Doing an ETHF inspection for cracks, and doing a doubler repair to the rear spar upper and lower caps in accordance with Boeing Alert Service Bulletin MD90–57A026, dated February 11, 2010, before the effective date of this AD, are acceptable for compliance with the corresponding actions required by paragraphs (g), (h), and (i) of this AD.

Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in 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.

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

Related Information

(l) For more information about this AD, contact Roger Durbin, Airframe Branch, ANM–120L, FAA, Los Angeles ACO, 3960 Paramount Boulevard, Lakewood, California 90712–4137; phone: (562) 627–5233; fax: (562) 627–5210; e-mail: *roger.durbin@faa.gov.*

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

Issued in Renton, Washington, on June 29, 2011.

Jeffrey E. Duven,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–17267 Filed 7–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0651; Directorate Identifier 2011–NM–041–AD]

RIN 2120–AA64

Airworthiness Directives; Learjet Inc. Model 45 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD would require revising the maintenance program to incorporate life limits for the main landing gear (MLG) actuator end cap. This proposed AD was prompted by a report of the potential for fatigue cracking of the end cap of the MLG prior to the published life limitation. We are proposing this AD to prevent fatigue cracking of the end cap of the MLG, which could result in the failure of the MLG actuator upon landing, and failure of the MLG to extend or retract during flight.

DATES: We must receive comments on this proposed AD by August 22, 2011.

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

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

For service information identified in this proposed AD, contact Learjet, Inc., One Learjet Way, Wichita, Kansas 67209–2942; telephone 316–946–2000; fax 316–946–2220; e-mail *ac.ict@aero.bombardier.com;* Internet *http://www.bombardier.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 proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Paul Chapman, Aerospace Engineer, Aviation Safety, ACE–118W, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, KS 67209; phone: 316–946–4152; fax: 316–946–4107; e-mail: *paul.chapman@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–0651; Directorate Identifier 2011–NM–041–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We received a report from Learjet that indicated the life limitation of the main landing gear actuator was determined using fatigue testing during the Model 45 certification; however, the supplier discovered they had not tested the actuator properly during subsequent testing for another application. Learjet identified the potential for fatigue cracking of the end cap of the main landing gear actuator prior to the published life limitation. This potential for fatigue cracking, if not corrected, could result in failure of the main landing gear actuator upon landing, and failure of the MLG to extend or retract during flight.

Relevant Service Information

We reviewed Learjet 40 Temporary Revision 4–23, dated January 24, 2011, to Learjet 40 Maintenance Manual MM–105; and Learjet 45 Temporary Revision 4–34, dated January 24, 2011, to Learjet 45 Maintenance Manual MM–104. Among other things, the Airworthiness Limitations sections contained in Learjet 40 Temporary Revision 4–23 and Learjet 45 Temporary Revision 4–34 provide new life limits and replacement compliance times for the MLG actuator end cap.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

Proposed AD Requirements

This proposed AD would require revising the maintenance program to incorporate life limits for the MLG actuator end cap.

Costs of Compliance

We estimate that this proposed AD affects 351 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revise maintenance plan	1 work-hour × $85 per hour = $85 per revision.	$0	$85 per revision	$29,835

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Learjet Inc.: Docket No. FAA–2011–0651; Directorate Identifier 2011–NM–041–AD.

Comments Due Date

(a) We must receive comments by August 22, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Learjet Inc. Model 45 airplanes, certificated in any category; all serial numbers.

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

Subject

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

Unsafe Condition

(e) This AD was prompted by a report of the potential for fatigue cracking of the end cap of the main landing gear (MLG) prior to the published life limitation. We are issuing this AD to prevent fatigue cracking of the end cap of the MLG, which could result in the failure of the MLG actuator upon landing, and failure of the MLG to extend or retract during flight.

Compliance

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

Maintenance Program Revision

(g) Within 30 days after the effective date of this AD, revise the maintenance program by incorporating IRN T3220105 (Main Landing Gear Actuator End Cap (P/N 200–0303)) as specified in Learjet 40 Temporary Revision 4–23, dated January 24, 2011, to Learjet 40 Maintenance Manual MM–105; or Learjet 45 Temporary Revision 4–34, dated January 24, 2011, to Learjet 45 Maintenance Manual MM–104; as applicable. The initial compliance for the replacement specified in IRN T3220105 is prior to the accumulation of 2,387 total flight cycles on the end cap (P/N 200–0303), or within 25 flight cycles after the effective date of this AD, whichever occurs later.

No Alternative Actions or Intervals

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

Alternative Methods of Compliance (AMOCs)

(i)(1) The Manager, Wichita Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in 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. The AMOC approval letter must specifically reference this AD.

Related Information

(j) For more information about this AD, contact Paul Chapman, Aerospace Engineer, Aviation Safety, ACE–118W, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, KS 67209; phone: 316–946–4152; fax: 316–946–4107; e-mail: *paul.chapman@faa.gov.*

(k) For service information identified in this AD, contact Learjet, Inc., One Learjet Way, Wichita, Kansas 67209–2942; telephone 316–946–2000; fax 316–946–2220; e-mail *ac.ict@aero.bombardier.com;* Internet *http://www.bombardier.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.

Issued in Renton, Washington, on June 29, 2011.

Jeffrey E. Duven,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–17265 Filed 7–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0425; Airspace Docket No. 11–ANM–9]

Proposed Amendment of Class D and Modification of Class E Airspace; Grand Junction, CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class E airspace at Grand Junction Regional Airport, Grand Junction, CO. Additional controlled airspace is necessary to facilitate vectoring of Instrument Flight Rules (IFR) traffic from Grand Junction Regional Airport to en route. The FAA is proposing this action to enhance the safety and management of aircraft operations at Grand Junction Regional Airport. This action also would amend Class D and Class E airspace to update the airport name from Grand Junction, Walker Field.

DATES: Comments must be received on or before August 22, 2011.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2011–0425; Airspace Docket No. 11–ANM–9, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.*

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

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA 2011–0425 and Airspace Docket No. 11–ANM–9) and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2011–0425 and Airspace Docket No. 11–ANM–9''. The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue, SW., Renton, WA 98057.

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

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by modifying Class E airspace at Grand Junction Regional Airport, Grand Junction, CO. Additional controlled airspace extending upward from 1,200 feet above the surface is necessary to accommodate vectoring IFR aircraft departing Grand Junction Regional Airport to en route airspace. This action would also amend Class D and the Class E airspace areas to update the airport name from Grand Junction, Walker Field, to Grand Junction Regional Airport, Grand Junction, CO.

Class D and Class E airspace designations are published in paragraphs 5000, 6002, 6004 and 6005, respectively, of FAA Order 7400.9U, dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document will be published subsequently in this Order.

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

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR Part 71.1 of the Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010 is amended as follows:

Paragraph 5000 Class D airspace.

* * * * *

ANM CO D Grand Junction, CO [Amended]

Grand Junction Regional Airport, CO
(Lat. 39°07′21″N., long. 108°31′36″W.)

That airspace extending upward from the surface to and including 7,400 feet MSL within a 4.7-mile radius of Grand Junction Regional Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6002 Class E airspace Designated as Surface Areas.

* * * * *

ANM CO E2 Grand Junction, CO [Amended]

Grand Junction Regional Airport, CO
(Lat. 39°07′21″N., long. 108°31′36″W.)

Within a 4.7-mile radius of Grand Junction Regional Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6004 Class E airspace Designated as an Extension to a Class D Surface Area.

* * * * *

ANM CO E4 Grand Junction, CO [Amended]

Grand Junction Regional Airport, CO
(Lat. 39°07′21″N., long. 108°31′36″W.)
Grand Junction Localizer
(Lat. 39°07′04″N., long. 108°30′48″W.)

That airspace extending upward from the surface within 1.8 miles each side of the Grand Junction Regional Airport Runway 11 ILS localizer northwest course extending from the 4.7-mile radius of Grand Junction Regional Airport to 7 miles northwest of the localizer.

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

* * * * *

ANM CO E5 Grand Junction, CO [Modified]

Grand Junction Regional Airport, CO
(Lat. 39°07′21″N., long. 108°31′36″W.)
Grand Junction VOR/DME
(Lat. 39°03′34″N., long. 108°47′33″W.)

That airspace extending upward from 700 feet above the surface within 7 miles northwest and 4.3 miles southeast of the Grand Junction VOR/DME 247° and 067° radials extending from 11.4 miles southwest to 12.3 miles northeast of the VOR/DME, and within 1.8 miles south and 9.2 miles north of the Grand Junction VOR/DME 110° radial extending from the VOR/DME to 19.2 miles southeast; that airspace extending upward from 1,200 feet above the surface within a 33.1-mile radius of the Grand Junction VOR/DME beginning at the 020° bearing of the Grand Junction VOR/DME, clockwise to the 270° bearing of the Grand Junction VOR/DME, and within a 63-mile radius of the Grand Junction VOR/DME beginning at the 270° bearing of the Grand Junction VOR/DME, clockwise to the 020° bearing of the Grand Junction VOR/DME.

Issued in Seattle, Washington on June 29, 2011.

Christine Mellon,

Acting Manager, Operations Support Group, Western Service Center

[FR Doc. 2011–17197 Filed 7–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0490; Airspace Docket No. 11–AWP–5]

Proposed Amendment of Class E Airspace; Tonopah, NV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class E airspace at Tonopah Airport, Tonopah, NV. Controlled airspace is necessary to accommodate aircraft using a new Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures at Tonopah Airport, Tonopah, NV. The FAA is proposing this action to enhance the safety and management of aircraft operations at the airport. This action also would make a minor adjustment to the geographic coordinates of the airport.

DATES: Comments must be received on or before August 22, 2011.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590; telephone (202) 366–9826. You must identify FAA Docket No. FAA–2011–0490; Airspace Docket No. 11–AWP–5, at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.*

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

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA 2011–0490 and Airspace Docket No. 11–AWP–5) and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2011–0490 and Airspace Docket No. 11–AWP–5''. The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

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

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue, SW., Renton, WA 98057.

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

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by modifying Class E airspace designated as surface area and Class E airspace extending upward from 700 feet above the surface at Tonopah Airport, Tonopah, NV. Controlled airspace is necessary to accommodate aircraft using new RNAV (GPS) standard instrument approach procedures at Tonopah Airport, Tonopah, NV. Also, the geographic coordinates of the airport would be updated to coincide with the FAA's aeronautical database. This action would enhance the safety and management of aircraft operations at the airport.

Class E airspace designations are published in paragraph 6002 and 6005, respectively, of FAA Order 7400.9U, dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in this Order.

The FAA has determined this proposed regulation only involves an established body of technical

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

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR Part 71.1 of the Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010 is amended as follows:

Paragraph 6002 Class E airspace Designated as Surface Areas.

* * * * *

AWP NV E2 Tonopah, NV [Modified]

Tonopah Airport, NV
(Lat. 38°03′37″ N., long. 117°05′13″ W.)

Within a 8.2-mile radius of the Tonopah Airport and within 2 miles each side of the 358° bearing from the Tonopah Airport extending from the 8.2-mile radius to 10.5 miles north of the Tonopah Airport, and within 2 miles each side of the Tonopah Airport 117° bearing extending from the 8.2-mile radius to 11.5 miles southeast of the Tonopah Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

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

* * * * *

AWP NV E5 Tonopah, NV [Modified]

Tonopah Airport, NV
(Lat. 38°03′37″ N., long. 117°05′13″ W.)

That airspace extending upward from 700 feet above the surface within a 10.7-mile radius of the Tonopah Airport, and that airspace northwest of the Tonopah Airport bounded by a line beginning at lat. 38°10′30″ N., long. 117°16′00″ W.; to lat. 38°12′00″ N., long. 117°17′00″ W.; to lat. 38°18′00″ N., long. 117°17′00″ W.; to lat. 38°18′00″ N., long. 117°03′00″ W.; to lat. 38°14′00″ N., long. 117°03′14″ W.; thence clockwise via the 10.7-mile radius of the Tonopah Airport to lat. 38°00′20″ N., long. 116°52′20″ W.; to lat. 37°59′45″ N., long. 116°51′00″ W.; to lat. 37°56′20″ N., long. 116°53′00″ W.; to lat. 37°57′00″ N., long. 116°54′45″ W.; thence clockwise via the 10.7-mile radius of the Tonopah Airport to the point of beginning. That airspace extending upward from 1,200 feet above the surface within the area bounded by a line beginning at lat. 37°53′00″ N., long. 117°05′41″ W.; to lat. 37°39′00″ N., long. 117°22′00″ W.; to lat. 37°35′00″ N., long. 117°36′00″ W.; to lat. 37°56′00″ N., long. 117°54′00″ W.; to lat. 37°56′50″ N., long. 117°32′00″ W.; to lat. 38°08′00″ N., long. 117°41′00″ W.; to lat. 38°18′00″ N., long. 117°24′00″ W.; to lat. 38°18′00″ N., long. 117°00′00″ W.; to lat. 38°14′00″ N., long. 117°00′00″ W.; to lat. 38°17′00″ N., long. 116°36′00″ W.; to lat. 38°00′00″ N., long. 116°33′00″ W.; to lat. 37°59′30″ N., long. 116°38′30″ W.; to lat. 37°53′00″ N., long. 116°38′30″ W., thence to the point of beginning.

Issued in Seattle, Washington, on June 29, 2011.

Christine Mellon,

Acting Manager, Operations Support Group, Western Service Center

[FR Doc. 2011–17200 Filed 7–7–11; 8:45 am]

BILLING CODE 4910–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Part 1260

[FDMS NARA–11–0001]

RIN 3095–AB64

Declassification of National Security Information

AGENCY: National Archives and Records Administration.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update NARA's regulations related to declassification of classified national security information in records transferred to NARA's legal custody. The rule incorporates changes resulting from issuance of Executive Order 13526, Classified National Security Information, and its Implementing Directive. These changes include establishing procedures for the automatic declassification of records in NARA's legal custody and revising requirements for reclassification of information to meet the provisions of E.O. 13526. Executive Order 13526 also created the National Declassification Center (NDC) with a mission to align people, processes, and technologies to advance the declassification and public release of historically valuable permanent records while maintaining national security. This rule will affect members of the public and Federal agencies.

DATES: Comments are due by September 6, 2011.

ADDRESSES: You may submit comments, identified by RIN 3095–AB64, by any of the following methods:

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

Fax: (301) 837–0319.

Mail: Regulation Comments Desk (NPOL), Room 4100, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001.

Hand Delivery/Courier: Regulation Comments Desk (NPOL), Room 4100, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD.

FOR FURTHER INFORMATION CONTACT: Marilyn Redman at (301) 837–1850; *e-mail: marilyn.redman@nara.gov.*

SUPPLEMENTARY INFORMATION: Following is a discussion of substantive changes contained in this proposed rule. Additional nonsubstantive changes have been made and the proposed regulation has been written in plain language

where possible in accordance with the Presidential Memorandum of June 1, 1998, Plain Language in Government Writing.

What changes have been made in this proposed rule?

We propose to amend the existing regulation to reflect changes resulting from the issuance of Executive Order 13526, replacing Executive Order 12958 as amended. In particular we are adding sections that discuss the National Declassification Center and Automatic Declassification. We are also updating policies managing Mandatory Declassification Review appeals. NARA's proposed section on the National Declassification Center (NDC) includes:

- The purpose of the NDC.
- How the NDC will ensure the quality of the final product.
- How referrals to other agencies will be processed through the NDC.

This proposed rule is a significant regulatory action for the purpose of Executive Order 12866 and has been reviewed by the Office of Management and Budget. As required by the Regulatory Flexibility Act, I certify that this rule will not have a significant impact on a substantial number of small entities because it affects Federal agencies and individual researchers. This regulation does not have any federalism implications.

List of Subjects in 36 CFR Part 1260

Archives and records, Classified information.

For the reasons set forth in the preamble, NARA proposes to revise Subchapter D of Chapter XII of title 36, Code of Federal Regulations, to read as follows:

SUBCHAPTER D—DECLASSIFICATION

PART 1260—DECLASSIFICATION OF NATIONAL SECURITY INFORMATION

Subpart A—General Information

Sec.
1260.1 What is the purpose of this part?
1260.2 What definitions apply to the regulations in this part?
1260.4 What NARA holdings are covered by this part?

Subpart B—Responsibilities

1260.20 Who is responsible for the declassification of classified national security Executive Branch information that has been accessioned by NARA?
1260.22 Who is responsible for the declassification of classified national security White House originated information in NARA's holdings?
1260.24 Who is responsible for declassification of foreign government information in NARA's holdings?
1260.26 Who is responsible for issuing special procedures for declassification of records pertaining to intelligence activities and intelligence sources or methods, or of classified cryptologic records in NARA's holdings?
1260.28 Who is responsible for declassifying Restricted Data, Formerly Restricted Data, and Transclassified Foreign Nuclear Information?

Subpart C—The National Declassification Center (NDC)

1260.30 What is the NDC?
1260.32 How is the NDC administered?
1260.34 What are the responsibilities of the NDC?
1260.36 What are agency responsibilities with the NDC?
1260.38 How does the NDC ensure the quality of declassification reviews?
1260.40 What types of referrals will the NDC process?
1260.42 How does the NDC process referrals of Federal Records?
1260.44 How does the NDC process RAC Project referrals?
1260.46 How does the Department of Defense process referrals?

Subpart D—Automatic Declassification

1260.50 How are records at NARA reviewed as part of the automatic declassification process?
1260.52 What are the procedures when agency personnel review records in NARA's legal and physical custody?
1260.54 Will NARA loan accessioned records back to the agencies to conduct declassification review?
1260.56 What are NARA considerations when implementing automatic declassification?

Subpart E—Systematic Declassification

1260.60 How does the NDC facilitate systematic review of records exempted at the individual record or file series level?

Subpart F—Mandatory Declassification Review (MDR)

1260.70 How does a researcher submit a MDR request?
1260.72 What procedures does NARA follow when it receives a request for Executive Branch records under MDR?
1260.74 What are agency responsibilities after receiving a MDR request forwarded by NARA?
1260.76 What are NARA's procedures after it has received the agency's declassification determination?
1260.78 What is the appeal process when a MDR request for Executive Branch information in NARA's legal custody is denied in whole or in part?

Subpart G—Reclassification of Records Transferred to NARA

1260.80 What actions must NARA take when information in its physical and legal custody is reclassified after declassification under proper authority?
1260.82 What actions must NARA take with information in its physical and legal custody that has been made available to the public after declassification without proper authority?

Authority: 44 U.S.C. 2101 to 2118; 5 U.S.C. 552; E.O. 13526, 75 FR 707, 3 CFR, 2009 Comp., p. 298; Presidential Memorandum of December 29, 2009 ''Implementation of the Executive Order, Classified National Security Information, 75 FR 733, 3 CFR, 2009 Comp., p. 412; 32 CFR part 2001.

Subpart A—General Information

§ 1260.1 What is the purpose of this part?

(a) This subchapter defines the responsibilities of NARA and other Federal agencies for declassification of classified national security information in the holdings of NARA. This part also describes NARA's procedures for:

(1) Operation of the National Declassification Center,

(2) Processing referrals to other agencies,

(3) Facilitating systematic reviews of NARA holdings, and

(4) Processing mandatory declassification review requests for NARA holdings.

(b) Regulations for researchers who wish to request access to materials containing classified national security information are found in 36 CFR part 1256.

(c) For the convenience of the user, the following table provides references between the sections contained in this part and the relevant sections of the Order and the Implementing Directive.

CFR section	Related section of E.O. 13526	Related section of implementing directive
1260.20 Who is responsible for the declassification of classified national security Executive Branch information that has been accessioned by NARA?	3.3, 3.3(d)(3), 3.6.	

CFR section	Related section of E.O. 13526	Related section of implementing directive
1260.22 Who is responsible for the declassification of classified national security White House originated information in NARA's holdings?	3.3(d)(3), 3.6.	
1260.24 Who is responsible for declassification of foreign government information in NARA's holdings?	6.1(s).	
1260.28 Who is responsible for declassifying Restricted Data, Formerly Restricted Data, and Transclassified Foreign Nuclear Information?	.....	2001.24(i).
1260.34 What are the responsibilities of the NDC?	3.3. 3.3(d)(3), 3.4.	
1260.36 What are agency responsibilities with the NDC?	3.3(d)(3).	
1260.40 What types of referrals will the NDC process?	3.3.	
1260.42 How does the NDC process referrals of Federal Records?	3.3(d)(3)(B).	
1260.46 How does the Department of Defense process referrals?	3.3.	
1260.50 How are records at NARA reviewed as part of the automatic declassification process?	3.3.	
1260.52 What are the procedures when agency personnel review records in NARA's legal and physical custody?	3.3	2001.30(p).
1260.56 What are NARA considerations when implementing automatic declassification?	3.3.	
1260.72 What procedures does NARA follow when it receives a request for Executive Branch records under MDR?	3.6(a), 3.6(b)	2001.33.
1260.74 What are agency responsibilities after receiving a MDR request forwarded by NARA?	3.5(c).	
1260.76 What are NARA's procedures after it has received the agency's declassifications determination?	.....	Appendix A.
1260.78 What is the appeal process when a MDR request for Executive Branch information in NARA's legal custody is denied in whole or in part?	3.3	2001.30(p), 2001.33.
1260.80 What actions must NARA take when information in its physical and legal custody is reclassified after declassification under proper authority?	.....	2001.13.
1260.82 What actions must NARA take with information in its physical and legal custody that has been made available to the public after declassification without proper authority?	.....	2001.13.

§ 1260.2 What definitions apply to the regulations in this part?

Classified national security information, or *classified information,* means information that has been determined under Executive Order 13526 or any predecessor order to require protection against unauthorized disclosure and is marked to indicate its classified status when in documentary form.

Declassification means the authorized change in the status of information from classified information to unclassified information.

Equity refers to information:

(1) Originally classified by or under the control of an agency;

(2) In the possession of the receiving agency in the event of transfer of function; or

(3) In the possession of a successor agency for an agency that has ceased to exist.

File series means file units or documents arranged according to a filing system or kept together because they relate to a particular subject or function, result from the same activity, document a specific kind of transaction, take a particular physical form, or have some other relationship arising out of their creation, receipt, or use, such as restrictions on access or use.

Integral file block means a distinct component of a file series, as defined in this section, that should be maintained as a separate unit in order to ensure the integrity of the records. An integral file block may consist of a set of records covering either a specific topic or a range of time such as presidential administration or a 5-year retirement schedule within a specific file series that is retired from active use as a group. For purposes of automatic declassification, integral file blocks shall contain only records dated within 10 years of the oldest record in the file block.

Mandatory declassification review means the review for declassification of classified information in response to a request for declassification that meets the requirements under section 3.5 of Executive Order 13526.

Records means the records of an agency and Presidential materials or Presidential records, as those terms are defined in title 44, United States Code, including those created or maintained by a government contractor, licensee, certificate holder, or grantee that are subject to the sponsoring agency's control under the terms of the contract, license, certificate, or grant.

Referral means that information in an agency's records that was originated by or is of interest to another agency is sent to that agency for a determination of its classification status.

Systematic declassification review means the review for declassification of classified information, including previously exempted information, contained in records that have been determined by the Archivist of the United States to have permanent historical value in accordance with 44 U.S.C. 2107.

§ 1260.4 What NARA holdings are covered by this part?

The NARA holdings covered by this part are records legally transferred to NARA, including Federal records, 44 U.S.C. 2107; Presidential records, 44 U.S.C. 2201–2207; Nixon Presidential materials, 44 U.S.C. 2111 note; and donated historical materials, 44 U.S.C. 2111.

Subpart B—Responsibilities

§ 1260.20 Who is responsible for the declassification of classified national security Executive Branch information that has been accessioned by NARA?

(a) Consistent with the requirements of section 3.3 of the Order on automatic declassification, the originating agency is responsible for declassification of its

information and identifying equity holders.

(b) An agency may delegate declassification authority to NARA.

(c) If an agency does not delegate declassification authority to NARA, the agency is responsible for reviewing the records to identify the equities of other agencies before the date that the records become eligible for automatic declassification.

(d) NARA is responsible for the declassification of records in its legal custody of defunct agencies that have no successor. NARA will consult with agencies having an equity in the records before making declassification determinations in accordance with sections 3.3(d)(3) and 3.6 of the Order.

§ 1260.22 Who is responsible for the declassification of classified national security White House originated information in NARA's holdings?

(a) NARA is responsible for declassification of information from a previous administration that was originated by:

(1) The President and Vice President;

(2) The White House staff;

(3) Committees, commissions, or boards appointed by the President; or,

(4) Others specifically providing advice and counsel to the President or acting on behalf of the President.

(b) NARA will consult with agencies having equity in the records before making declassification determinations in accordance with sections 3.3(d)(3) and 3.6 of Executive Order 13526.

§ 1260.24 Who is responsible for declassification of foreign government information in NARA's holdings?

(a) The agency that received or classified the information is responsible for its declassification.

(b) In the case of a defunct agency, NARA is responsible for declassification of foreign government information, as defined in section 6.1(s) of the Order, in its holdings and will consult with the agencies having equity in the records before making declassification determinations.

§ 1260.26 Who is responsible for issuing special procedures for declassification of records pertaining to intelligence activities and intelligence sources or methods, or of classified cryptologic records in NARA's holdings?

(a) The Director of National Intelligence is responsible for issuing special procedures for declassification of classified records pertaining to intelligence activities and intelligence sources and methods.

(b) The Secretary of Defense is responsible for issuing special procedures for declassification of classified cryptologic records.

§ 1260.28 Who is responsible for declassifying Restricted Data, Formerly Restricted Data, and Transclassified Foreign Nuclear Information?

(a) Only designated officials within the Department of Energy (DOE) may declassify Restricted Data (RD) (as defined by the Atomic Energy Act of 1954, as amended). The declassification of Formerly Restricted Data (FRD) (as defined in 10 CFR 1045.3) may only be performed after designated officials within DOE, in conjunction with designated officials within DOD, have determined that the FRD marking may be removed. Declassification of Transclassified Foreign Nuclear Information (TFNI) (as defined in 32 CFR 2001.24(i)) may be performed only by designated officials within DOE.

(b) Any record that contains RD, FRD, or TFNI shall be excluded from automatic declassification and referred by the primary reviewing agency to DOE using a completed SF 715 to communicate both the referral action and the actions taken on the equities of the primary reviewing agency. Any record identified by the primary reviewing agency as potentially containing RD, FRD, or TFNI shall be referred to DOE using a completed SF 715.

Subpart C—The National Declassification Center (NDC)

§ 1260.30 What is the NDC?

The National Declassification Center (NDC) is established within NARA to streamline declassification processes, facilitate quality-assurance measures, and implement standardized training for declassification of records determined to have permanent historical value.

§ 1260.32 How is the NDC administered?

(a) The NDC is administered by a Director, who shall be appointed by the Archivist of the United States, in consultation with the Secretaries of State, Defense, Energy, and Homeland Security, the Attorney General, and the Director of National Intelligence.

(b) The Archivist, in consultation with the representatives of the participants in the NDC and after receiving comments from the general public, shall develop priorities for declassification activities under the responsibility of the NDC that are based upon researcher interest and likelihood of declassification.

§ 1260.34 What are the responsibilities of the NDC?

The NDC shall coordinate the following activities:

(a) Referrals, to include:

(1) Timely and appropriate processing of all referrals in accordance with section 3.3(d)(3) of Executive Order 13526; and

(2) The exchange among agencies of detailed declassification guidance to enable referrals as identified in paragraph (a)(1) of this section.

(b) General interagency declassification activities as necessary to fulfill the requirements of sections 3.3 and 3.4 of the Order;

(c) The development of effective, transparent, standard declassification work processes, training, and quality assurance measures;

(d) The development of solutions to declassifying information contained in electronic records and special media; and planning for solutions for declassifying information as new technologies emerge;

(e) The documentation and publication of declassification review decisions; and support of NDC declassification responsibilities by linking and using existing agency databases; and

(f) Storage, and related services, on a reimbursable basis, for Federal records containing classified national security information.

§ 1260.36 What are agency responsibilities with the NDC?

Agency heads shall fully cooperate with the Archivist and the activities of the NDC and provide the following resources for NDC operations:

(a) Adequate and current declassification guidelines to process referrals in accordance with section 3.3(d)(3) of the Order and as indicated in § 1260.54(a); and

(b) Assignment of agency personnel to the NDC, at the request of the Archivist, with delegated authority by the agency head to review and exempt or declassify information originated by that agency found in records accessioned into the National Archives of the United States; and

(c) Coordination with the NDC of the establishment of any agency centralized facilities and internal operations to conduct declassification reviews to ensure that such agencies conduct internal declassification reviews of records of permanent historical value.

§ 1260.38 How does the NDC ensure the quality of declassification reviews?

An interagency team of experienced declassification reviewers, established

by NDC, conducts a sampling of reviewed records according to a sampling regime approved by a separate interagency program management team. The interagency team will verify that each series of agency reviewed records complies with the requirements of the Special Historical Records Review Plan (Supplement) dated March 3, 2000 (DOE–NARA Plan), pursuant to the requirements of Public Law 105–261 (112 Stat. 2259) and Public Law 106–65 (113 Stat. 938). Record series that cannot be verified to have been reviewed in accordance with the DOE–NARA Plan will not proceed through the NDC verification process until verification is received by the NDC. The DOE will participate on the interagency team to conduct the quality control reviews required by the DOE–NARA Plan in accordance with priorities established by the NDC.

§ 1260.40 What types of referrals will the NDC process?

The NDC processes referrals of both Federal records and Presidential records. Referrals identified in accessioned Federal records will be processed by the Interagency Referral Center (IRC); referrals identified in records maintained by the Presidential Libraries will be processed by the Remote Archives Capture (RAC) Project. (The RAC Project is a collaborative program to facilitate the declassification review of classified records in the Presidential Libraries in accordance with section 3.3 of the Order. In this project, classified Presidential records at the various Presidential Libraries are scanned and brought to the Washington, DC, metropolitan area in electronic form for review by equity-holding agencies.)

§ 1260.42 How does the NDC process referrals of Federal Records?

(a) All referrals are processed through the IRC.

(b) Agencies will have one year from the time they receive formal notification of referrals by the NDC to review their equity in the records. If an agency does not complete its review within one year of formal notification, its information will be automatically declassified in accordance with section 3.3(d)(3)(B) of the Order unless the information has been properly exempted by an equity holding agency under section 3.3 of the Order.

(c) Once notified, the agencies will coordinate their review with the NDC so the NDC can properly manage the workflow of the IRC.

§ 1260.44 How does the NDC process RAC Project referrals?

(a) The Presidential Libraries use the RAC Project to process referrals.

(b) Agencies will be notified of RAC Project referrals according to an annual prioritization schedule via the NDC.

(c) The RAC Project identifies the primary agency with equity in the record.

(d) The primary agency will have up to one year from the time it is notified of their referral to complete the review of its equity and identify all other agencies (''secondary agencies'') with an interest in the record. If an agency does not complete its review in one year, its equity will be automatically declassified.

(e) Secondary agencies receiving notification of their referrals through the RAC Project will have up to one year to complete their review.

§ 1260.46 How does the Department of Defense process referrals?

(a) The Department of Defense (DOD) established the Joint Referral Center (JRC) to review DOD agencies' records and all DOD equities within those records for declassification in accordance with section 3.3 of the Order.

(b) The JRC shall include sufficient quality assurance review policies that are in accordance with policies at the NDC and will provide the NDC with sufficient information on the results of these reviews to facilitate non-DOD agency referral processing and final archival processing for public release.

(c) NARA may loan accessioned records to the JRC for this purpose.

Subpart D—Automatic Declassification

§ 1260.50 How are records at NARA reviewed as part of the automatic declassification process?

(a) Consistent with the requirements of section 3.3 of Executive Order 13526 on automatic declassification, NARA staff may review for declassification records for which the originating agencies have provided written authority to apply their approved declassification guides. The originating agency must review records for which this authority has not been provided.

(b) Agencies may choose to review their own records that have been transferred to NARA's legal custody, by sending personnel to the NARA facility where the records are located to conduct the declassification review.

(c) Classified materials in the Presidential Libraries may be referred to agencies holding equity in the records through the RAC Project.

§ 1260.52 What are the procedures when agency personnel review records in NARA's legal and physical custody?

(a) NARA will:

(1) Make the records available to properly cleared agency reviewers;

(2) Provide space for agency reviewers in the facility in which the records are located to the extent that space is available; and

(3) Provide training and guidance for agency reviewers on the proper handling of archival materials.

(b) Agency reviewers must:

(1) Follow NARA security regulations and abide by NARA procedures for handling archival materials;

(2) Use the Standard Form (SF) 715 and follow NARA procedures for identifying and documenting records that require exemption, referral, or exclusion in accordance with section 3.3 of the Order or 32 CFR 2001.30(p); and

(3) Obtain permission from NARA before bringing into a NARA facility computers, scanners, tape recorders, microfilm readers, and other equipment necessary to view or copy records. NARA will not allow the use of any equipment that poses an unacceptable risk of damage to archival materials. See 36 CFR part 1254 for more information on acceptable equipment.

(4) Provide NARA with information, as requested by the Archivist and/or NDC Director, on their review so as to facilitate the processing of referrals and archival processing.

§ 1260.54 Will NARA loan accessioned records back to the agencies to conduct declassification review?

In rare cases, when agency reviewers cannot be accommodated at a NARA facility, NARA will consider a request to loan records back to an originating agency in the Washington, DC, metropolitan area for declassification review. Each request will be judged on a case-by-case basis. The requesting agency must:

(a) Ensure that the facility in which the documents will be stored and reviewed passes a NARA inspection to ensure that the facility maintains:

(1) The correct archival environment for the storage of permanent records; and

(2) The correct security conditions for the storage and handling of classified national security materials.

(b) Meet NARA requirements for ensuring the safety of the records;

(c) Abide by NARA procedures for handling of archival materials;

(d) Identify and mark documents that cannot be declassified in accordance with NARA procedures; and

(e) Obtain NARA approval for use of any equipment such as scanners, copiers, or cameras to ensure that they do not pose an unacceptable risk of damage to archival materials.

§ 1260.56 What are NARA considerations when implementing automatic declassification?

(a) *Integral file blocks.* Classified records within an integral file block that have not been reviewed and properly exempted from declassification, or referred to an equity holder, will be automatically declassified on December 31 of the year that is 25 years from the date of the most recent record within the file block, except as specified in paragraphs (b), (c), and (d) of this section. For the purposes of automatic declassification, integral file blocks shall contain only records dated within 10 years of the oldest record in the block. The records of each Presidential Administration will be treated as an integral file block and will be scanned for declassification review through the RAC Project.

(b) *Special media records.* After consultation with the Director of the National Declassification Center and before the records are subject to automatic declassification, an agency head or senior agency official may delay automatic declassification for up to five additional years for classified information contained in media that make a review for possible declassification exemptions more difficult or costly. NARA, through the NDC, will coordinate processing of referrals made in these special media records as part of its overall prioritization strategy.

(c) *Referrals.* The IRC at the NDC will provide official notification for Federal records, while the RAC Project will provide formal notification for Presidential records. For agencies which fail to act on their referrals after formal notification by the IRC or the RAC Project, NARA will automatically declassify their information in accordance with section 3.3(d)(3)(B) of the Order.

(d) *Additional referrals.* Agencies will identify referrals in accordance with section 3.3(d)(3) of the Order. NARA will delay automatic declassification for up to 1 year for classified records that have been identified by the originating agency or by NARA as having classified information that requires referral that were not identified by the primary reviewing agency

(e) *Other circumstances.* Information from another agency that has not been properly identified and referred is not subject to automatic declassification. When NARA identifies information, in accordance with section 3.3 of the Order, that agency will have up to 1 year from the date of formal notification to review its information for declassification.

(f) *Discovery of information inadvertently not reviewed.* When NARA identifies a file series or collection in its physical and legal custody that contains classified information over 25 years old and that was inadvertently not reviewed before the effective date of automatic declassification, NARA must report the discovery to the Information Security Oversight Office (ISOO) and to the responsible agency head or senior agency official within 90 days of discovery. ISOO, the responsible agency, and NARA will consult on a delay of up to three years to review the records.

Subpart E—Systematic Declassification

§ 1260.60 How does the NDC facilitate systematic review of records exempted at the individual record or file series level?

(a) NARA, through the NDC, follows the procedures established in § 1260.52 of this part regarding agency access for review of exempt file series.

(b) NARA, through the NDC, will establish a prioritization schedule for review of exempted individual Federal records. This schedule will take into account upcoming exemption expiration, researcher interest and likelihood of declassification. This schedule will be included as part of the NDC annual work plan.

(c) The Presidential Libraries will work directly with agencies to facilitate the review of records exempted at the file series level.

(d) The Presidential Libraries, through the NDC, will establish a prioritization schedule for review of previously exempted classified materials in the Presidential Library system. These materials will be referred to agencies holding equity in the records via the RAC Project.

Subpart F—Mandatory Declassification Review (MDR)

§ 1260.70 How does a researcher submit a MDR request?

(a) For Federal records in NARA's physical and legal custody, requests for MDR should be submitted to: National Archives at College Park, NWD (*Attn:* MDR Staff), 8601 Adelphi Road, Room 2600, College Park MD 20740 or *specialaccess_foia@nara.gov;*

(b) For Presidential records, Nixon Presidential materials, or donated presidential materials in the custody of the Presidential Libraries, MDR requests should be submitted to the Presidential Library with physical and legal custody of the records;

(c) For Congressional records in NARA's custody, MDR requests should be submitted to: The Center for Legislative Archives, 700 Pennsylvania Ave., NW., Washington, DC 20408 or *legislative.archives@nara.gov.*

(d) For all records in NARA's physical and legal custody, MDR requests must describe the record or material with sufficient specificity to enable NARA to locate it with a reasonable amount of effort. If NARA is unable to locate the record or material, or requires additional information, NARA will inform the requester.

§ 1260.72 What procedures does NARA follow when it receives a request for Executive Branch records under MDR?

(a) NARA will review the requested records and determine if they have already been released. If not, NARA will refer copies of the records to the originating agency and to agencies that may have an interest or activity with respect to the classified information for declassification review. Agencies may also send personnel to a NARA facility where the records are located to conduct a declassification review, or may delegate declassification authority to NARA.

(b) When the records were originated by a defunct agency that has no successor agency, NARA is responsible for making the declassification determinations, but will consult with agencies having interest in or activity with respect to the classified information.

(c) If the document or information has been reviewed for declassification within the past 2 years, NARA may opt not to conduct a second review and may instead inform the requester of this fact and of the prior review decision and advise the requester of appeal rights in accordance with 32 CFR 2001.33.

(d) If NARA determines that a requester has submitted a request for the same information under both MDR and the Freedom of Information Act (FOIA), as amended, NARA will notify the requester that he/she is required to elect one process or the other. If the requester fails to elect one or the other, the request will be treated under the FOIA, unless the requested information or materials are subject only to mandatory review.

(e) In every case, NARA will acknowledge receipt of the request and inform the requester of the action taken. If additional time is necessary to make

a declassification determination on material for which NARA has delegated authority, NARA will tell the requester how long it will take to process the request and advise the requester of available appeal rights. NARA may also inform the requester if part or all of the requested information is referred to other agencies for declassification review in accordance with sections 3.6(a) and (b) of the Executive Order.

(f) If NARA fails to provide the requester with a final decision on the mandatory review request within one year of the original date of the request, the requester may appeal to the Interagency Security Classification Appeals Panel (ISCAP).

§ 1260.74 What are agency responsibilities after receiving a MDR request forwarded by NARA?

(a) The agency receiving the referral will promptly process and review the referral for declassification and public release on a line-by-line basis in accordance with section 3.5(c) of the Order and communicate its review decisions to NARA.

(b) The agency must notify NARA of any other agency to which it forwards the request in those cases requiring the declassification determination of another agency to which NARA has not already sent a referral for review.

(c) The agency must return to NARA a complete copy of each referred document with the agency determination clearly stated to leave no doubt about the status of the information and the authority for its continued classification or its declassification.

§ 1260.76 What are NARA's procedures after it has received the agency's declassifications determination?

(a) If a document cannot be declassified in its entirety, the agency must return to NARA a copy of the document with those portions that require continued classification clearly marked. If a document requires continued classification in its entirety, the agency must return to NARA a copy of the document clearly so marked.

(b) NARA will notify the requester of the results of its review and make available copies of documents declassified in full and in part. If the requested information cannot be declassified in its entirety, NARA will send the requester a notice of the right to appeal the determination within 60 calendar days to the Deputy Archivist of the United States, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001. Additional information on appeals is located in 36 CFR Part 1264 and in Appendix A to 32 CFR Part 2001 (Article VIII).

§ 1260.78 What is the appeal process when a MDR for Executive Branch information in NARA's legal custody is denied in whole or in part?

(a) NARA shall respond to the requester in writing that her/his mandatory declassification review request was denied in full or in part and the rationale for the denial by using the appropriate category in either section 1.4 of the Order for information that is less than 25 years old, or section 3.3 of the Order for information that is older than 25 years, or 32 CFR 2001.30(p) for information governed by the Atomic Energy Act of 1954, as amended, or the National Security Act of 1947, as amended. NARA will send the requester a notice of the right to appeal the determination within 60 calendar days to the Deputy Archivist of the United States, National Archives and Records Administration, 8601 Adelphi Road, College Park, If a final decision on the appeal is not made within 60 working days of the date of the appeal, the requester may appeal to the Interagency Security Classification Appeals Panel (ISCAP).

(b) NARA will process all appeals in accordance with 32 CFR 2001.33(a)(2)(iii). NARA will inform all agencies with equity interests in the denied information. Those agencies will assist NARA in the appellate process and provide NARA with final declassification review decisions in a timely manner and consistent with 32 CFR 2001.33(a)(2)(iii).

(c) NARA will also notify the requester of the right to appeal denials of access to the Interagency Security Classification Appeals Panel, *Attn:* Mandatory Declassification Review Appeals, c/o Information Security Oversight Office, National Archives and Records Administration, 700 Pennsylvania Avenue, NW., Room 503, Washington, DC 20408; *iscap@nara.gov.*

(d) The pertinent NARA office or Presidential Library will coordinate the potential release of information declassified by the Interagency Security Classification Appeals Panel (ISCAP).

Subpart G—Reclassification of Records Transferred to NARA

§ 1260.80 What actions must NARA take when information in its physical and legal custody is reclassified after declassification under proper authority?

(a) When information in the physical and legal custody of NARA that has been available for public use following declassification under proper authority is proposed for reclassification in accordance with 32 CFR 2001.13(b)(1), NARA shall take the following actions:

(1) The agency head making the determination to reclassify the information shall notify the Archivist of the potential reclassification in writing,

(2) The Archivist shall suspend public access pending approval or disapproval by the Director of the Information Security Oversight Office of the reclassification request, and

(3) The Director of the Information Oversight Office shall normally make a decision on the validity of the reclassification request within 30 days, and

(4) The decision of the Director of ISOO may be appealed by the Archivist or the agency head to the President through the National Security Advisor.

(5) Access shall remain suspended pending a prompt decision on the appeal.

(b) [Reserved.]

§ 1260.82 What actions must NARA take with information in its physical and legal custody that has been made available to the public after declassification without proper authority?

(a) When information in the physical and legal custody of NARA has been made available for public use following declassification without proper authority and needs to have its original classification markings restored, the original classification authority shall notify the Archivist in writing in accordance with 32 CFR 2001.13(a)(1).

(b) If the Archivist does not agree with the reclassification decision and the information is more than 25 years old, the information will be temporarily withdrawn from public access and the Archivist will appeal the agency decision to the Director of ISOO, who will make a final decision in accordance with 32 CFR 2001.13(a)(1). The decision of the Director of ISOO may be appealed by the Archivist or the agency head to the President through the National Security Advisor.

(c) Information about records that have been reclassified or have had their classification restored as described in §§ 1260.80 and 1260.82 will be made available quarterly through the NARA Web site, *http://www.archives.gov/about/plans-reports/withdrawn/.* Information will include the responsible agency, NARA location, date withdrawn, number of records, and number of pages.

Dated: June 30, 2011.

David S. Ferriero,

Archivist of the United States.

[FR Doc. 2011–17128 Filed 7–7–11; 8:45 am]

BILLING CODE 7515–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2010–1002 FRL–9430–8]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Modifications to Indiana Prevention of Significant Deterioration and Non-Attainment New Source Review Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve Indiana's modifications to its Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) rules. The amendments include grammatical changes, corrections to numbering, addition of definitions consistent with Federal PSD and NNSR regulations, and removal of references to provisions which were vacated in the Federal rules. Indiana submitted these rule revisions for approval on November 24, 2010. They are consistent with the current Federal PSD and NNSR regulations.

DATES: Comments must be received on or before August 8, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2010–1002, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *E-mail: blakley.pamela@epa.gov.*
3. *Fax:* (312) 692–2450.
4. *Mail:* Pamela Blakley, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* Pamela Blakley, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Charmagne Ackerman, Environmental Engineer, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–0448, *ackerman.charmagne@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's State Implementation Plan submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: June 28, 2011.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2011–17037 Filed 7–7–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2011–0396; FRL–9432–2]

Revisions to the California State Implementation Plan, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a limited approval and limited disapproval of revisions to the South Coast Air Quality Management District (SCAQMD) portion of the California State Implementation Plan (SIP). These revisions concern oxides of nitrogen (NO_X) emissions from boiler, steam generators and process heaters larger than 2 MMBtu/hour that are not subject to RECLAIM. We are proposing action on local rules that regulate these emission sources under the Clean Air Act as amended in 1990 (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 August 8, 2011.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2011–0396, by one of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions.
2. *E-mail: 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 *http://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 *http://www.regulations.gov* or e-mail. *http://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 e-mail directly to EPA, your e-mail 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 *http://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 *http://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.

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I. The State's Submittal

A. What rules did the State submit?

Table 1 lists the rules addressed by this proposal with the dates that they were adopted by the local air agency and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED RULES

Local agency	Rule No.	Rule title	Adopted	Submitted
SCAQMD	1146	Emissions of Oxides of Nitrogen from Industrial, Institutional, and Commercial Boilers, Steam Generators and Process Heaters.	09/05/08	07/20/10
SCAQMD	1146.1	Emissions of Oxides of Nitrogen from Small Industrial, Institutional, and Commercial Boilers, Steam Generators and Process Heaters.	09/05/08	07/20/10

On August 25, 2010, the submittal for SCAQMD Rules 1146 and 1146.1 was found to meet the completeness criteria in 40 CFR part 51 appendix V, which must be met before formal EPA review.

B. Are there other versions of these rules?

We approved an earlier version of Rule 1146 into the SIP on April 8, 2008 (67 FR 16640) and of Rule 1146.1 on September 6, 1995 (60 FR 46220).

C. What is the purpose of the submitted rule revisions?

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 1146 limits NO_X and carbon monoxide (CO) emissions from boilers, steam generators and process heaters with a total rated heat input larger than 5 MMBtu/hour. Rule 1146.1 limits NO_X and CO emissions from boilers, steam generators and process heaters with a total rated heat input larger than 2 MMBtu/hour and less than 5 MMBtu/hour. EPA's technical support documents (TSD) have more information about these rules.

II. EPA's Evaluation and Action

A. How is EPA evaluating the rules?

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 certain ozone nonattainment areas (see sections 182(b)(2) and 182(f)), must not interfere with any applicable requirements concerning attainment and reasonable further progress (RFP) or any other applicable requirement of the Act (CAA 110(l)) or modify, in a nonattainment area, any SIP-approved control requirement in effect before November 15, 1990 (CAA 193). Section 172(c)(1) of the Act also requires implementation of all reasonably available control measures (RACM) as expeditiously as practicable in nonattainment areas. Because the area regulated by SCAQMD is designated nonattainment for the fine particulate matter (PM2.5) National Ambient Air Quality Standards (NAAQS) and designated and classified as extreme nonattainment for the ozone NAAQS (see 40 CFR 81.305), Rules 1146 and 1146.1 must ensure RACT. Additionally, the RACM requirement in CAA section 172(c)(1) applies to this area.

Guidance and policy documents that we use to evaluate enforceability, RACT and RACM 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. ''Clean Air Fine Particle Implementation Rule,'' 72 FR 20586, April 25, 2007.
5. ''Credible Evidence Revisions; Final Rule,'' 62 FR 8314, February 24, 1997.
6. ''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.
7. ''Alternative Control Techniques Document—NO_X Emissions from Industrial/Commercial/Institutional (ICI) Boilers'', U.S. EPA, March 1994.
8. ''Alternative Control Techniques Document—NO_X Emissions from Utility Boilers'', U.S. EPA, March 1994.
9. ''Review of State Implementation Plans and Revisions for Enforceability and Legal Sufficiency'', Memorandum from J. Craig Potter, Thomas L. Adams Jr., Francis S. Blake, U.S. EPA, September 23, 1987.
10. ''State Implementation Plans (SIPs): Policy Regarding Excess Emissions During Malfunctions, Startup and Shutdown'', Memorandum from Steven A. Herman, Assistant Administrator for Enforcement and Compliance Assurance, and Robert Perciasepe, Assistant Administrator for Air and Radiation, September 20, 1999.

B. Do the rules meet the evaluation criteria?

Rules 1146 and 1146.1 improve the SIP by establishing more stringent emission limits. The rules are largely consistent with the relevant policy and guidance regarding enforceability, RACT and SIP relaxations. We believe that in implementing RACT for NO_X, the submitted rules also satisfy RACM requirements for NO_X as a $PM_{2.5}$ precursor. Rule provisions which do not meet the evaluation criteria are summarized below and discussed further in the TSD.

C. What are the rule deficiencies?

These provisions in Rule 1146 conflict with section 110 and part D of the Act and prevent full approval of the SIP revision. Section (d)(8) and Section (d)(10) preclude the use of both source test data and portable analyzers test results from being used to prove a violation of the emission standard. This

contradicts CAA requirements for enforceability and the national credible evidence rule from 1997 (62 FR 8314).

These provisions in Rule 1146.1 conflict with section 110 and part D of the Act and prevent full approval of the SIP revision. Section (d)(7) and Section (d)(9) preclude the use of both source test data and portable analyzers test results from being used to prove a violation of the emission standard. This contradicts CAA requirements for enforceability and the national credible evidence rule from 1997 (62 FR 8314).

D. EPA Recommendations To Further Improve the Rules

The TSDs describe additional rule revisions that we recommend for the next time the local agency modifies the rules.

E. Proposed Action and Public Comment

As authorized in sections 110(k)(3) and 301(a) of the Act, EPA is proposing a limited approval of the submitted rules to improve the SIP. If finalized, this action would incorporate the submitted rules into the SIP, including those provisions identified as deficient. This approval is limited because EPA is simultaneously proposing a limited disapproval of the rules under sections 110(k)(3) and 301(a). The South Coast AQMD has included these rules in the demonstration, required by CAA section 172(c)(1), that its SIP provides for the implementation of RACM as necessary to attain the 8-hour ozone and $PM_{2.5}$ NAAQS as expeditiously as practicable. While we are proposing to find that the rules provide RACM level controls, we are also proposing to find that certain provisions of the rules raise enforcement concerns. Because of these concerns and the District's inclusion of these rules in its CAA-required RACM demonstration, if this disapproval is finalized, sanctions will be imposed under section 179 of the Act unless EPA approves subsequent SIP revisions that correct the rule deficiencies within 18 months of the disapproval. These sanctions would be imposed according to 40 CFR 52.31. A final disapproval would also trigger the 2-year clock for the Federal implementation plan (FIP) requirement under section 110(c). Note that the submitted rules have been adopted by the SCAQMD, and EPA's final limited disapproval would not prevent the local agency from enforcing them. The limited disapproval also would not prevent any portion of the rules from being incorporated by reference into the Federally enforceable SIP as discussed in a July 9, 1992 EPA memo found at: *http://www.epa.gov/nsr/ttnnsr01/gen/pdf/memo-s.pdf.*

We will accept comments from the public on the proposed limited approval and limited disapproval for the next 30 days.

III. Statutory and Executive Order Reviews

A. Executive Order 12866, Regulatory Planning and Review

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled ''Regulatory Planning and Review.''

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*. Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This rule will not have a significant impact on a substantial number of small entities because SIP approvals or disapprovals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve or disapprove requirements that the State is already imposing. Therefore, because the proposed Federal SIP limited approval/limited disapproval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.,* v. *U.S. EPA,* 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

D. Unfunded Mandates Reform Act

Under sections 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or Tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the limited approval/limited disapproval action proposed does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or Tribal governments in the aggregate, or to the private sector. This Federal action proposes to approve and disapprove pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or Tribal governments, or to the private sector, result from this action.

E. Executive Order 13132, Federalism

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612 (Federalism) and 12875 (Enhancing the Intergovernmental Partnership). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include 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.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, because it merely proposes to approve or disapprove State rules implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

F. Executive Order 13175, Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications.'' This proposed rule does not have Tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on Tribal governments, 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. Thus, Executive Order 13175 does not apply to this rule.

EPA specifically solicits additional comment on this proposed rule from Tribal officials.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045, because it approves state rules implementing a Federal standard.

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

This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

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

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

EPA lacks the discretionary authority to address environmental justice in this rulemaking.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

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

Dated: June 21, 2011.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2011–17262 Filed 7–7–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 382 and 391

[Docket No. FMCSA–2011–0073]

RIN 2126–AB35

Harmonizing Schedule I Drug Requirements

AGENCY: Federal Motor Carrier Safety Administration, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) proposes to amend the physical qualifications for drivers and the instructions for the medical examination report to clarify that drivers may not use Schedule I drugs and be qualified to drive commercial motor vehicles under any circumstances. The proposal also harmonizes FMCSA's provisions regarding pre-employment and return-to-duty test refusals with corresponding Department of Transportation (DOT)-wide provisions. Finally, the proposal corrects inaccurate uses of the term ''actual knowledge.''

DATES: Comments and related material must be submitted on or before September 6, 2011.

ADDRESSES: You may submit comments identified by docket number FMCSA–2011–0073 using any one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.*
- *Fax:* 202–493–2251.
- *Mail:* 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.
- *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

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

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail Angela Ward, Nurse Consultant, Medical Programs Office, Federal Motor Carrier Safety Administration, telephone: 202–366–

3109; e-mail: *angela.ward@dot.gov.* 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:

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I. Public Participation and Request for Comments
A. Submitting Comments
B. Viewing Comments and Documents
C. Privacy Act
II. Abbreviations
III. Background
A. History
B. Legal Authority
C. Discussion of Proposed Rule
IV. Section-by-Section Analysis
V. Regulatory Analyses

I. Public Participation and Request for Comments

FMCSA encourages you to participate in this rulemaking by submitting comments and related materials.

A. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (FMCSA–2011–0073), 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 or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that the Agency can contact you if it has 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 ''Rules,'' insert ''FMCSA–2011–0073'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on ''Submit a Comment'' 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 comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period and may change this proposed rule based on your comments.

B. 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* and click on the ''Read Comments'' box in the upper right hand side of the screen. Then, in the ''Keyword'' box, insert ''FMCSA–2011–0073'' and click ''Search.'' Next, click ''Open Docket Folder'' in the ''Actions'' column. Finally, in the ''Title'' column, click on the document you would like to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

C. Privacy Act

All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. Anyone is able to search the electronic form for all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

II. Abbreviations

CAA	Clean Air Act.
CFR	Code of Federal Regulations.
CMV	Commercial Motor Vehicle.
DEA	Drug Enforcement Administration.
FMCSA	Federal Motor Carrier Safety Administration.
FR	**Federal Register**.
NEPA	National Environmental Policy Act.
OTETA	Omnibus Transportation Employee Testing Act of 1991.
U.S.C	United States Code.

III. Background

A. History

The Omnibus Transportation Employee Testing Act of 1991 (OTETA), 49 U.S.C. 31306, mandated that DOT establish a controlled substances (drug) and alcohol testing program applicable to regulated entities and individuals performing safety sensitive functions. Entitled ''Procedures for Transportation Workplace Drug and Alcohol Testing Programs,'' 49 CFR part 40 contains the DOT regulations that detail how testing must be administered and prescribes procedures to protect the integrity of the process. The FMCSA's related drug and alcohol testing regulations are in 49 CFR part 382, ''Controlled Substances and Alcohol Use and Testing.''

DEA implemented the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act and the Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended. DEA published regulations implementing these statutes in 21 CFR Parts 1300 to 1399. These regulations are designed to ensure an adequate supply of controlled substances for legitimate medical, scientific, research, and industrial purposes, and to deter the diversion of controlled substances to illegal purposes. Controlled substances are drugs and other substances that have a potential for abuse and psychological and physical dependence. DEA lists controlled substances in 21 CFR part 1308. The substances are divided into five schedules. The substances listed in the schedule that are relevant to this rulemaking, Schedule I, have a high potential for abuse and have no currently accepted medical use in the United States (DEA Interim Final Rule on Electronic Prescriptions for Controlled Substances, 75 FR 16237, March 31, 2010). These substances may only be used for research, chemical analysis, or manufacture of other drugs.

Section 382.213 prohibits commercial motor vehicle (CMV) drivers from using any controlled substances when on duty or reporting for duty except when prescribed by a licensed medical practitioner who has advised the driver that the prescribed substance will not adversely affect the driver's ability to operate a CMV. Section 382.213 has remained largely unchanged since its adoption in 1994, outside of a technical amendment changing the term ''physician'' to ''licensed medical practitioner'' for the purpose of the prescription exception (61 FR 9556, March 8, 1996).

In addition to those in part 382, FMCSA has several other regulations governing drivers' use of drugs. Section 391.41(b)(12) was first promulgated in 1970, and stated that persons who ''use an amphetamine, narcotic, or any habit-forming drug, are not medically qualified to operate a commercial motor vehicle'' (35 FR 6463, April 22, 1970). Section 391.43(f) incorporates the substance of § 391.41(b)(12) in the instructions to the medical examiner. Section 391.41(b)(12) was revised several times, most notably in 1984, when the DEA's Schedule I drugs were added to the list of drugs prohibited by

§ 391.41(b)(12) (49 FR 44215, November 5, 1984). Sections 382.213 and 391.41(b)(12) were designed to complement § 392.4, which prohibits the use of drugs by CMV drivers. Section 392.4 contains an exception for use of non-Schedule I drugs ''administered to a driver by or under the instructions of a licensed medical practitioner, as defined in § 382.107 of this subchapter, who has advised the driver that the substance will not affect the driver's ability to safely operate a motor vehicle'' (49 CFR 392.4).

B. Legal Authority

FMCSA has general authority to promulgate safety standards, including those governing drivers' use of drugs while operating a CMV. The Motor Carrier Safety Act of 1984 (Pub. L. 98–554, Title II, 98 Stat. 2832, October 30, 1984) (the 1984 Act) provides authority to regulate drivers, motor carriers, and vehicle equipment. It requires the Secretary to ensure that—(1) CMVs are maintained, equipped, loaded, and operated safely; (2) the responsibilities imposed on operators of CMVs do not impair their ability to operate the vehicles safely; (3) the physical condition of CMV operators is adequate to enable them to operate the vehicles safely; and (4) the operation of CMVs does not have a deleterious effect on the physical condition of the operators (49 U.S.C. 31136(a)). Section 211 of the 1984 Act also grants the Secretary broad power in carrying out motor carrier safety statutes and regulations to ''prescribe recordkeeping and reporting requirements'' and to ''perform other acts the Secretary considers appropriate'' (49 U.S.C. 31133(a)(8) and (10)).

The FMCSA Administrator has been delegated authority under 49 CFR 1.73(g) to carry out the functions vested in the Secretary of Transportation by 49 U.S.C. chapter 311, subchapters I and III, relating to CMV programs and safety regulation.

As stated above, OTETA (Pub. L. 102–143, Title V, 105 Stat. 917, at 952, Oct. 28, 1991, codified at 49 U.S.C. 31306), mandated the alcohol and controlled substances (drug) testing program for DOT. OTETA required the Secretary of Transportation to promulgate regulations for alcohol and controlled substances testing for persons in safety-sensitive positions in four modes of transportation—motor carrier, airline, railroad, and mass transit. Those regulations, including subsequent amendments, are codified at 49 CFR part 40, ''Procedures for Transportation Workplace Drug and Alcohol Testing Programs.'' Part 40 prescribes drug and alcohol testing requirements for all DOT-regulated parties, including employers of drivers with commercial driver's licenses subject to FMCSA testing requirements. FMCSA's related drug and alcohol testing regulations are in 49 CFR part 382, ''Controlled Substances and Alcohol Use and Testing.''

C. Discussion of the Proposed Rule

This rulemaking is necessary to reconcile and resolve a perceived inconsistency among: §§ 382.213, 391.41(b)(12), 391.43(f), and 392.4 of the Federal Motor Carrier Safety Regulations (FMCSRs); DOT-wide drug regulations in part 40; and DEA regulations. Although § 392.4 clearly prohibits drivers from using Schedule I drugs, it has come to FMCSA's attention that some people might interpret §§ 382.213, 391.41(b)(12) and 391.43(f) to permit their use if recommended by a licensed medical practitioner. The FMCSA has always considered §§ 382.213, 391.41(b)(12), 391.43(f), and 392.4 to prohibit any and all use of Schedule I drugs by CMV drivers. In fact, Federal law prohibits Schedule I drugs from being prescribed in the United States (75 FR 16237, March 31, 2010). Schedule I drugs have a high potential for abuse and no medically accepted therapeutic use (*id.*). Currently, Federal law only allows for their use in research, chemical analysis, or manufacture of other drugs (*id.*).

In certain circumstances, a medical review officer can verify a drug test negative when he or she has information that a driver is using a drug under a physician's prescription. However, under DOT-wide rules, no medical review officer may verify a drug test negative for a Schedule I drug, even if he or she has information that a driver is using the Schedule I drug in accordance with a physician's recommendation (49 CFR 40.151(e)). Interpreting FMCSA's regulations to permit drivers to use Schedule I drugs would put the FMCSRs in direct conflict with DOT's comprehensive drug testing program under 49 CFR part 40, which does not permit drivers to use Schedule I drugs. The FMCSA does not believe this is a reasonable interpretation of the regulations. Regardless, to avoid any confusion, this rulemaking would harmonize §§ 382.213, 391.41(b)(12), 391.43(f), and 392.4 with DOT-wide regulations and DEA regulations, and make it clear that drivers may not use Schedule I drugs under any circumstances.

In addition, 49 CFR 382.211 prohibits drivers from refusing to submit to certain types of drug or alcohol tests and establishes such refusals as violations of FMCSA's drug and alcohol regulations. Currently, under DOT-wide regulations, drivers who refuse to submit to pre-employment and return-to-duty tests must complete the return-to-duty process prescribed in part 40, subpart O. However, § 382.211 is inconsistent with the DOT-wide drug and alcohol rules in that it does not include refusals to submit to pre-employment and return-to-duty tests as violations. The FMCSA proposes to correct this inconsistency by adding these two types of refusals to the prohibitions at § 382.211.

Finally, FMCSA proposes changes to 49 CFR 382.201 and 382.215 to clarify the Agency's rules prohibiting an employer from using a driver about whom the employer has actual knowledge of drug or alcohol use, as defined at § 382.107. Sections 382.201 and 382.215 currently state that an employer may not allow an employee to perform safety-sensitive functions if the employer has actual knowledge that the employee has tested positive for drugs or has an alcohol concentration of .04 or greater. However, the term ''actual knowledge'' is defined in § 382.107 to mean the observation of alcohol or controlled substances use, and is not intended to refer to testing results. As a result, the use of the term ''actual knowledge'' in these sections is not appropriate. FMCSA proposes to replace the term ''actual knowledge'' with ''knowledge'' in these sections. This should clarify that these prohibitions refer to the knowledge of test results, not employer observation of prohibited conduct.

IV. Section-by-Section Analysis

Sections 382.201 and 382.215

An employer has ''actual knowledge'' that an employee has used drugs or alcohol in violation of FMCSA rules when he or she directly observes or otherwise learns that a driver is using controlled substances or consuming alcohol while on duty (49 CFR 382.107). Actual knowledge, as defined at § 382.107, is distinct from an employer knowing that his or her employee-driver tested positive or refused a DOT drug or alcohol test. Because §§ 382.201 and 382.215 set forth prohibitions related to an employer's knowledge related to testing, not observation, the use of the term ''actual knowledge'' is not appropriate. The FMCSA proposes to replace the term ''actual knowledge'' with ''knowledge'' in these sections. This would clarify that these prohibitions refer to the knowledge of test results, not employer observation of prohibited conduct.

Section 382.211

Current § 382.211 prohibits drivers from refusing to submit to a post-accident, random, or reasonable suspicion drug or alcohol test. The Agency proposes to amend § 382.211 to also prohibit refusals for pre-employment testing and return-to-duty testing. This would make this regulation consistent with 49 CFR 40.191(a)(3).

Section 382.213

Section 382.213 currently prohibits CMV drivers from using any drugs when on duty or reporting for duty except when prescribed by a licensed medical practitioner who has advised the driver that the prescribed substance will not adversely affect the driver's ability to operate a CMV. The Agency proposes to amend the language regarding the drugs that CMV drivers are prohibited from using in order to differentiate between Schedule I drugs and non-Schedule I drugs. The proposed changes would make it clear that Schedule I drugs may not be used by a CMV driver under any circumstances. The FMCSA's regulations would continue to permit the use of non-Schedule I drugs under limited circumstances, when prescribed by a licensed medical practitioner.

Sections 391.41 and 391.43

Section 391.41(b)(12)(i) currently states that a driver may not use: Controlled substances on the DEA Schedule I, amphetamines, narcotics, or other habit-forming drugs. Section 391.41(b)(12)(ii) contains an exception for a substance or drug prescribed by a licensed medical practitioner who is familiar with the driver's history and work duties and has advised the driver that the prescribed substance or drug will not adversely affect his or her ability to safely operate a CMV. The FMCSA has never considered this exception to permit use of Schedule I drugs by CMV drivers under any circumstance because Federal law prohibits Schedule I drugs from being prescribed in the United States (75 FR 16237, March 31, 2010). Section 391.43(f) incorporates the substance of § 391.41(b)(12) into pages 4 and 8 of the Instructions to the Medical Examiner. The FMCSA makes no others changes to this document.

Section 391.41(b)(12) and the Instructions for Medical Examiners at § 391.43(f) currently do not differentiate between Schedule I and non-Schedule I drugs for the purpose of the prescription exception. The prescription exception currently states that a CMV driver may use a substance or drug that is prescribed by a licensed medical practitioner who is familiar with the driver's medical history and has advised the driver that the prescribed substance or drug will not adversely affect the driver's ability to safely operate a CMV. The Agency proposes to amend these sections to clarify that this exception only applies to non-Schedule I prescribed substances, amphetamines, narcotics, or other habit-forming drugs.

V. Regulatory Analyses

Regulatory Planning and Review

This action does not meet the criteria for a ''significant regulatory action,'' either as specified in Executive Order 12866 as supplemented by Executive Order 13563 (76 FR 3821, January 18, 2011) or within the meaning of the DOT regulatory policies and procedures (44 FR 1103, February 26, 1979). The estimated economic costs of the proposed rule do not exceed the $100 million annual threshold nor does the Agency expect the proposed rule to have substantial Congressional or public interest. Therefore, this proposed rule has not been formally reviewed by the Office of Management and Budget. No expenditures would be required of the affected population because the proposed rule would only clarify existing rules, amend inconsistencies in FMCSA's current regulations, and harmonize them with the DOT-wide regulations and DEA regulations.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612) requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term ''small entities'' comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, as well as governmental jurisdictions with populations of less than 50,000. Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities and mandates that agencies strive to lessen any adverse effects on these businesses.

Under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, the proposed rule is not expected to have a significant economic impact on a substantial number of small entities because the proposed rule would only clarify existing rules, amend inconsistencies in FMCSA's current regulations, and harmonize them with the DOT-wide regulations and DEA regulations. Accordingly, I certify that a regulatory flexibility analysis is not necessary.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), FMCSA wants to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking initiative. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult the FMCSA point of contact, Angela Ward, listed in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule. FMCSA will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Agency.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of FMCSA, call 1–888–REG–FAIR (1–888–734–3247).

Unfunded Mandates Reform Act of 1995

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 $140.8 million (which is the value of $100 million in 2010 after adjusting for inflation) or more in any 1 year. This proposed rule would not result in such expenditure; FMCSA expects the effects of this proposed rule to be minimal because the proposed rule would only clarify existing rules, amend inconsistencies in FMCSA's current regulations, and harmonize them with the DOT-wide regulations and DEA regulations.

Paperwork Reduction Act

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Privacy Impact Assessment

FMCSA conducted a Privacy Threshold Analysis for the Notice of Proposed Rulemaking (NPRM) and determined that this proposed rule is not a privacy-sensitive rulemaking because if promulgated as a final rule it would not require any collection, maintenance, or dissemination of Personally Identifiable Information from or about members of the public.

Executive Order 13132 (Federalism)

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on States or localities. FMCSA has analyzed this proposed rule under that Order and has determined that it does not have implications for federalism.

Executive Order 12630 (Taking of Private Property)

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

Executive Order 12988 (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.

Executive Order 13045 (Protection of Children)

FMCSA has analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This proposed 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.

Executive Order 13211 (Energy Effects)

FMCSA has analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The Agency has determined that it is not a ''significant energy action'' under that order 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies. This proposed rule does not use technical standards. Therefore, FMCSA did not consider the use of voluntary consensus standards.

National Environmental Policy Act

FMCSA analyzed this NPRM for the purpose of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 et seq.) and determined under our environmental procedures Order 5610.1, published February 24, 2004 (69 FR 9680), that this proposed action does not have any effect on the quality of the environment. Therefore, this NPRM is categorically excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1, paragraph 6(r) of Appendix 2. The Categorical Exclusion under paragraph 6(y)(6) relates to ''regulations implementing employer controlled substances and alcohol use and testing procedures * * *,'' which is the focus of this rulemaking. A Categorical Exclusion determination is available for inspection or copying in the regulations.gov Web site listed under **ADDRESSES**.

In addition to the NEPA requirements to examine impacts on air quality, the Clean Air Act (CAA) as amended (42 U.S.C. 7401 et seq.) also requires FMCSA to analyze the potential impact of its actions on air quality and to ensure that FMCSA actions conform to State and local air quality implementation plans. The additional contributions to air emissions are expected to fall within the CAA *de minimis* standards and are not expected to be subject to the Environmental Protection Agency's General Conformity Rule (40 CFR parts 51 and 93).

FMCSA seeks comment on these determinations.

List of Subjects

49 CFR Part 382

Administrative practice and procedure, Alcohol abuse, Drug abuse, Drug testing, Highway safety, Motor carriers, Penalties, Safety, Transportation.

49 CFR Part 391

Alcohol abuse, Drug abuse, Drug testing, Highway safety, Motor carriers, Reporting and recordkeeping requirements, Safety, Transportation.

For the reasons stated in the preamble, FMCSA proposes to amend 49 CFR, parts 382 and 391 as follows:

PART 382—CONTROLLED SUBSTANCES AND ALCOHOL USE AND TESTING

1. The authority citation for part 382 continues to read as follows:

Authority: 49 U.S.C. 31133, 31136, 31301 *et seq.,* 31502; and 49 CFR 1.73.

§ 382.201 [Amended]

2. Amend § 382.201 by removing the word ''actual'' between the words ''having'' and ''knowledge.''

3. Revise § 382.211 to read as follows:

§ 382.211 Refusal to submit to a required alcohol or controlled substances test.

No driver shall refuse to submit to a pre-employment controlled substance test required under § 382.301, a post-accident alcohol or controlled substance test required under § 382.303, a random alcohol or controlled substances test required under § 382.305, a reasonable suspicion alcohol or controlled substance test required under § 382.307, a return-to-duty alcohol or controlled substances test required under § 382.309, or a follow-up alcohol or controlled substance test required under § 382.311. No employer shall permit a driver who refuses to submit to such tests to perform or continue to perform safety-sensitive functions.

4. Revise § 382.213 to read as follows:

§ 382.213 Controlled substance use.

(a) No driver shall report for duty or remain on duty requiring the performance of safety sensitive functions when the driver uses any controlled substance identified in 21 CFR 1308.11.

(b) No driver shall report for duty or remain on duty requiring the performance of safety-sensitive functions when the driver uses any non-Schedule I drug except when the use is pursuant to the instructions of a licensed medical practitioner, as defined in § 382.107, who is familiar with the driver's medical history and

has advised the driver that the substance will not adversely affect the driver's ability to safely operate a commercial motor vehicle.

(c) No employer having actual knowledge that a driver has used a controlled substance shall permit the driver to perform or continue to perform a safety-sensitive function.

(d) An employer may require a driver to inform the employer of any therapeutic drug use.

§ 382.215 [Amended]

5. Amend § 382.215 by removing the word ''actual'' between the words ''having'' and ''knowledge.''

PART 391—QUALIFICATIONS OF DRIVERS AND LONGER COMBINATION VEHICLE (LCV) DRIVER INSTRUCTORS

6. The authority citation for part 391 continues to read as follows:

Authority: 49 U.S.C. 322, 504, 508, 31133, 31136, and 31502; sec. 4007(b) of Pub. L. 102–240, 105 Stat. 2152; sec. 114 of Pub. L. 103–311, 108 Stat. 1673, 1677; sec. 215 of Pub. L. 106–159, 113 Stat. 1767; and 49 CFR 1.73.

7. Amend § 391.41 by revising paragraphs (b)(12)(i) and (ii) to read as follows:

§ 391.41 Physical qualifications for drivers.

* * * * *

(b) * * *

(12)(i) Does not use any controlled substance identified in 21 CFR 1308.11 Schedule I, an amphetamine, a narcotic, or other habit-forming drug.

(ii) Does not use any non-Schedule I controlled substance except when the use is pursuant to the instructions of a licensed medical practitioner, as defined in § 382.107, who is familiar with the driver's medical history and has advised the driver that the substance will not adversely affect the driver's ability to safely operate a commercial motor vehicle.

* * * * *

8. Amend § 391.43(f) by removing the Medical Examination Report for Commercial Driver Fitness Determination, form 649–F (6045), and adding in its place the following form, to read as follows:

§ 391.43 Medical examination; certificate of physical examination.

* * * * *

(f) * * *

BILLING CODE 4910–EX–P

Medical Examination Report
FOR COMMERCIAL DRIVER FITNESS DETERMINATION

649-F (6045)

1. DRIVER'S INFORMATION Driver completes this section

Driver's Name (Last, First, Middle)	Social Security No.	Birthdate M / D / Y	Age	Sex ☐ M ☐ F	New Certification ☐ Recertification ☐ Follow-up ☐	Date of Exam

Address	City, State, Zip Code	Work Tel: ( ) Home Tel: ( )	Driver License No.	License Class ☐ A ☐ B ☐ C ☐ D ☐ Other	State of Issue

2. HEALTH HISTORY Driver completes this section, but medical examiner is encouraged to discuss with driver.

Yes No

☐ ☐ Any illness or injury in the last 5 years?
☐ ☐ Head/Brain injuries, disorders or illnesses
☐ ☐ Seizures, epilepsy
☐ medication_____

☐ ☐ Eye disorders or impaired vision (except corrective lenses)
☐ ☐ Ear disorders, loss of hearing or balance
☐ ☐ Heart disease or heart attack; other cardiovascular condition
☐ medication_____

☐ ☐ Heart surgery (valve replacement/bypass, angioplasty, pacemaker)
☐ ☐ High blood pressure ☐ medication_____
☐ ☐ Muscular disease
☐ ☐ Shortness of breath

Yes No

☐ ☐ Lung disease, emphysema, asthma, chronic bronchitis
☐ ☐ Kidney disease, dialysis
☐ ☐ Liver disease
☐ ☐ Digestive problems
☐ ☐ Diabetes or elevated blood sugar controlled by:
☐ diet
☐ pills
☐ insulin
☐ ☐ Nervous or psychiatric disorders, e.g., severe depression
☐ ☐ medication_____

☐ ☐ Loss of, or altered consciousness

Yes No

☐ ☐ Fainting, dizziness
☐ ☐ Sleep disorders, pauses in breathing while asleep, daytime sleepiness, loud snoring

☐ ☐ Stroke or paralysis
☐ ☐ Missing or impaired hand, arm, foot, leg, finger, toe
☐ ☐ Spinal injury or disease

☐ ☐ Chronic low back pain

☐ ☐ Regular, frequent alcohol use
☐ ☐ Narcotic or habit forming drug use

For any YES answer, indicate onset date, diagnosis, treating physician's name and address, and any current limitation. List all medications (including over-the-counter medications) used regularly or recently.

_____
_____
_____

I certify that the above information is complete and true. I understand that inaccurate, false or missing information may invalidate the examination and my Medical Examiner's Certificate.

Driver's Signature_____ Date_____

Medical Examiner's Comments on Health History (The medical examiner must review and discuss with the driver any "yes" answers and potential hazards of medications, including over-the-counter medications, while driving. This discussion must be documented below.)

TESTING (Medical Examiner completes Section 3 through 7) Name: Last, First, Middle,

3. VISION **Standard: At least 20/40 acuity (Snellen) in each eye with or without correction. At least 70 degrees peripheral in horizontal meridian measured in each eye. The use of corrective lenses should be noted on the Medical Examiner's Certificate.**

INSTRUCTIONS: When other than the Snellen chart is used, give test results in Snellen-comparable values. In recording distance vision, use 20 feet as normal. Report visual acuity as a ratio with 20 as numerator and the smallest type read at 20 feet as denominator. If the applicant wears corrective lenses, these should be worn while visual acuity is being tested. If the driver habitually wears contact lenses, or intends to do so while driving, sufficient evidence of good tolerance and adaptation to their use must be obvious. ***Monocular drivers are not qualified.***

Numerical readings must be provided.

ACUITY	UNCORRECTED	CORRECTED	HORIZONTAL FIELD OF VISION
Right Eye	20/	20/	Right Eye °
Left Eye	20/	20/	Left Eye °
Both Eyes	20/	20/	

Applicant can recognize and distinguish among traffic control signals and devices showing standard red, green, and amber colors? ☐ Yes ☐ No

Applicant meets visual acuity requirement only when wearing: ☐ Corrective Lenses

Monocular Vision: ☐ Yes ☐ No

Complete next line only if vision testing is done by an opthalmologist or optometrist

Date of Examination | Name of Ophthalmologist or Optometrist (print) | Tel. No. | License No./ State of Issue | Signature

4. HEARING **Standard: a) Must first perceive forced whispered voice ≥ 5 ft., with or without hearing aid, or b) average hearing loss in better ear ≤ 40 dB**
☐ Check if hearing aid used for tests. ☐ Check if hearing aid required to meet standard.

INSTRUCTIONS: To convert audiometric test results from ISO to ANSI, -14 dB from ISO for 500Hz, -10dB for 1,000 Hz, -8.5 dB for 2000 Hz. To average, add the readings for 3 frequencies tested and divide by 3.

Numerical readings must be recorded.

a) Record distance from individual at which forced whispered voice can first be heard.	Right ear \ Feet	Left Ear \ Feet

b) If audiometer is used, record hearing loss in decibels. (acc. to ANSI Z24.5-1951)	Right Ear			Left Ear		
	500 Hz	1000 Hz	2000 Hz	500 Hz	1000 Hz	2000 Hz
	Average:			Average:		

5. BLOOD PRESSURE/ PULSE RATE **Numerical readings must be recorded. Medical Examiner should take at least two readings to confirm BP.**

Blood Pressure	Systolic	Diastolic

Driver qualified if ≤140/90.

Pulse Rate: ☐ Regular ☐ Irregular

Record Pulse Rate:_____

Reading	Category	Expiration Date	Recertification
140-159/90-99	Stage 1	1 year	1 year if ≤140/90. One-time certificate for 3 months if 141-159/91-99.
160-179/100-109	Stage 2	One-time certificate for 3 months.	1 year from date of exam if ≤140/90
≥180/110	Stage 3	6 months from date of exam if ≤140/90	6 months if ≤ 140/90

6. LABORATORY AND OTHER TEST FINDINGS **Numerical readings must be recorded.**

URINE SPECIMEN	SP. GR.	PROTEIN	BLOOD	SUGAR

Urinalysis is required. Protein, blood or sugar in the urine may be an indication for further testing to rule out any underlying medical problem.

Other Testing (Describe and record) _____

7. PHYSICAL EXAMINATION Height:_____ (in.) Weight:_____ (lbs.) Name: Last, First, Middle,

The presence of a certain condition may not necessarily disqualify a driver, particularly if the condition is controlled adequately, is not likely to worsen or is readily amenable to treatment. Even if a condition does not disqualify a driver, the medical examiner may consider deferring the driver temporarily. Also, the driver should be advised to take the necessary steps to correct the condition as soon as possible particularly if the condition, if neglected, could result in more serious illness that might affect driving.

Check YES if there are any abnormalities. Check NO if the body system is normal. Discuss any YES answers in detail in the space below, and indicate whether it would affect the driver's ability to operate a commercial motor vehicle safely. Enter applicable item number before each comment. If organic disease is present, note that it has been compensated for. See *Instructions to the Medical Examiner* for guidance.

BODY SYSTEM	CHECK FOR:	YES*	NO	BODY SYSTEM	CHECK FOR:	YES*	NO
1. General Appearance	Marked overweight, tremor, signs of alcoholism, problem drinking, or drug abuse.			7. Abdomen and Viscera	Enlarged liver, enlarged spleen, masses, bruits, hernia, significant abdominal wall muscle weakness.		
2. Eyes	Pupillary equality, reaction to light, accommodation, ocular motility, ocular muscle imbalance, extraocular movement, nystagmus, exophthalmos. Ask about retinopathy, cataracts, aphakia, glaucoma, macular degeneration and refer to a specialist if appropriate.			8. Vascular System	Abnormal pulse and amplitude, cartoid or arterial bruits, varicose veins.		
				9. Genito-urinary System	Hernias.		
3. Ears	Scarring of tympanic membrane, occlusion of external canal, perforated eardrums.			10. Extremities- Limb impaired. Driver may be subject to SPE certificate if otherwise qualified.	Loss or impairment of leg, foot, toe, arm, hand, finger, Perceptible limp, deformities, atrophy, weakness, paralysis, clubbing, edema, hypotonia. Insufficicent grasp and prehension in upper limb to maintain steering wheel grip. Insufficient mobility and strength in lower limb to operate pedals properly.		
4. Mouth and Throat	Irremediable deformities likely to interfere with breathing or swallowing.						
5. Heart	Murmurs, extra sounds, enlarged heart, pacemaker, implantable defibrillator.			11. Spine, other musculoskeletal	Previous surgery, deformities, limitation of motion, tenderness.		
6. Lungs and chest, not including breast examination	Abnormal chest wall expansion, abnormal respiratory rate, abnormal breath sounds including wheezes or alveolar rales, impaired respiratory function, cyanosis. Abnormal findings on physical exam may require further testing such as pulmonary tests and/ or xray of chest.			12. Neurological	Impaired equilibrium, coordination or speech pattern; asymmetric deep tendon reflexes, sensory or positional abnormalities, abnormal patellar and Babinki's reflexes, ataxia.		

***COMMENTS:** _____

Note certification status here. See Instructions to the Medical Examiner for guidance.

- ☐ Meets standards in 49 CFR 391.41; qualifies for 2 year certificate
- ☐ Does not meet standards
- ☐ Meets standards, but periodic monitoring required due to _____
  Driver qualified only for: ☐3 months ☐6 months ☐1 year ☐ Other

Temporarily disqualified due to (condition or medication):_____

Return to medical examiner's office for follow up on _____

- ☐ Wearing corrective lense
- ☐ Wearing hearing aid
- ☐ Accompanied by a _____waiver/ exemption. Driver must present exemption at time of certification.
- ☐ Skill Performance Evaluation (SPE) Certificate
- ☐ Driving within an exempt intracity zone (See 49 CFR 391.62)
- ☐ Qualified by operation of 49 CFR 391.64

Medical Examiner's signature_____
Medical Examiner's name _____
Address _____
Telephone Number _____

If meets standards, complete a Medical Examiner's Certificate as stated in 49 CFR 391.43(h). (Driver must carry certificate when operating a commercial vehicle.)

49 CFR 391.41 Physical Qualifications for Drivers

THE DRIVER'S ROLE

Responsibilities, work schedules, physical and emotional demands, and lifestyles among commercial drivers vary by the type of driving that they do. Some of the main types of drivers include the following: turn around or short relay (drivers return to their home base each evening); long relay (drivers drive 9-11 hours and then have at least a 10-hour off-duty period), straight through haul (cross country drivers); and team drivers (drivers share the driving by alternating their 5-hour driving periods and 5-hour rest periods.)

The following factors may be involved in a driver's performance of duties: abrupt schedule changes and rotating work schedules, which may result in irregular sleep patterns and a driver beginning a trip in a fatigued condition; long hours; extended time away from family and friends, which may result in lack of social support; tight pickup and delivery schedules, with irregularity in work, rest, and eating patterns, adverse road, weather and traffic conditions, which may cause delays and lead to hurriedly loading or unloading cargo in order to compensate for the lost time; and environmental conditions such as excessive vibration, noise, and extremes in temperature. Transporting passengers or hazardous materials may add to the demands on the commercial driver.

There may be duties in addition to the driving task for which a driver is responsible and needs to be fit. Some of these responsibilities are: coupling and uncoupling trailer(s) from the tractor, loading and unloading trailer(s) (sometimes a driver may lift a heavy load or unload as much as 50,000 lbs. of freight after sitting for a long period of time without any stretching period); inspecting the operating condition of tractor and/or trailer(s) before, during and after delivery of cargo; lifting, installing, and removing heavy tire chains; and, lifting heavy tarpaulins to cover open top trailers. The above tasks demand agility, the ability to bend and stoop, the ability to maintain a crouching position to inspect the underside of the vehicle, frequent entering and exiting of the cab, and the ability to climb ladders on the tractor and/or trailer(s).

In addition, a driver must have the perceptual skills to monitor a sometimes complex driving situation, the judgment skills to make quick decisions, when necessary, and the manipulative skills to control an oversize steering wheel, shift gears using a manual transmission, and maneuver a vehicle in crowded areas.

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§391.41 PHYSICAL QUALIFICATIONS FOR DRIVERS

(a) A person shall not drive a commercial motor vehicle unless he is physically qualified to do so and, except as provided in §391.67, has on his person the original, or a photographic copy, of a medical examiner's certificate that he is physically qualified to drive a commercial motor vehicle.

(b) A person is physically qualified to drive a motor vehicle if that person:

(1) Has no loss of a foot, a leg, a hand, or an arm, or has been granted a Skill Performance Evaluation (SPE) Certificate (formerly Limb Waiver Program) pursuant to §391.49.

(2) Has no impairment of: (i) A hand or finger which interferes with prehension or power grasping; or (ii) An arm, foot, or leg which interferes with the ability to perform normal tasks associated with operating a commercial motor vehicle; or any other significant limb defect or limitation which interferes with the ability to perform normal tasks associated with operating a commercial motor vehicle; or has been granted a SPE Certificate pursuant to §391.49.

(3) Has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control;

(4) Has no current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive cardiac failure.

(5) Has no established medical history or clinical diagnosis of a respiratory dysfunction likely to interfere with his ability to control and drive a commercial motor vehicle safely.

(6) Has no current clinical diagnosis of high blood pressure likely to interfere with his ability to operate a commercial motor vehicle safely.

(7) Has no established medical history or clinical diagnosis of rheumatic, arthritic, orthopedic, muscular, neuromuscular, or vascular disease which interferes with his ability to control and operate a commercial motor vehicle safely.

(8) Has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a commercial motor vehicle;

(9) Has no mental, nervous, organic, or functional disease or psychiatric disorder likely to interfere with his ability to drive a commercial motor vehicle safely;

(10) Has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70degrees in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing standard red, green and amber;

(11) First perceives a forced whispered voice in the better ear not less than 5 feet with or without the use of a hearing aid, or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz and 2,000 Hz with or without a hearing device when the audiometric device is calibrated to the American National Standard (formerly ASA Standard) Z24.5-1951;

(12)(i) Does not use any controlled substance identified in 21 CFR 1308.11 Schedule I, an amphetamine, a narcotic, or other habit-forming drug.

(ii) Does not use any non-Schedule I controlled substance except when the use is pursuant to the instructions of a licensed medical practitioner, as defined in § 382.107, who is familiar with the driver's medical history and has advised the driver that the substance will not adversely affect the driver's ability to safely operate a commercial motor vehicle.

(13) Has no current clinical diagnosis of alcoholism.

INSTRUCTIONS TO THE MEDICAL EXAMINER

General Information

The purpose of this examination is to determine a driver's physical qualification to operate a commercial motor vehicle (CMV) in interstate commerce according to the requirements in 49 CFR 391.41-49. Therefore, the medical examiner must be knowledgeable of these requirements and guidelines developed by the FMCSA to assist the medical examiner in making the qualification determination. The medical examiner should be familiar with the driver's responsibilities and work environment and is referred to the section on the form, **The Driver's Role**.

In addition to reviewing the **Health History** section with the driver and conducting the physical examination, the medical examiner should discuss common prescriptions and over-the-counter medications relative to the side effects and hazards of these medications while driving. Educate the driver to read warning labels on all medications. History of certain conditions may be cause for rejection, particularly if required by regulation, or may indicate the need for additional laboratory tests or more stringent examination perhaps by a medical specialist. These decisions are usually made by the medical examiner in light of the driver's job responsibilities, work schedule and potential for the conditions to render the driver unsafe.

Medical conditions should be recorded even if they are not cause for denial, and they should be discussed with the driver to encourage appropriate remedial care. This advice is especially needed when a condition, if neglected, could develop into a serious illness that could affect driving.

If the medical examiner determines that the driver is fit to drive and is also able to perform non-driving responsibilities as may be required, the medical examiner signs the medical certificate which the driver must carry with his/her license. The certificate must be dated. **Under current regulations, the certificate is valid for two years, unless the driver has a medical condition that does not prohibit driving but does require more frequent monitoring**. In such situations, the medical certificate should be issued for a shorter length of time. The physical examination should be done carefully and at least as complete as is indicated by the attached form. Contact the FMCSA at (202) 366-1790 for further information (a vision exemption, qualifying drivers under 49 CFR 391.64, etc.).

Interpretation of Medical Standards

Since the issuance of the regulations for physical qualifications of commercial drivers, the Federal Motor Carrier Safety Administration (FMCSA) has published recommendations called Advisory Criteria to help medical examiners in determining whether a driver meets the physical qualifications for commercial driving. These recommendations have been condensed to provide information to medical examiners that (1) is directly relevant to the physical examination and (2) is not already included in the medical examination form. The specific regulation is printed in italics and it's reference by section is highlighted.

Federal Motor Carrier Safety Regulations
-Advisory Criteria-

Loss of Limb:
§391.41(b)(1)
A person is physically qualified to drive a commercial motor vehicle if that person:
Has no loss of a foot, leg, hand or an arm, or has been granted a Skill Performance Evaluation (SPE) Certificate pursuant to Section 391.49.

Limb Impairment:
§391.41(b)(2)
A person is physically qualified to drive a commercial motor vehicle if that person:
Has no impairment of: (i) A hand or finger which interferes with prehension or power grasping; or (ii) An arm, foot, or leg which interferes with the ability to perform normal tasks associated with operating a commercial motor vehicle; or (iii) Any other significant limb defect or limitation which interferes with the ability to perform normal tasks associated with operating a commercial motor vehicle; or (iv) Has been granted a Skill Performance Evaluation (SPE) Certificate pursuant to Section 391.49.

A person who suffers loss of a foot, leg, hand or arm or whose limb impairment in any way interferes with the safe performance of normal tasks associated with operating a commercial motor vehicle is subject to the Skill Performance Evaluation Certification Program pursuant to section 391.49, assuming the person is otherwise qualified.

With the advancement of technology, medical aids and equipment modifications have been developed to compensate for certain disabilities. The SPE Certification Program (formerly the Limb Waiver Program) was designed to allow persons with the loss of a foot or limb or with functional impairment to qualify under the Federal Motor Carrier Safety Regulations (FMCSRs) by use of prosthetic devices or equipment modifications which enable them to safely operate a commercial motor vehicle. Since there are no medical aids equivalent to the original body or limb, certain risks are still present, and thus restrictions may be included on individual SPE certificates when a State Director for the FMCSA determines they are necessary to be consistent with safety and public interest.

If the driver is found otherwise medically qualified (391.41(b)(3) through (13)), the medical examiner must check on the medical certificate that the driver is qualified only if accompanied by a SPE certificate. The driver and the employing motor carrier are subject to appropriate penalty if the driver operates a motor vehicle in interstate or foreign commerce without a curent SPE certificate for his/her physical disability.

Diabetes
§391.41(b)(3)
A person is physically qualified to drive a commercial motor vehicle if that person:
Has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control.

Diabetes mellitus is a disease which, on occasion, can result in a loss of consciousness or disorientation in time and space. Individuals who require insulin for control have conditions which can get out of control by the use of too much or too little insulin, or food intake not consistent with the insulin dosage. Incapacitation may occur from symptoms of hyperglycemic or hypoglycemic reactions (drowsiness, semiconsciousness, diabetic coma or insulin shock).

The administration of insulin is, within itself, a complicated process requiring insulin, syringe, needle, alcohol sponge and a sterile technique. Factors related to long-haul commercial motor vehicle operations, such as fatigue, lack of sleep, poor diet, emotional conditions, stress, and concomitant illness, compound the dangers, the FMCSA has consistently held that a diabetic who uses insulin for control does not meet the minimum physical requirements of the FMCSRs.

Hypoglycemic drugs, taken orally, are sometimes prescribed for diabetic individuals to help stimulate natural body production of insulin. If the condition can be controlled by the use of oral medication and diet, then an individual may be qualified under the present rule. CMV drivers who do not meet the Federal diabetes standard may call (202) 366-1790 for an application for a diabetes exemption.
(See Conference Report on Diabetic Disorders and Commercial Drivers and Insulin-Using Commercial Motor Vehicle Drivers at:
http://www.fmcsa.dot.gov/rulesregs/medreports.htm)

Cardiovascular Condition
§391.41(b)(4)
A person is physically qualified to drive a commercial motor vehicle if that person:
Has no current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse or congestive cardiac failure.

The term "has no current clinical diagnosis of" is specifically designed to encompass: "*a clinical diagnosis of*" (1) a current cardiovascular condition, or (2) a cardiovascular condition which has not fully stabilized regardless of the time limit The term "*known to be*

accompanied by" is designed to include a clinical diagnosis of a cardiovascular disease (1) which is accompanied by symptoms of syncope, dyspnea, collapse or congestive cardiac failure; and/or (2) which is likely to cause syncope, dyspnea, collapse or congestive cardiac failure.

It is the intent of the FMCSRs to render unqualified, a driver who has a current cardiovascular disease which is accompanied by and/or likely to cause symptoms of syncope, dyspnea, collapse, or congestive cardiac failure. However, the subjective decision of whether the nature and severity of an individual's condition will likely cause symptoms of cardiovascular insufficiency is on an individual basis and qualification rests with the medical examiner and the motor carrier. In those cases where there is an occurrence of cardiovascular insufficiency (myocardial infarction, thrombosis, etc.), it is suggested before a driver is certified that he or she have a normal resting and stress electrocardiogram (ECG), no residual complications and no physical limitations, and is taking no medication likely to interfere with safe driving.

Coronary artery bypass surgery and pacemaker implantation are remedial procedures and thus, not unqualifying. Implantable cardioverter defibrillators are disqualifying due to risk of syncope. Coumadin is a medical treatment which can improve the health and safety of the driver and should not, by its use, medically disqualify the commercial driver. The emphasis should be on the underlying medical condition(s) which require treatment and the general health of the driver. The FMCSA should be contacted at (202) 366-1790 for additional recommendations regarding the physical qualification of drivers on coumadin.

(See Cardiovasular Advisory Panel Guidelines for the Medical examination of Commercial Motor Vehicle Drivers at: http://www.fmcsa.dot.gov/rulesregs/medreports.htm)

Respiratory Dysfunction
§391.41(b)(5)

A person is physically qualified to drive a commercial motor vehicle if that person:

Has no established medical history or clinical diagnosis of a respiratory dysfunction likely to interfere with ability to control and drive a commercial motor vehicle safely.

Since a driver must be alert at all times, any change in his or her mental state is in direct conflict with highway safety. Even the slightest impairment in respiratory function under emergency conditions (when greater oxygen supply is necessary for performance) may be detrimental to safe driving.

There are many conditions that interfere with oxygen exchange and may result in incapacitation, including emphysema, chronic asthma, carcinoma, tuberculosis, chronic bronchitis and sleep apnea. If the medical examiner detects a respiratory dysfunction, that in any way is likely to interfere with the driver's ability to safely control and drive a commercial motor vehicle, the driver must be referred to a specialist for further evaluation and therapy. Anticoagulation therapy for deep vein thrombosis and/or pulmonary thromboembolism is not unqualifying once optimum dose is achieved, provided lower extremity venous examinations remain normal and the treating physician gives a favorable recommendation.

(See Conference on Pulmonary/Respiratory Disorders and Commercial Drivers at: http://www.fmcsa.dot.gov/rulesregs/medreports.htm

Hypertension
§391.41(b)(6)

A person is physically qualified to drive a commercial motor vehicle if that person:

Has no current clinical diagnosis of high blood pressure likely to interfere with ability to operate a commercial motor vehicle safely.

Hypertension alone is unlikely to cause sudden collapse; however, the likelihood increases when target organ damage, particularly cerebral vascular disease, is present. This regulatory criteria is based on FMCSA's Cardiovascular Advisory Guidelines for the Examination of CMV Drivers, which used the Sixth Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (1997).

Stage 1 hypertension corresponds to a systolic BP of 140-159 mmHg and/or a diastolic BP of 90-99 mmHg. The driver with a BP in this range is at low risk for hypertension-related acute incapacitation and may be medically certified to drive for a one-year period. Certification examinations should be done annually thereafter and should be at or less than 140/90. If less than 160/100, certification may be extended one time for 3 months.

A blood pressure of 160-179 systolic and/or 100-109 diastolic is considered Stage 2 hypertension, and the driver is not necessarily unqualified during evaluation and institution of treatment. The driver is given a one time certification of three months to reduce his or her blood pressure to less than or equal to 140/90. A blood pressure in this range is an absolute indication for anti-hypertensive drug therapy. Provided treatment is well tolerated and the driver demonstrates a BP value of 140/90 or less, he or she may be certified for one year from date of the initial exam. The driver is certified annually thereafter.

A blood pressure at or greater than 180 (systolic) and 110 (diastolic) is considered Stage 3, high risk for an acute BP-related event. The driver may **not** be qualified, even temporarily, until reduced to 140/90 or less and treatment is well tolerated. The driver may be certified for 6 months and biannually (every 6 months) thereafter if at recheck BP is 140/90 or less.

Annual recertification is recommended if the medical examiner does not know the severity of hypertension prior to treatment.

An elevated blood pressure finding should be confirmed by at least two subsequent measurements on different days.

Treatment includes nonpharmacologic and pharmacologic modalities as well as counseling to reduce other risk factors. Most antihypertensive medications also have side effects, the importance of which must be judged on an individual basis. Individuals must be alerted to the hazards of these medications while driving. Side effects of somnolence or syncope are particulary undesirable in commercial drivers.

Secondary hypertension is based on the above stages. Evaluation is warranted if patient is persistently hypertensive on maximal or near-maximal doses of 2-3 pharmacologic agents. Some causes of secondary hypertension may be amenable to surgical intervention or specific pharmacologic disease.

(See Cardiovascular Advisory Panel Guidelines for the Medical Examination of Commercial Motor Vehicle Drivers at: http://www.fmcsa.dot.gov/rulesregs/medreports.htm)

Rheumatic, Arthritic, Orthopedic, Muscular, Neuromuscular or Vascular Disease §391.41(b)(7)

A person is physically qualified to drive a commercial motor vehicle if that person:

Has no established medical history or clinical diagnosis of rheumatic, arthritic, orthopedic, muscular, neuromuscular or vascular disease which interferes with the ability to control and operate a commercial motor vehicle safely.

Certain diseases are known to have acute episodes of transient muscle weakness, poor muscular coordination (ataxia), abnormal sensations (paresthesia), decreased muscular tone (hypotonia), visual disturbances and pain which may be suddenly incapacitating. With each recurring episode, these symptoms may become more pronounced and remain for longer periods of time. Other diseases have more insidious onsets and display symptoms of muscle wasting (atrophy), swelling and paresthesia which may not suddenly incapacitate a person but may restrict his/her movements and eventually interfere with the ability to safely operate a motor vehicle. In many instances these diseases are degenerative in nature or may result in deterioration of the involved area.

Once the individual has been diagnosed as having a rheumatic, arthritic, orthopedic, muscular, neuromuscular or vascular disease, then he/she has an established history of that disease. The physician, when examining an individual, should consider the following: (1) the nature and severity of the individual's condition (such as sensory loss or loss of strength); (2) the degree of limitation present (such as range of motion); (3) the likelihood of progressive limitation (not always present initially but may manifest itself over time); and (4) the likelihood of sudden incapacitation. If severe functional impairment exists, the driver does not qualify. In cases where more frequent monitoring is required, a certificate for a shorter period of time may be issued. (See Conference on Neurological Disorders and Commercial Drivers at: http://www.fmcsa.dot.gov/rulesregs/medreports.htm)

Epilepsy
§391.41(b)(8)
A person is physically qualified to drive a commercial motor vehicle if that person:
Has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a motor vehicle.

Epilepsy is a chronic functional disease characterized by seizures or episodes that occur without warning, resulting in loss of voluntary control which may lead to loss of consciousness and/or seizures. Therefore, the following drivers cannot be qualified: (1) a driver who has a medical history of epilepsy; (2) a driver who has a current clinical diagnosis of epilepsy; or (3) a driver who is taking antiseizure medication.

If an individual has had a sudden episode of a nonepileptic seizure or loss of consciousness of unknown cause which did not require antiseizure medication, the decision as to whether that person's condition will likely cause loss of consciousness or loss of ability to control a motor vehicle is made on an individual basis by the medical examiner in consultation with the treating physician. Before certification is considered, it is suggested that a 6 month waiting period elapse from the time of the episode. Following the waiting period, it is suggested that the individual have a complete neurological examination. If the results of the examination are negative and antiseizure medication is not required, then the driver may be qualified.

In those individual cases where a driver has a seizure or an episode of loss of consciousness that resulted from a known medical condition (e.g., drug reaction, high temperature, acute infectious disease, dehydration or acute metabolic disturbance), certification should be deferred until the driver has fully recovered from that condition and has no existing residual complications, and not taking antiseizure medication.

Drivers with a history of epilepsy/seizures off antiseizure medication **and** seizure-free for 10 years may be qualified to drive a CMV in interstate commerce. Interstate drivers with a history of a single unprovoked seizure may be qualified to drive a CMV in interstate commerce if seizure-free **and** off antiseizure medication for a 5-year period or more.
(See Conference on Neurological Disorders and Commercial Drivers at:
http://www.fmcsa.dot.gov/rulesregs/medreports.htm)

Mental Disorders
§391.41(b)(9)
A person is physically qualified to drive a commercial motor vehicle if that person:
Has no mental, nervous, organic or functional disease or psychiatric disorder likely to interfere with ability to drive a motor vehicle safely.

Emotional or adjustment problems contribute directly to an individual's level of memory, reasoning, attention, and judgment. These problems often underlie physical disorders. A variety of functional disorders can cause drowsiness, dizziness, confusion, weakness or paralysis that may lead to incoordination, inattention, loss of functional control and susceptibility to accidents while driving. Physical fatigue, headache, impaired coordination, recurring physical ailments and chronic "nagging" pain may be present to such a degree that certification for commercial driving is inadvisable. Somatic and psychosomatic complaints should be thoroughly examined when determining an individual's overall fitness to drive. Disorders of a periodically incapacitating nature, even in the early stages of development, may warrant disqualification.

Many bus and truck drivers have documented that "nervous trouble" related to neurotic, personality, or emotional or adjustment problems is responsible for a significant fraction of their preventable accidents. The degree to which an individual is able to appreciate, evaluate and adequately respond to environmental strain and emotional stress is critical when assessing an individual's mental alertness and flexibility to cope with the stresses of commercial motor vehicle driving.

When examining the driver, it should be kept in mind that individuals who live under chronic emotional upsets may have deeply ingrained maladaptive or erratic behavior patterns. Excessively antagonistic, instinctive, impulsive, openly aggressive, paranoid or severely depressed behavior greatly interfere with the driver's ability to drive safely. Those individuals who are highly susceptible to frequent states of emotional instability (schizophrenia, affective psychoses, paranoia, anxiety or depressive neuroses) may warrant disqualification. Careful consideration should be given to the side effects and interactions of medications in the overall qualification determination. See Psychiatric Conference Report for specific recommendations on the use of medications and potential hazards for driving.
(See Conference on Psychiatric Disorders and Commercial Drivers at:
http://www.fmcsa.dot.gov/rulesregs/medreports.htm)

Vision
§391.41(b)(10)
A person is physically qualified to drive a commercial motor vehicle if that person:
Has distant visual acuity of at least 20/40 (Snellen) in each eye with or without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70 degrees in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing standard red, green, and amber.

The term "ability to recognize the colors of" is interpreted to mean if a person can recognize and distinguish among traffic control signals and devices showing standard red, green and amber, he or she meets the minimum standard, even though he or she may have some type of color perception deficiency. If certain color perception tests are administered, (such as Ishihara, Pseudoisochromatic, Yarn) and doubtful findings are discovered, a controlled test using signal red, green and amber may be employed to determine the driver's ability to recognize these colors.

Contact lenses are permissible if there is sufficient evidence to indicate that the driver has good tolerance and is well adapted to their use. Use of a contact lens in one eye for distance visual acuity and another lens in the other eye for near vision is not acceptable, nor telescopic lenses acceptable for the driving of commercial motor vehicles.

If an individual meets the criteria by the use of glasses or contact lenses, the following statement shall appear on the Medical Examiner's Certificate: "Qualified only if wearing corrective lenses."

CMV drivers who do not meet the Federal vision standard may call (202) 366-1790 for an application for a vision exemption.
(See Visual Disorders and Commercial Drivers at:
http://www.fmcsa.dot.gov/rulesregs/medreports.htm)

Hearing
§391.41(b)(11)
A person is physically qualified to drive a commercial motor vehicle if that person:
First perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid, or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ADA Standard) Z24.5-1951.

Since the prescribed standard under the FMCSRs is the American Standards Association (ANSI), it may be necessary to convert the audiometric results from the ISO standard to the ANSI standard. Instructions are included on the Medical Examination report form.

If an individual meets the criteria by using a hearing aid, the driver must wear that hearing aid and have it in operation at all times while driving. Also, the driver must be in possession of a spare power source for the hearing aid.

For the whispered voice test, the individual should be stationed at least 5 feet from the examiner with the ear being tested turned toward the examiner. The other ear is covered. Using the breath which remains after a normal expiration, the examiner whispers words or random numbers such as 66, 18,

23, etc. The examiner should not use only sibilants (s sounding materials). The opposite ear should be tested in the same manner. If the individual fails the whispered voice test, the audiometric test should be administered.

If an individual meets the criteria by the use of a hearing aid, the following statement must appear on the Medical Examiner's Certificate "Qualified only when wearing a hearing aid." (See Hearing Disorders and Commercial Motor Vehicle Drivers at: http://www/fmcsa.dot.gov/rulesregs/medreports.htm)

Drug Use
§391.41(b)(12)
A person is physically qualified to drive a commercial motor vehicle if that person does not use any controlled substance identified in 21 CFR 1308.11, an amphetamine, a narcotic, or other habit-forming drug. A driver may use a non-Schedule I substance or drug, if the substance or drug is prescribed by a licensed medical practitioner who: (A) is familiar with the driver's medical history, and assigned duties; and (B) has advised the driver that the prescribed substance or drug will not adversely affect the driver's ability to safely operate a commercial motor vehicle.

This exception does not apply to methadone. The intent of the medical certification process is to medically evaluate a driver to ensure that the driver has no medical condition which interferes with the safe performance of driving tasks on a public road. If a driver uses a Schedule I drug or other substance, an amphetamine, a narcotic, or any other habit-forming drug, it may be cause for the driver to be found medically unqualified. Motor carriers are encouraged to obtain a practitioner's written statement about the effects on transportation safety of the use of a particular drug.

A test for controlled substances is not required as part of this biennial certification process. The FMCSA or the driver's employer should be contacted directly for information on controlled substances and alcohol testing under Part 382 of the FMCSRs.

The term "uses" is designed to encompass instances of prohibited drug use determined by a physician through established medical means. This may or may not involve body fluid testing. If body fluid testing takes place, positive test results should be confirmed by a second test of greater specificity. The term "habit-forming" is intended to include any drug or medication generally recognized as capable of becoming habitual, and which may impair the user's ability to operate a commercial motor vehicle safely.

The driver is medically unqualified for the duration of the prohibited drug(s) use and until a second examination shows the driver is free from the prohibited drug(s) use. Recertification may involve a substance abuse evaluation, the successful completion of a drug rehabilitation program, and a negative drug test result. Additionally, given that the certification period is normally two years, the examiner has the option to certify for a period of less than 2 years if this examiner determines more frequent monitoring is required.
(See Conference on Neurological Disorders and Commercial Drivers and Conference on Psychiatric Disorders and Commercial Drivers at: http://www.fmcsa.dot.gov/rulesregs/medreports.htm)

Alcoholism
§391.41(b)(13)
A person is physically qualified to drive a commercial motor vehicle if that person:
Has no current clinical diagnosis of alcoholism.

The term "current clinical diagnosis of" is specifically designed to encompass a current alcoholic illness or those instances where the individual's physical condition has not fully stabilized, regardless of the time element. If an individual shows signs of having an alcohol-use problem, he or she should be referred to a specialist. After counseling and/or treatment, he or she may be considered for certification.

BILLING CODE 4910–EX–C

* * * * *

Issued on: July 5, 2011.

William Bronrott,

Deputy Administrator.

[FR Doc. 2011–17192 Filed 7–7–11; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Chapter II

[Docket No. FRA–2009–0038]

RIN 2130–AC11

Risk Reduction Program

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of public hearings.

SUMMARY: FRA is announcing public hearings to provide interested persons an opportunity to discuss the development of a regulation requiring certain railroads to develop a Risk Reduction Program (RRP). The Rail Safety Improvement Act of 2008 requires the development and implementation of railroad safety risk reduction programs. Risk reduction is a comprehensive, system-oriented approach to safety that (1) determines an operation's level of risk by identifying and analyzing applicable hazards and (2) develops plans to mitigate that risk. Each RRP is statutorily required to be supported by a risk analysis and a Risk Reduction Program Plan (RRPP), which must include a Technology Implementation Plan and a Fatigue Management Plan.

DATES: To encourage participation, two public hearings will be held. A public hearing will be held on July 19, 2011, in Chicago, and a public hearing will be held on July 21, 2011, in Washington, DC. At both locations, the times of the public hearings will be from 9 a.m. to 4 p.m.

ADDRESSES: *Public Hearings.* The public hearing in Chicago will be held at the W Chicago City Center Hotel located at 172 West Adams, in the Great Room I, Plateau. The public hearing in Washington, DC, will be held at the Doubletree Hotel located at 1515 Rhode Island Avenue, NW., in the Terrace Ballroom.

Attendance: Any persons wishing to make a statement at the hearing should notify FRA's Docket Clerk, Michelle Silva, by telephone, e-mail, or in writing, at least five business days before the date of the hearing. Ms. Silva's contact information is as follows: FRA, Office of Chief Counsel, Mail Stop 10, 1200 New Jersey Avenue, SE., Washington, DC 20590; *telephone:* 202–493–6030; *e-mail: michelle.silva@dot.gov.* For information on facilities or services for persons with disabilities or to request special assistance at the meetings, please contact by telephone or e-mail as soon as possible, Wendy A. Noble Burns at 202–493–6304 or *wendy.noble@dot.gov.*

FOR FURTHER INFORMATION CONTACT: Miriam Kloeppel, Staff Director, Risk Reduction Program Division, Office of Safety Analysis, FRA, 1200 New Jersey Avenue, SE., Mail Stop 25, Washington, DC 20590; *telephone:* 202–493–6224; e-mail: *miriam.kloeppel@dot.gov;* or Matthew L. Navarrete, Trial Attorney, Office of Chief Counsel, FRA, 1200 New Jersey Avenue, SE., Mail Stop 10, Washington, DC 20590; *telephone:* 202–493–0138; *e-mail: matthew.navarrete@dot.gov.*

SUPPLEMENTARY INFORMATION: Interested parties are invited to present oral statements and to proffer information and views at the hearings. The hearings will be informal and will be conducted by a representative designated by FRA in accordance with FRA's Rules of Practice (49 CFR 211.25). The hearings will be non-adversarial proceedings; therefore, there will be no cross examination of persons presenting statements or proffering evidence. An FRA representative will make an opening statement outlining the scope of each hearing. After all initial statements have been completed, those persons wishing to make a brief rebuttal will be given the opportunity to do so in the same order in which the initial statements were made. Additional procedures, as necessary for the conduct of the hearings, will be announced at the hearings. The purpose of these hearings is to receive oral comments in response to an Advanced Notice of Proposed Rulemaking (ANPRM) that requested public comment on a potential risk reduction rulemaking. *See* 75 FR 76345–76351, Dec. 8, 2010. A transcript of the discussions will be made part of the public docket in this proceeding.

Public Participation Procedures. Any person wishing to participate in one of the public hearings should notify the Docket Clerk by mail or at the address or fax number provided in the Attendance section at least five working days prior to the date of the hearing and submit three copies of the oral statement that he or she intends to make at the proceeding. The notification should identify the party the person represents, the particular subject(s) the person plans to address, and the time requested. The notification should also provide the Docket Clerk with the participant's mailing address and other contact information. FRA reserves the right to limit participation in the hearings of persons who fail to provide such notification. FRA reserves the right to limit the duration of presentations if necessary to afford all persons with the opportunity to speak.

Background

In § 103 of the Rail Safety Improvement Act of 2008, Public Law 110–432, 122 Stat. 4854 (Oct. 16, 2008) (codified at 49 U.S.C. 20156) (hereinafter RSIA), Congress directed the Secretary of Transportation to issue a regulation by October 16, 2012, requiring certain railroads to develop an RRP. While the statute vests certain responsibilities with the Secretary of the U.S. DOT (Secretary), the Secretary has since delegated those responsibilities to the FRA Administrator. *See* 49 CFR 1.49(oo); 74 FR 26981 (June 5, 2009); *see also* 49 U.S.C. 103(g).

Each railroad subject to the regulation would have to develop and implement an RRP approved by FRA. *See* 49 U.S.C. 20156(a)(1). This RRP is required to be supported by an RRPP. *See* 49 U.S.C. 20156(d)(2). FRA would conduct an annual review to ensure that each railroad has complied with its RRP. *See* 49 U.S.C. 20156(a)(3). The RSIA mandates that the following three categories of railroads be required to develop and implement an FRA-approved RRP:

(1) Class I railroads;

(2) Railroad carriers with inadequate safety performance, as determined by the Secretary; and

(3) Railroad carriers that provide intercity rail passenger or commuter rail passenger transportation (passenger railroads).

See 49 U.S.C. 20156(a)(1).

Railroads not required to implement RRPs under the RSIA would be permitted to voluntarily submit plans meeting the requirements of any final RRP regulation for FRA review and approval. *See* 49 U.S.C. 20156(a)(4).

On December 8, 2010, FRA published an ANPRM soliciting public comment on how FRA can best develop a risk reduction regulation based upon the RSIA's requirements. *See* 75 FR 76345–76351. The ANPRM discussed certain major components that must be included in the final rule under the RSIA and identified various approaches that FRA could take in developing the rule. The purpose of these hearings is to

receive oral comment in response to the issues discussed in the ANPRM.

FRA encourages all interested persons to participate in one of these hearings, at the addresses noted above. We encourage participants wishing to make oral statements to plan on attending an entire hearing, since FRA may not be able to accommodate competing requests to appear at specific times.

Issued in Washington, DC, on June 29, 2011.

Jo Strang,

Associate Administrator for Railroad Safety/ Chief Safety Officer, Federal Railroad Administration.

[FR Doc. 2011–16983 Filed 7–7–11; 8:45 am]

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Notices

Federal Register

Vol. 76, No. 131

Friday, July 8, 2011

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

Forest Service

Mt. Hood Meadows Ski Resort Parking Improvements

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Mt. Hood National Forest (Forest) will prepare an Environmental Impact Statement (EIS) to document and disclose the potential environmental effects of improving the parking at Mt. Hood Meadows Ski Resort. The proposed action is to construct the Twilight Parking Lot, an eight-acre parking lot for both downhill and Nordic customers at Mt Hood Meadows Ski Area. An additional 4.5 acres would be cleared for access roads, cut/fill slopes, storm water swales, snow storage, and an equipment maintenance yard. In addition, the proposed action includes the construction of the new Sunrise Vehicle Maintenance Shop on the north side of the Sunrise parking lot.

DATES: Comments concerning the scope of this analysis must be received no later than August 8, 2011 to ensure they are fully incorporated into the Draft EIS.

ADDRESSES: Please send your written comments to: Jennie O'Connor Card, Mt. Hood Meadows Ski Resort Parking Improvements Team Leader, 6780 Highway 35, Parkdale, Oregon 97041; *Fax:* (541) 352–7365. You may also hand-deliver your comments to the above address during normal business hours from 8 a.m. to 4:30 Monday through Friday, excluding federal holidays. Electronic comments may be submitted to *comments-pacific northwest-mthood-hoodriver@fs.fed.us* in a format such as an e-mail message, plain text (.txt), rich text format (.rtf), or Word (.doc).

FOR FURTHER INFORMATION CONTACT: Jennie O'Connor Card, Natural Resource Planner, Mt. Hood National Forest, 6780 Highway 35, Parkdale, Oregon 97041 or by e-mailing *jennieoconnorcard@fs.fed.us* or by calling (541) 352–1255.

SUPPLEMENTARY INFORMATION:

Need for the Proposal

The overall purpose of this project is to improve public and customer safety by increasing parking capacity and improving traffic flow in at Mt. Hood Meadows Ski Resort. Parking capacity would be increased by building the new Twilight Parking Lot and by moving the vehicle maintenance operations from the main lot to an alternate location. Also, traffic flow would be improved by constructing a left turn lane for northbound traffic turning onto the Mt. Hood Meadows Access Road.

Specific management objectives and underlying needs are to:

- Provide for public and customer safety by improving parking capacity;
- Provide for public safety on Highway 35 by constructing a left turn lane, with adequate vehicle capacity, for ski traffic waiting to turn onto the Mt. Hood Meadows Access Road;
- Provide additional parking, including area for snow storage, to serve the design capacity that was conceptually approved in the Record of Decision for the Mt. Hood Meadows Ski Area Master Plan published in 1997 while also minimizing environmental impact from parking lot construction and maintenance; and,
- Separate the industrial bus parking and vehicle maintenance functions away from public areas at the Mt Hood Meadows Main Parking lot to further improve safety and parking capacity.

Proposed Action

The Proposed Action is to construct the Twilight Parking Lot, an eight-acre parking lot for both downhill and Nordic customers at Mt Hood Meadows Ski Area (see attached map). An additional 4.5 acres would be cleared for access roads, cut/fill slopes, storm water swales, snow storage, and an equipment maintenance yard. In order to facilitate the building of the new parking lot, the following actions are included in the proposal.

- Construct a one-half acre equipment maintenance yard including bus and snow equipment parking, and equipment maintenance building.
- Construct a Guest Services building to serve both downhill and Nordic customers. Services to be provided include: bathrooms, lockers, limited food and beverage services, guest seating, Nordic equipment rental, and covered bus stop.
- Construct a left turn lane with adequate vehicle storage for north bound traffic at the intersection of Highway 35 and the Mt. Hood Meadows Access Road (Forest Service Road 3545).
- Bury utility lines from existing Nordic Center to the Twilight Lot in two 36-inch deep trenches separated by at least 10-feet following existing clearings.
- Construct 0.42 miles of Nordic ski trails (to replace trail segments bisected by the proposed parking area). New trails would result in disturbance of an additional 2.75 acres. There would be no net loss of Nordic ski trails.
- Any live whitebark pine trees that are removed as part of this project would be transplanted within the MHM permit area, if feasible. If it is not feasible to transplant the impacted whitebark pine, a new rust resistant seedling would be planted within the permit area.

The equipment maintenance associated with the Twilight Parking Lot is light maintenance and de-icing/washing of buses and snow removal equipment. In addition to the new Twilight Parking Lot, the Proposed Action includes the construction of the new Sunrise Vehicle Maintenance Shop on the north side of the Sunrise parking lot to provide maintenance services for snow cats and a location for larger maintenance needs (see attached map). The existing shop, built in 1967, is not large enough to service the number and size of the present snow cat, snowmobile, truck, and bus fleet. Also, the location of the current maintenance shop impedes traffic flow and removes potential parking capacity at the main lot. The new facility would include a fueling station and storm water management system. A water supply line and fiber optic communication line would be buried from the Administration building to the shop following the route of existing buried power line. The maintenance shop would provide adequate capacity for the size of the current and projected future fleet.

The existing maintenance shop initially would be used for storage and eventually redeveloped for skier

services. The existing maintenance shop has three underground fuel storage tanks. Two of the tanks would be moved to the new maintenance facilities for the fueling operation at the new Sunrise Maintenance Shop. The area would be decommissioned per Oregon Department of Environmental Quality (DEQ) standards. One of the existing tanks would remain for fuel for the emergency power generators. It will be maintained, as it is now, per DEQ standards. The redevelopment of the building for skier services would require additional site-specific NEPA as required by the ROD, if any additional exterior improvements or changes are made to the building.

The Proposed Action would be implemented as described below:

- Remove trees and vegetation from a 12.5-acres site near the state sand shed for parking for the Twilight Parking Lot, storm water treatment, snow storage, circulation, buildings, and access roads. Pile and burn stumps and slash.
- Remove trees from 2.8-acres to replace nordic trails impacted by parking lot construction. Flush cut or grind stumps, scatter or hand pile and burn slash, minimize damage to existing low growing vegetation.
- Remove trees from 1.8-acre site next to Sunrise Lot for the vehicle maintenance shop. Pile and burn stumps and slash.
- Install silt fence and other construction Best Mangement Practices (BMP) in compliance with erosion control plan.
- Stockpile topsoil within the disturbed areas. Grade areas to prepare for surfacing then place saved topsoil on cut and fill slopes.
- Hydro-seed disturbed areas with approved native vegetation. Place jute matting on steep slopes.
- Place gravel sub-grade and install asphalt.
- Construct buildings.
- Twilight utility line installation would result in 1.1-acres of disturbance within an existing ski trail
- Sunrise utility line installation would result in 0.38-acres of disturbance in an existing buried power line corridor.
- Include passive storm water treatment features into design of project.
- The fill associated with these projects would be used and balanced between the Twilight Park Lot, Sunrise Maintenance Shop and Highway 35 left turn lane.

The total disturbance associated with this project is approximately 18 acres. All projects would occur within the Mt. Hood Meadows Ski Resort Permit Area. The entire permit area occurs on A11–Winter Recreation Area according to the Mt. Hood National Forest Land and Resource Management Plan (Forest Plan). The proposed projects meet the standards and guidelines for this land use allocation. The legal description of these projects is: Sections 10 & 11, T3S, R 9E.

Proposed Scoping

As directed by the National Environmental Policy Act (1969), the Forest Service is now seeking comments from individuals, organizations, local and state governments, and other federal agencies that may be interested in or affected by the proposed action. Comments may pertain to the nature and scope of the environmental, social, and economic issues, and possible alternatives to the proposed action. Comments will help the Forest Service assess the proposed action, develop alternatives and prepare a draft environmental impact statement.

Alternatives Considered

The No Action alternative will serve as a baseline for comparison of alternatives. This alternative will offer no changes to the parking within the permit area. It will be fully developed and analyzed. The proposed action, as described above will be considered as an alternative. Additional alternatives may be developed around the proposed action to address key issues identified in the scoping and public involvement process.

Estimated Dates for Draft and Final EIS

The draft EIS is expected to be filed with the Environmental Protection Agency (EPA) and to be available for public comment by April 2012. The comment period on the draft EIS will be 45 days from the date the EPA publishes the notice of availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of the draft EIS must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC.* 435 U.S. 519. 553 (1978). Also, environmental objectives that could be raised at the draft EIS stage but that are not raised until after the completion of the final EIS may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F. 2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritage, Inc.* v. *Harris,* 490 F. Supp. 1334 (E.D.Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period; so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final EIS.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft EIS should be as specific as possible. It is also helpful if the comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft EIS or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provision of the National Environmental Policy Act (40 CFR 1503.3).

Comments received in response to this solicitation, including names and addresses of those who comment, will be considered part of the public record on this proposed action and will be available for public inspection. Comments submitted anonymously will be accepted and considered; however, those who submit anonymous comments may not have standing to appeal the subsequent decision under 36 CFR Part 215. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of Information Act (FOIA) permits such confidentiality. Persons requesting such confidentiality should be aware that, under the FOIA, confidentiality may be granted in only very limited circumstances, such as to protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request for confidentiality, and where the request is denied, the agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address within a specified number of days.

Comments on the draft EIS will be analyzed, considered, and responded to by the Forest Service in preparing the final EIS. The final EIS is scheduled to be completed in November 2012. The Responsible Official will be Daina Bambe, Hood River District Ranger on the Mt. Hood National Forest. She will consider comments, responses, environmental consequences discussed in the final EIS, and applicable laws, regulations, and policies in making a decision regarding this proposed action.

The responsible official will document the decision and rationale for the decision in the Record of Decision. It will be subject to Forest Service Appeal Regulations (36 CFR Part 215).

Dated: June 29, 2011.

Daina L. Bambe,

Hood River District Ranger, Mt. Hood National Forest.

[FR Doc. 2011–17143 Filed 7–7–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Forest Service

Ravalli County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Ravalli County Resource Advisory Committee will meet in Hamilton, Montana. The purpose of the meeting is project discussion and presentations.

DATES: The meeting will be held August 23, 2011 at 6:30 p.m.

ADDRESSES: The meeting will be held at 1801 N. First Street. Written comments should be sent to Stevensville RD, 88 Main Street, Stevensville, MT 59870. Comments may also be sent via e-mail to *dritter@fs.fed.us* or via facsimile to 406–777–5461.

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 88 Main Street, Stevensville, MT. Visitors are encouraged to call ahead to 406–777–5461 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Dan Ritter, District Ranger, 406–777–7410 or Nancy Trotter, RAC coordinator, 406–777–7413.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Council discussion is limited to Forest Service staff and Council members. However, persons who wish to bring concerns to the attention of the Council may file written statements with the Council staff before or after the meeting. Public input sessions will be provided and individuals who made written requests by August 22, 2011 will have the opportunity to address the Council at those sessions.

Dated: July 1, 2011.

Julie K. King,

Forest Supervisor.

[FR Doc. 2011–17198 Filed 7–7–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Economic Surveys of American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands (CNMI) Small Boat-based Fisheries.

OMB Control Number: None.

Form Number(s): NA.

Type of Request: Regular submission (request for a new information collection).

Number of Respondents: 366.

Average Hours per Response: 10 minutes.

Burden Hours: 160.

Needs and Uses: The National Marine Fisheries Service (NMFS) proposes to collect information about fishing expenses in the American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands (CNMI) boat-based reef fish, bottomfish, and pelagics fisheries with which to conduct economic analyses that will improve fishery management in those fisheries; satisfy NMFS' legal mandates under Executive Order 12866, the Magnuson-Steven Fishery Conservation and Management Act (U.S.C. 1801 et seq.), the Regulatory Flexibility Act, the Endangered Species Act, and the National Environmental Policy Act; and quantify achievement of the performances measures in the NMFS Strategic Operating Plans. An example of these performance measures: The economic data collected will allow quantitative assessment of the fisheries sector's social and economic contribution, linkages and impacts of the fisheries sector to the overall economy through Input-output (I–O) models analyses. Results from I–O analyses will not only provide indicators of social-economic benefits of the marine ecosystem, a performance measure in the NMFS Strategic Operating Plans, but also be used to assess how fishermen and economy will be impacted by and respond to regulations likely to be considered by fishery managers. These data will be collected in conjunction with catch and effort data already being collected in this fishery as part of a creel survey program.[1]

Affected Public: Business or other for-profit organizations.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: *OIRA_Submission@omb.eop.gov.*

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov.*

Dated: July 5, 2011.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2011–17177 Filed 7–7–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–855]

Diamond Sawblades and Parts Thereof From the Republic of Korea: Extension of Time Limit for the Preliminary Results of the Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* July 8, 2011.

FOR FURTHER INFORMATION CONTACT: Scott Holland or Chris Siepmann, AD/CVD Operations, Office 1, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–1279 and (202) 482–7958, respectively.

SUPPLEMENTARY INFORMATION:

[1] The Creel Survey Program is one of the major data collection systems to monitor fisheries resources in these three geographic areas. The survey monitors the islands' fishing activities and interviews returning fishermen at the most active launching ramps/docks during selected time periods on the islands.

Background

On December 28, 2010, the U.S. Department of Commerce (''Department'') published a notice of initiation of administrative review of the antidumping duty order on diamond sawblades and parts thereof from the Republic of Korea, covering the period January 23, 2009, through October 31, 2010. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation In Part,* 75 FR 81565 (December 28, 2010). The preliminary results of this administrative review are currently due no later than August 2, 2011.

Statutory Time Limits

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act''), requires the Department to issue the preliminary results of an administrative review within 245 days after the last day of the anniversary month of an order for which a review is requested and issue the final results within 120 days after the date on which the preliminary results are published. However, if it is not practicable to complete the review within the time period, section 751(a)(3)(A) of the Act allows the Department to extend these deadlines to a maximum of 365 days and 180 days, respectively.

Extension of Time Limit for Preliminary Results

The Department devoted substantial time to resolving model-matching issues earlier in this proceeding and requires additional time to analyze the complex issues in this case, such as the further manufacturing performed by some of the respondents. Therefore, it is not practicable to complete the preliminary results of this review within the original time limit, and the Department is extending the time limit for completion of the preliminary results by 120 days. The preliminary results will now be due no later than November 30, 2011, which is 120 days from the current deadline. The final results continue to be due 120 days after the publication of the preliminary results.

This notice is issued and published in accordance with sections 751(a)(3)(A) and 777(i)(1) of the Act.

Dated: July 1, 2011.

Gary Taverman,

Acting Deputy Assistant Secretary for Antidumping and Antidumping Duty Operations.

[FR Doc. 2011–17211 Filed 7–7–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–807]

Polyethylene Terephthalate Film, Sheet, and Strip From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on polyethylene terephthalate film, sheet and strip (PET film) from the Republic of Korea (Korea). This review covers one company, Kolon Industries Inc. (Kolon) for the period of review (POR) of June 1, 2009, through May 31, 2010. We preliminarily determine that Kolon has made sales below normal value (NV). The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

Interested parties are invited to comment on these preliminary results. We will issue the final results no later than 120 days from the date of publication of this notice.

DATES: *Effective Date:* July 8, 2011.

FOR FURTHER INFORMATION CONTACT: Tyler Weinhold or Robert James, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–1121 or (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION:

Background

On, June 1, 2010, the Department published in the **Federal Register** notice of opportunity to request an administrative review of the antidumping duty order on PET film from Korea. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 75 FR 30383 (June 1, 2010).

In accordance with section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b)(2), on June 30, 2010, Kolon requested an administrative review of the antidumping duty order on PET film from Korea, and requested that the Department revoke the antidumping duty order with regard to Kolon.

On July 28, 2010, the Department initiated an administrative review for Kolon for the POR. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocations in Part,* 75 FR 44224 (July 28, 2010).

On August 9, 2010, we issued our antidumping questionnaire to Kolon. We received Kolon's response to section A of our questionnaire on September 14, 2010 (Kolon's section A response). We received Kolon's response to sections B, C, and D of our questionnaire on October 4, 2010 (Kolon's section B, C, and D response). On January 14, 2011, we issued a supplemental questionnaire to Kolon which covered sections A through C. Kolon responded to this supplemental questionnaire on February 22, 2011 (Kolon's February 22, 2011 response). On June 21, 2011, we issued a supplemental questionnaire to Kolon which covered elements of section B. Kolon responded to this supplemental questionnaire on June 27, 2011

On January 25, 2011, we extended the deadline for the preliminary results of this review until no later than June 30, 2011. *See Polyethylene Terephthalate Film, Sheet, and Strip From the Republic of Korea: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Review,* 76 FR 4288 (January 25, 2011).

Verification

Between March 23, 2011 and March 25, 2011, the Department verified Kolon's questionnaire responses at Kolon's U.S. reseller, Kolon USA, at Kolon USA's headquarters in Fairfield, New Jersey. *See* Memorandum from Tyler Weinhold and Scott Hoefke to Richard Weible Regarding ''Verification of the Cost of Production and constructed Value Data Submitted by Kolon industries, Inc. in the Review of Polyethylene Terephalate (PET) Film from South Korea,'' which will soon be released. Between April 4, 2011, and April 8, 2011, the Department verified Kolon's questionnaire responses at Kolon's headquarters in Kwachon, Kyonggi-Do, Korea. *See* Memorandum from Tyler Weinhold and Scott Hoefke to Richard Weible Regarding ''Verification of the Cost of Production and constructed Value Data Submitted by Kolon industries, Inc. in the Review of Polyethylene Terephalate (PET) Film from South Korea,'' which will soon be released. Between April 25, 2011, and April 29, 2011, the Department also verified Kolon's questionnaire responses regarding its costs of production and constructed value data at Kolon's

headquarters in Kwachon, Kyonggi-Do, Korea. *See* Memorandum from Christopher Zimpo and Theresa Deeley to Neal Halper, regarding ''Verification of the Cost of Production and constructed Value Data Submitted by Kolon industries, Inc. in the Review of Polyethylene Terephalate (PET) Film from South Korea,'' dated June 30, 2011 (Cost Calculation Memorandum).

Requests for Revocation, In Part

In its request for this review, Kolon requested that the order be partially revoked with respect to Kolon. Kolon argued that assuming that it had maintained three consecutive years of sales at not less than NV, the company would be eligible for revocation under section 751(d) of the Act and 19 CFR 351.222(b)(2). We preliminarily determine not to revoke the order with respect to Kolon. 19 CFR 351.222(b)(2) sets out rules and procedures for possible partial revocation of a dumping order under section 751(d) of the Act if a respondent has maintained three consecutive years of sales at not less than NV. In its request for revocation, Kolon argued that with the completion of this review, it would have maintained three consecutive years of sales at not less than NV and would, therefore, be eligible for revocation under section 751(d)(1) of the Act and 19 CFR 351.222(b)(2). Kolon was found to have had *de minimus* margins of dumping (below 0.5 percent) in the two administrative reviews immediately prior to the instant administrative review. However, for these preliminary results, based on sales and production data provided by Kolon, and as adjusted by the Department, we have calculated a non-*de minimis* margin for Kolon, *i.e.,* 0.81 percent. Therefore, under section 751(d)(1) of the Act and 19 CFR 351.222(b)(2), we have preliminarily determined not to revoke the order with respect to Kolon.

Scope of the Order

Imports covered by this order are shipments of all gauges of raw, pretreated, or primed polyethylene terephthalate film, sheet, and strip, whether extruded or coextruded. The films excluded from this review are metallized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer more than 0.00001 inches (0.254 micrometers) thick.

PET film is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheading 3920.62.00. The HTSUS subheading is provided for convenience and for customs purposes. The written description remains dispositive as to the scope of the product coverage.

Period of Review

The POR is June 1, 2009, to May 31, 2010.

Comparisons to Normal Value

To determine whether sales of PET film from Korea to the United States were made at less than normal value (NV), we compared Kolon's constructed export price (CEP) or export price (EP) sales made in the United States to unaffiliated purchasers to NV, as described in the ''United States Price'' and ''Normal Value'' sections of this notice, below. In accordance with section 777A(d)(2) of the Act, we compared the CEP and EP of individual transactions to monthly weighted-average NVs.

Product Comparisons

In accordance with section 771(16) of the Act we considered all products produced by Kolon covered by the description in the ''Scope of the Order'' section, above, and sold in the home market during the POR, to be foreign like products for purposes of determining appropriate product comparisons to U.S. sales. We first attempted to compare contemporaneous U.S. and comparison-market sales of products that are identical with respect to the following characteristics: (1) Specification; (2) thickness; (3) surface treatment; and (4) grade. Consistent with the methodology employed in the 2008 to 2009 administrative review of this order, and in the less than fair value (LTFV) investigation of PET film from Thailand, we used the actual thicknesses of the film rather than a range of thicknesses for product comparison purposes. *See Polyethylene Terephthalate Film, Sheet, and Strip from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review,* 75 FR 40784 (July 14, 2010) (unchanged in the *Final Results,* 75 FR 70901 (November 19, 2010)) and *Notice of Preliminary Determination of Sales at Not Less Than Fair Value: Polyethylene Terephthalate Film, Sheet, and Strip from Thailand,* 73 FR 24565, 24567 (May 5, 2008) (unchanged in the *Final Determination,* 73 FR 64912 (October 31, 2008)). Where we were unable to compare sales of identical merchandise, we compared U.S. sales to home market sales of the most similar merchandise based on the above characteristics. Where there were no sales of the foreign like product of the identical merchandise in the ordinary course of trade in the home market to compare to a U.S. sale, we compared the price of the U.S. sale to constructed value (CV).

Level of Trade

In accordance with section 773(a)(1)(B) of the Act, to the extent practicable, we base NV on sales made in the home market at the same level of trade (LOT) as the CEP or EP sales in the U.S. market. The NV LOT is defined as the starting-price sales in the home market or, when NV is based on CV, as the sales from which selling, general, and administrative (SG&A) expenses and profit are derived. *See* 19 CFR 351.412(c)(1). The EP LOT is defined as the starting price in the United States to the unaffiliated U.S. customer. *See id.* With respect to CEP transactions in the U.S. market, the CEP LOT is defined as the level of the constructed sale from the exporter to the importer. *See* 19 CFR 351.412(c)(1)(ii).

To determine whether home market sales are at a different LOT than CEP sales, we examine stages in the marketing process and selling functions along the chain of distribution between the producer and the unaffiliated customer. *See* 19 CFR 351.412(c)(2). If the home-market sales are at different LOTs, and the difference affects price comparability, as manifested in a pattern of consistent price differences between the sales on which NV is based and comparison-market sales at the LOT of the export transaction, we make a LOT adjustment under section 773(a)(7)(A) of the Act. For CEP sales, if the NV level is more remote from the factory than the CEP level and there is no basis for determining whether the difference in the levels between NV and CEP affects price comparability, we adjust NV under section 773(a)(7)(B) of the Act (the CEP offset provision). *See, e.g., Certain Hot-Rolled Flat-Rolled Carbon Quality Steel Products from Brazil; Preliminary Results of Antidumping Duty Administrative Review,* 70 FR 17406, 17410 (April 6, 2005); unchanged in *Notice of Final Results of Antidumping Duty Administrative Review: Certain Hot-Rolled Flat-Rolled Carbon Quality Steel Products from Brazil,* 70 FR 58683 (October 7, 2005). For CEP sales, we consider only the selling activities reflected in the price after the deduction of expenses and CEP profit under section 772(d) of the Act. *See Micron Technology, Inc.* v. *United States,* 243 F.3d 1301, 1314–1315 (Fed. Cir. 2001). We expect that if the LOTs claimed by the respondent are the same, the functions and activities of the seller should be similar. Conversely, if a party claims that the LOTs are different for

different groups of sales, the functions and activities of the seller should be dissimilar. *See Porcelain-on-Steel Cookware from Mexico: Final Results of Administrative Review,* 65 FR 30068 (May 10, 2000) and accompanying Issues and Decisions Memorandum at Comment 6.

We obtained information from Kolon regarding the marketing stages involved in making its reported foreign market and U.S. sales to unaffiliated customers. Kolon provided a description of all selling activities performed, along with a flowchart and tables comparing the LOTs among each channel of distribution and customer category for both markets. *See* Kolon's section A response at Exhibit A–12.

For the home market, Kolon identified two channels of distribution described as follows: (1) Direct shipments (*i.e.,* products produced to order); and (2) warehouse shipments from inventory. *Id.* Within each of these two channels of distribution, Kolon made sales to unaffiliated customers. *Id.* We reviewed the level at which Kolon performed each of these selling functions with respect to each claimed channel of distribution and customer category. For all of the activities listed (which included sales forecasting, strategic/economic planning, sales promotion, packing, inventory maintenance, order input/processing, direct sales personnel, sales/marketing support, market research, technical assistance, warranty service, and freight and delivery), the level of performance for both direct shipments and warehouse shipments was identical across all types of customers. Based on our analysis of all of Kolon's home market selling functions, we find all home market sales were made at a single LOT, the home market LOT. We also found that Kolon provided a similar level of selling functions on all of its EP sales, and that the level of these EP selling functions was comparable to the level of selling functions Kolon performed on its home market sales. Based on the foregoing, we determine there is one LOT for Kolon's EP sales and that the EP LOT is comparable to the home market LOT.

Kolon also indicated it made CEP sales through its U.S. affiliate, Kolon USA. *Id.* We then compared the CEP LOT to the NV LOT. The CEP LOT is based on the selling activities associated with the transaction between Kolon and its affiliated importer, Kolon USA, whereas the NV LOT is based on the selling activities associated with the transactions between Kolon and unaffiliated customers in the home market. Our analysis indicates the selling functions performed for sales to unaffiliated home market customers are either performed at a higher degree of intensity or are greater in number than the selling functions performed for sales to Kolon USA. For example, in comparing Kolon's selling activities, we find there are several functions performed in the home market which are a performed to a lesser degree for CEP transactions. For selling activities performed for both home market sales and CEP sales (which included sales forecasting, strategic/economic planning, sales promotion, packing, inventory maintenance, order input/processing, direct sales personnel, sales/marketing support, market research, technical assistance, warranty service, and freight and delivery), we find Kolon performed each activity except packing, order input/processing, and freight and delivery at a higher level of intensity in the home market.

We note that CEP sales from Kolon to Kolon USA generally occur at the beginning of the distribution chain, representing essentially a logistical transfer of inventory that resembles ex-factory sales. In contrast, all sales in the home market occur closer to the end of the distribution chain and involve smaller volumes and more customer interaction which, in turn, require the performance of more selling functions. *Id.* Based on the foregoing, we conclude that the NV LOT is at a more advanced stage than the CEP LOT. Because we found the home market and CEP sales were made at different LOTs, we examined whether a LOT adjustment or a CEP offset may be appropriate in this review. As we found only one LOT in the home market, it was not possible to make a LOT adjustment to home market prices, because such an adjustment is dependent on our ability to identify a pattern of consistent price differences between the home market sales on which NV is based and home market sales at the LOT of the export transaction. *See* 19 CFR 351.412(d)(1). Furthermore, we have no other information that provides an appropriate basis for determining a LOT adjustment. Because the data available do not form an appropriate basis for making a LOT adjustment, and because the NV LOT is at a more advanced stage of distribution than the CEP LOT, we have made a CEP offset to NV in accordance with section 773(a)(7)(B) of the Act.

United States Price

Section 772(a) of the Act defines EP as ''the price at which the subject merchandise is first sold (or agreed to be sold) before the date of importation by the producer or exporter of the subject merchandise outside of the United States to an unaffiliated purchaser in the United States or to an unaffiliated purchaser for exportation to the United States, as adjusted under subsection (c) of this section.'' Section 772(b) of the Act defines CEP as ''the price at which the subject merchandise is first sold (or agreed to be sold) in the United States before or after the date of importation by or for the account of the producer or exporter of the subject merchandise or by a seller affiliated with the producer or exporter, to a purchaser not affiliated with the producer or exporter, as adjusted under subsections (c) and (d).'' For purposes of this administrative review, Kolon classified all of its U.S. sales invoiced by Kolon and shipped directly from Korea to the unaffiliated U.S. customer as EP sales. Kolon reported all sales that were invoiced through its U.S. subsidiary Kolon USA as CEP transactions. For these preliminary results, we have accepted these classifications. The merchandise shipped directly to unaffiliated customers in the U.S. market was not sold through an affiliated U.S. importer, and we find no other grounds for treating these transactions as CEP sales. We, therefore, preliminarily determine that these transactions were EP sales. We have classified as CEP transactions the merchandise invoiced through Kolon USA because these sales were ''sold in the United States'' within the meaning of section 772(b) of the Act.

Export Price

We calculated EP in accordance with section 772(a) of the Act. We based EP on packed prices to customers in the United States. We made adjustments for the following movement expenses in accordance with section 772(c)(2)(A) of the Act: foreign inland freight from plant to port of exportation, brokerage and handling incurred in the country of manufacture, and international freight. Finally, we made an addition to U.S. price for duty drawback in accordance with section 772(c)(1)(B) of the Act based upon Kolon's demonstration that it received duty drawback on imported materials used in the production of PET film. *See* Kolon's sections B and D responses, and section C response at C–34 to C–35 and Exhibit C–16.

Constructed Export Price

In accordance with section 772(b) of the Act, for those sales to the first unaffiliated purchaser that took place after importation into the United States, we calculated CEP. We based CEP on packed prices to unaffiliated purchasers in the United States. We made adjustments for billing adjustments. We

made deductions for movement expenses in accordance with section 772(c)(2)(A) of the Act; these included foreign inland freight from plant to port of exportation, brokerage and handling incurred in the country of manufacture, international freight, marine insurance, brokerage and handling incurred in the United States, U.S. customs duties, other U.S. transportation port storage charges, U.S. warehousing expense, and U.S. inland freight from port or warehouse to customer. As further directed by section 772(d)(1) of the Act, we deducted those selling expenses associated with economic activity in the United States including direct selling expenses (*i.e.,* commissions, U.S. credit expenses, and bank charges), inventory carrying costs, and other U.S. indirect selling expenses. We also made an adjustment for profit in accordance with section 772(d)(3) of the Act. Finally, we made an addition to U.S. price for duty drawback in accordance with section 772(c)(1)(B) of the Act based upon Kolon's demonstration that it received duty drawback on imported materials used in the production of PET film. *See* Kolon's section B, C, and D response at C–34 to C–35 and Exhibit C–16 and Kolon's February 22, 2011, response at SC–37.

Normal Value

A. Selection of Comparison Market

To determine whether there is a sufficient volume of sales in the home market to serve as a viable basis for calculating NV (*i.e.,* the aggregate volume of home market sales of the foreign like product is greater than five percent of the aggregate volume of U.S. sales), we compared Kolon's volume of home market sales of the foreign like product to the volume of its U.S. sales of the subject merchandise, in accordance with section 773(a)(1)(B) of the Act. Because Kolon's aggregate volume of home market sales of the foreign like product was greater than five percent of its aggregate volume of U.S. sales for subject merchandise, we determined the home market was viable. *See* Kolon's section A response at Exhibit A–1.

B. Cost of Production Analysis

Pursuant to 773(b)(2)(A)(ii) of the Act, because the Department had disregarded certain of Kolon's sales in the most recently completed review in which Kolon participated, the Department had reasonable grounds to believe or suspect that Kolon made home market sales at prices below Kolon's costs of production (COP) in this review. *See Polyethylene Terephthalate Film, Sheet, and Strip From the Republic of Korea: Final Results of Antidumping Duty Administrative Review,* 74 FR 57993 (November 10, 2009). As a result, the Department was directed under section 773(b) of the Act to determine whether Kolon made home market sales during the POR at prices below its COP.

In accordance with section 773(b)(3) of the Act, we calculated COP based on the sum of Kolon's cost of materials and fabrication for the foreign like product, plus amounts for selling, general, and administrative expenses (SG&A), interest expenses, and home market packing costs. We relied on the COP information provided by Kolon, except for an adjustment to cost of manufacturing (COM) related to losses sustained by its affiliate for processing PET film, and for an adjustment to the financial expense ratio. *See* Cost Calculation Memorandum.

To determine whether Kolon's home market sales had been made at prices below the COP, we computed weighted-average COPs during the POR, and compared the weighted-average COP figures to home market sales prices of the foreign like product as required under section 773(b) of the Act. On a product-specific basis, we compared the COP to the home market prices net of billing adjustments, discounts and rebates, any applicable movement charges, selling expenses, and packing expenses.

In determining whether to disregard home market sales made at prices below the COP, we examined, in accordance with sections 773(b)(1)(A) and (B) of the Act, whether, within an extended period of time, such sales were made in substantial quantities, and whether such sales were made at prices which did not permit the recovery of all costs within a reasonable period of time in the normal course of trade. Where less than 20 percent of the respondent's home market sales of a given model were at prices below the COP, we did not disregard any below-cost sales of that model because we determined that the below-cost sales were not made within an extended period of time and in ''substantial quantities.'' *See* section 773(b)(2)(C) of the Act. Where 20 percent or more of the respondent's home market sales of a given model were at prices less than the COP, we normally disregard the below-cost sales because: (1) They were made within an extended period of time in ''substantial quantities,'' in accordance with sections 773(b)(2)(B) and (C) of the Act; and (2) based on our comparison of prices to the weighted-average COPs for the POR, they were at prices which would not permit the recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act.

We examined the cost data and determined that our quarterly cost methodology is not warranted and, therefore, we have applied our standard methodology of using annual costs based on the data Kolon reported, adjusted as described in the ''Cost of Production'' section above. Because we are applying our standard annual-average cost test in these preliminary results, we have also applied our standard cost-recovery test with no adjustments.

Our cost test for Kolon revealed that, for home market sales of certain models, less than 20 percent of the sales of those models were at prices below the COP. We therefore retained all such sales in our analysis and used them as the basis for determining NV. Our cost test also indicated that for home market sales of other models, more than 20 percent were sold at prices below the COP within an extended period of time and were at prices which would not permit the recovery of all costs within a reasonable period of time. Thus, in accordance with section 773(b)(1) of the Act, we excluded these below-cost sales from our analysis and used the remaining above-cost sales as the basis for determining NV.

C. Price-to-Price Comparisons

We calculated NV based on prices to unaffiliated customers in Korea. We used Kolon's adjustments and deductions as reported. We made deductions, where appropriate, for foreign inland freight from plant to distribution warehouse, warehousing expense, and foreign inland freight from plant or distribution warehouse to customer. Kolon incurred commission expenses in the United States but not in Korea. Accordingly, pursuant to 19 CFR section 351.410(e) of the Department's regulations, we made an offset to normal value for selling expenses that Kolon incurred in Korea. As directed by 19 CFR section 351.410(e), we limited the offset to the amount of the commissions that Kolon incurred in the United States. In addition, for comparisons involving similar merchandise, we made adjustments for differences in cost attributable to differences in physical characteristics of the merchandise compared pursuant to section 773(a)(6)(C)(ii) of the Act and 19 CFR 351.411. We also made adjustments for differences in circumstances of sale (COS) in accordance with section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410. We made COS adjustments for imputed credit expenses. As noted

above in the ''Level of Trade'' section of this notice, we also made an adjustment for the CEP offset in accordance with section 773(a)(7)(B) of the Act. Finally, we deducted home market packing costs and added U.S. packing costs in accordance with sections 773(a)(6)(A) and (B) of the Act.

Currency Conversion

We made currency conversions into U.S. dollars based on the exchange rates in effect on the dates of the U.S. sales, as certified by the Federal Reserve Bank, in accordance with section 773A(a) of the Act.

Preliminary Results of Review

We preliminarily determine the following weighted-average dumping margin exists for the period June 1, 2009 through May 31, 2010:

Manufacturer/exporter	Weighted average margin (percentage)
Kolon Industries, Inc.	0.81

The Department will disclose to parties the calculations performed in connection with these preliminary results within five days of the date of publication of this notice. *See* 19 CFR 351.224(b). Pursuant to 19 CFR 351.309, interested parties may submit case briefs not later than 30 days after the publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than 35 days after the date of publication of this notice. Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each argument: (1) A statement of the issue, (2) a brief summary of the argument; and (3) a table of authorities.

Interested parties who wish to request a hearing or to participate if one is requested must submit a written request to the Assistant Secretary for Import Administration, Room 1870, within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. *See* 19 CFR 351.310(c). Issues raised in the hearing will be limited to those raised in the case briefs.

The Department will issue the final results of this administrative review, including the results of its analysis of issues raised in any written briefs, not later than 120 days after the publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment

Pursuant to 19 CFR 351.212(b), the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries. The Department will issue appropriate assessment instructions directly to CBP 15 days after the date of publication of the final results of this review. For assessment purposes, we calculated importer-specific *ad valorem* assessment rates for PET film from Korea based on the ratio of the total amount of the dumping duties calculated for the examined sales to the total entered value of those same sales. *See* 19 CFR 351.212(b).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Kolon will be the rate established in the final results of review; (2) if the exporter is not a firm covered in this review or the LTFV 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; and (3) if neither the exporter nor the manufacturer is a firm covered in this or any previous review, the cash deposit rate will be the all-others rate of 21.50 percent from the LTFV investigation. *See Polyethylene Terephthalate Film, Sheet, and Strip From the Republic of Korea; Notice of Final Court Decision and Amended Final Determination of Antidumping Duty Investigation,* 62 FR 50557 (September 26, 1997).

Notification to Importers

This notice also serves as a preliminary 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 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 double antidumping duties.

These preliminary results of administrative review are issued and this notice is published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: June 30, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–17210 Filed 7–7–11; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–905]

Certain Polyester Staple Fiber From the People's Republic of China: Notice of Preliminary Results of the Antidumping Duty Administrative Review, and Intent To Revoke Order in Part

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''Department'') is conducting the third administrative review of the antidumping duty order on certain polyester staple fiber from the People's Republic of China (''PRC'') for the period of review (''POR'') June 1, 2009, through May 31, 2010. The Department has preliminarily determined that sales have not been made below normal value (''NV'') with respect to Ningbo Dafa Chemical Fiber Co., Ltd. (''Ningbo Dafa'') and Cixi Santai Chemical Fiber Co., Ltd. (''Cixi Santai'') during the POR. If these preliminary results are adopted in our final results of review, we will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on entries of subject merchandise during the POR for which the importer-specific assessment rates are above *de minimis.*

We invite interested parties to comment on these preliminary results. We intend to issue the final results no later than 120 days from the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act'').

DATES: *Effective Date:* July 8, 2011.

FOR FURTHER INFORMATION CONTACT: Jerry Huang or Steven Hampton, 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 or (202) 482–0116, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 1, 2007, the Department published in the **Federal Register** an antidumping duty order on certain

polyester staple fiber from the PRC. *See Notice of Antidumping Duty Order: Certain Polyester Staple Fiber from the People's Republic of China,* 72 FR 30545 (June 1, 2007) (''Order''). On July 28, 2010, the Department published in the **Federal Register** a notice of initiation of an administrative review of certain polyester staple fiber from the People's Republic of China covering the period June 1, 2009, through May 31, 2010, for 11 companies.[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Deferral of Administrative Review,* 75 FR 44225 (July 28, 2010) (''*Initiation Notice''*). On February 10, 2011, the Department published in the **Federal Register** a notice extending the time period for issuing the preliminary results by 90 days. *See Certain Polyester Staple Fiber from the People's Republic of China: Extension of Preliminary Results of the Antidumping Duty Administrative Review,* 76 FR 7532 (February 10, 2011). On May 17, 2011, the Department published in the **Federal Register** a second notice extending the time period for issuing the preliminary results by an additional 30 days. *See Certain Polyester Staple Fiber from the People's Republic of China: Full Extension of Preliminary Results of the Antidumping Duty Administrative Review,* 76 FR 28420 (May 17, 2011).

Respondent Selection

Section 777A(c)(1) of the Act directs the Department to calculate individual dumping margins for each known exporter or producer of the subject merchandise. However, section 777A(c)(2) of the Act gives the Department discretion to limit its examination to a reasonable number of exporters or producers if, because of the large number of exporters or producers, it is not practicable to examine all exporters or producers involved in the review.

On August 12, 2010, the Department released CBP data for entries of the subject merchandise during the POR under administrative protective order (''APO'') to all interested parties having an APO, inviting comments regarding the CBP data and respondent selection. The Department received comments from parties on August 24 and 25, 2010.

On October 6, 2010, the Department issued its respondent selection memorandum after assessing its resources and determining that it could reasonably examine two exporters subject to this review. Pursuant to section 777A(c)(2)(B) of the Act, the Department selected Ningbo Dafa and Cixi Santai as mandatory respondents.[2] The Department sent antidumping duty questionnaires to Ningbo Dafa and Cixi Santai on October 13, 2010.

Ningbo Dafa and Cixi Santai submitted the Section A Questionnaire Responses on November 10, 2010, the Section C & D Questionnaire Responses on December 3, 2010. The Department issued supplemental questionnaires to Ningbo Dafa and Cixi Santai between January and February 2011 to which both companies responded.

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review in whole or in part, if the party that requested the review withdraws its request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation further states that the Secretary may extend the deadline if it is reasonable to do so. On August 17, 2010, Nantong Luolai Chemical Fiber Co., Ltd., NanYang Textiles Co., Ltd., and Cixi Sansheng Chemical Fiber Co., Ltd. (''Sansheng'') timely withdrew their requests for review. On September 9, 2010, Fibertex Corporation (''Fibertex''), an importer of polyester staple fiber from the PRC, timely withdrew its request for a review with respect to Far Eastern Industries, Ltd. (Shanghai) and Far Eastern Polychem Industries. On September 20, 2010, Cixi Waysun Chemical Fiber Co., Ltd. timely withdrew its request for review. On October 15, 2010, Fibertex timely withdrew its request for a review with respect to Sansheng.

Because these parties withdrew their respective requests for an administrative review within 90 days of the date of publication of the notice of initiation, and there were no outstanding requests for an administrative review for these exporters, the Department rescinded this review with respect to the five exporters, in accordance with 19 CFR 351.213(d)(1). *See Certain Polyester Staple Fiber From the People's Republic of China: Partial Rescission of the Third Antidumping Duty Administrative Review,* 75 FR 70906 (November 19, 2010).

Surrogate Country and Surrogate Value Data

On November 8, 2010, the Department sent interested parties a letter inviting comments on surrogate country selection and surrogate value (''SV'') data.[3] No parties provided comments with respect to selection of a surrogate country or information to value factors of production (''FOP'').

Scope of the Order

The merchandise subject to the order is synthetic staple fibers, not carded, combed or otherwise processed for spinning, of polyesters measuring 3.3 decitex (3 denier, inclusive) or more in diameter. This merchandise is cut to lengths varying from one inch (25 mm) to five inches (127 mm). The subject merchandise may be coated, usually with a silicon or other finish, or not coated. PSF is generally used as stuffing in sleeping bags, mattresses, ski jackets, comforters, cushions, pillows, and furniture.

The following products are excluded from the scope of the order: (1) PSF of less than 3.3 decitex (less than 3 denier) currently classifiable in the Harmonized Tariff Schedule of the United States (''HTSUS'') at subheading 5503.20.0025 and known to the industry as PSF for spinning and generally used in woven and knit applications to produce textile and apparel products; (2) PSF of 10 to 18 denier that are cut to lengths of 6 to 8 inches and that are generally used in the manufacture of carpeting; and (3) low-melt PSF defined as a bi-component fiber with an outer, non-polyester sheath that melts at a significantly lower temperature than its inner polyester core (classified at HTSUS 5503.20.0015).

Certain PSF is classifiable under the HTSUS subheadings 5503.20.0045 and 5503.20.0065. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise under the order is dispositive.

Verification

Pursuant to 19 CFR 351.307(b)(iv), between March 21 and March 30, 2011 the Department conducted verification of Ningbo Dafa and Cixi Santai's

[1] Those companies are: Far Eastern Industries, Ltd., (Shanghai) and Far Eastern Polychem Industries; Cixi Sansheng Chemical Fiber Co., Ltd.; Cixi Santai Chemical Fiber Co., Ltd.; Cixi Waysun Chemical Fiber Co., Ltd.; Hangzhou Sanxin Paper Co., Ltd.; Nantong Loulai Chemical Fiber Co., Ltd.; Nan Yang Textile Co., Ltd.; Ningbo Dafa Chemical Fiber Co., Ltd.; Zhaoqing Tifo New Fiber Co., Ltd.; Zhejiang Waysun Chemical Fiber Co., Ltd.; and Huvis Sichuan Chemical Fiber Corporation.

[2] *See* Memorandum to James Doyle, Director, Office 9, Import Administration, from Steven Hampton, International Trade Compliance Analyst, Office 9, Import Administration, regarding 3rd Administrative Review of Certain Polyester Staple Fiber from the PRC: Selection of Respondents for Individual Review, dated October 6, 2010 (''Respondent Selection Memo'').

[3] *See* the Department's Letter to All Interested Parties, regarding Antidumping Duty Administrative Review of Certain Polyester Staple Fiber from the People's Republic of China, dated November 8, 2010 (''Surrogate Country List'').

separate rate status, sales and FOP submissions.[4]

Non-Market Economy (''NME'') Country Status

In every case conducted by the Department involving the PRC, the PRC has been treated as an NME country. In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by the administering authority. *See, e.g., Brake Rotors from the People's Republic of China: Final Results and Partial Rescission of the 2004/2005 Administrative Review and Notice of Rescission of 2004/2005 New Shipper Review,* 71 FR 66304 (November 14, 2006). None of the parties to this proceeding have contested such treatment. Accordingly, the Department calculated NV in accordance with section 773(c) of the Act, which applies to NME countries.

Surrogate Country

When the Department investigates imports from an NME country and available information does not permit the Department to determine NV pursuant to section 773(a) of the Act, then, pursuant to section 773(c)(4) of the Act, the Department bases NV on an NME producer's FOPs, to the extent possible, in one or more market-economy countries that (1) are at a level of economic development comparable to that of the NME country, and (2) are significant producers of comparable merchandise. The Department determined Colombia, India, Indonesia, Peru, the Philippines, and Thailand are countries comparable to the PRC in terms of economic development.[5]

Based on publicly available information (*e.g.,* production data), the Department determines India to be a reliable source for SVs because India is at a comparable level of economic development pursuant to section 773(c)(4) of the Act, is a significant producer of subject merchandise, and has publicly available and reliable data. Accordingly, the Department has selected India as the surrogate country for purposes of valuing the FOPs because it meets the Department's criteria for surrogate country selection.

Separate Rates

In AD proceedings involving NME countries, it is the Department's practice to begin with a rebuttable presumption that the export activities of all companies within the country are subject to government control and thus should be assessed a single antidumping duty rate. *See, e.g., Policy Bulletin 05.1*;[6] *see also Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products from the People's Republic of China,* 71 FR 53079, 53082 (September 8, 2006); *Final Determination of Sales at Less Than Fair Value and Final Partial Affirmative Determination of Critical Circumstances: Diamond Sawblades and Parts Thereof from the People's Republic of China,* 71 FR 29303, 29307 (May 22, 2006) (''*Diamond Sawblades*''). It is the Department's policy to assign all exporters of merchandise subject to investigation in an NME country this single rate unless an exporter can affirmatively demonstrate that it is sufficiently independent so as to be entitled to a separate rate. *See, e.g., Diamond Sawblades,* 71 FR at 29307. Exporters can demonstrate this independence through the absence of both *de jure* and *de facto* government control over export activities. *Id.* The Department analyzes each entity exporting the subject merchandise under a test arising from the *Notice of Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588, 20589 (May 6, 1991) (''*Sparklers*''), as further developed in *Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585, 22586–87 (May 2, 1994) (''*Silicon Carbide*''). However, if the Department determines that a company is wholly foreign-owned or located in a market economy, then a separate rate analysis is not necessary to determine whether it is independent from government control. *See, e.g., Final Results of Antidumping Duty Administrative Review: Petroleum Wax Candles from the People's Republic of China,* 72 FR 52355, 52356 (September 13, 2007).

In addition to the two mandatory respondents, Ningbo Dafa and Cixi Santai, the Department received separate rate applications or certifications from the following four companies (''Separate-Rate Applicants''): Hangzhou Sanxin Paper Co., Ltd.; Huvis Sichuan Chemical Fiber Corporation; Zhaoqing Tifo New Fiber Co., Ltd.; and Zhejiang Waysun Chemical Fiber Co., Ltd.

a. Absence of De Jure Control

The Department considers the following *de jure* criteria in determining whether an individual company may be granted a separate rate: (1) An absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) any other formal measures by the government decentralizing control of companies. *See Sparklers,* 56 FR at 20589. The evidence provided by Ningbo Dafa, Cixi Santai, and the Separate-Rate Applicants supports a preliminary finding of *de jure* absence of government control based on the following: (1) An absence of restrictive stipulations associated with the individual exporter's business and export licenses; (2) there are applicable legislative enactments decentralizing control of the companies; and (3) there are formal measures by the government decentralizing control of companies. *See, e.g.,* Ningbo Dafa's Section A Questionnaire Response, dated November 10, 2010, at Exhibit A2.

b. Absence of De Facto Control

Typically the Department considers four factors in evaluating whether each respondent is subject to *de facto* government control of its export functions: (1) Whether the export prices are set by or are subject to the approval of a government agency; (2) whether the respondent has authority to negotiate and sign contracts and other agreements; (3) whether the respondent has autonomy from the government in making decisions regarding the selection of management; and (4) whether the respondent retains the proceeds of its export sales and makes independent decisions regarding disposition of profits or financing of losses. *See Silicon Carbide,* 59 FR at 22586–87; *see also Notice of Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol From the People's Republic of China,* 60 FR 22544, 22545 (May 8, 1995). The Department has determined that an analysis of *de facto* control is critical in

[4] *See* Memorandum to the File through Scot T. Fullerton, Program Manager, Office 9, from Jerry Huang, International Trade Analyst, ''Verification of the Sales and Factors of Production Response of Ningbo Dafa Chemical Fiber Co. Ltd. in the 2009–10 Administrative Review of Certain Polyester Staple Fiber from the People's Republic of China,'' dated June 30, 2011; Memorandum to the File through Scot T. Fullerton, Program Manager, Office 9, from Steven Hampton, International Trade Analyst, ''Verification of the Sales and Factors of Production Response of Cixi Santai Chemical Fiber Co. Ltd. in the 2009–10 Administrative Review of Certain Polyester Staple Fiber from the People's Republic of China,'' dated June 30, 2011.

[5] *See* Surrogate Country List.

[6] *See* Separate Rates and Combination Rates in Antidumping Investigations involving Non-Market Economy Countries, 70 FR 17233 (April 5, 2005), also available at: *http://ia.ita.doc.gov/policy/index.html.*

determining whether respondents are, in fact, subject to a degree of government control which would preclude the Department from assigning separate rates. The evidence provided by Ningbo Dafa, Cixi Santai, and the Separate-Rate Applicants supports a preliminary finding of *de facto* absence of government control based on the following: (1) The companies set their own export prices independent of the government and without the approval of a government authority; (2) the companies have authority to negotiate and sign contracts and other agreements; (3) the companies have autonomy from the government in making decisions regarding the selection of management; and (4) there is no restriction on any of the companies' use of export revenue.[7]

Separate Rate Calculation

In the ''Respondent Selection'' section above, we stated that the Department employed a limited examination methodology, as it did not have the resources to examine all companies for which a review request was made, and selected two exporters, Ningbo Dafa and Cixi Santai, as mandatory respondents in this review. The remaining companies submitted timely information as requested by the Department and thus, the Department has preliminary determined to treat these companies as cooperative Separate-Rate Applicants.

The statute and the Department's regulations do not address the establishment of a rate to be applied to individual companies not selected for examination where the Department limited its examination in an administrative review pursuant to section 777A(c)(2) of the Act. The Department's practice in cases involving limited selection based on exporters accounting for the largest volumes of trade has been to look to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for respondents we did not examine in an administrative review. Consequently, the Department generally weight-averages the rates calculated for the mandatory respondents, excluding zero and *de minimis* rates and rates based entirely on facts available (''FA'').[8]

This is the third administrative review of this order. In these preliminary results, as well as in the two prior administrative reviews, the two selected mandatory respondents received *de minimis* margins. As a result, in this case the Department must use another reasonable method to determine the margin applicable to the separate rate respondents. The Department's practice is first to apply the most recently calculated margin from a prior segment for any of the current separate rate respondents. In this case, the only other company with a calculated margin during this order is not currently a separate rate respondent. As a result of there being no other non-*de minimis* or non-AFA-based margins available, the Department has used the weighted-average margin from the investigation to apply to the separate rate respondents in this case. Pursuant to this method, we are assigning the rate of 4.44 percent, the most recent positive rate (from the less-than-fair-value (''LTFV'') investigation) calculated for cooperative separate rate respondents. Entities receiving this rate are identified by name in the ''Preliminary Results of Review'' section of this notice.

Date of Sale

Ningbo Dafa and Cixi Santai reported the invoice date as the date of sale because they claim that, for their U.S. sales of subject merchandise made during the POR, the material terms of sale were established on the invoice date. The Department preliminarily determines that the invoice date is the most appropriate date to use as Ningbo Dafa's and Cixi Santai's date of sale is in accordance with 19 CFR 351.401(i) and the Department's long-standing practice of determining the date of sale.[9]

Fair Value Comparisons

To determine whether sales of certain polyester staple fiber to the United States by Ningbo Dafa and Cixi Santai were made at less-than-fair-value, the Department compared the export price (''EP'') to NV, as described in the ''U.S. Price,'' and ''Normal Value'' sections below.

U.S. Price

Export Price

In accordance with section 772(a) of the Act, the Department calculated the EP for the sales to the United States from Ningbo Dafa and Cixi Santai because the first sale to an unaffiliated party was made before the date of importation. The Department calculated EP based on the price to unaffiliated purchasers in the United States. In accordance with section 772(c) of the Act, as appropriate, the Department deducted foreign inland freight and brokerage and handling from the starting price to unaffiliated purchasers. Each of these services was either provided by an NME vendor or paid for using an NME currency. Thus, the Department based the deduction of these movement charges on SVs.

Normal Value

Section 773(c)(1) of the Act provides that the Department shall determine the NV using an FOP methodology if the merchandise is exported from an NME and the information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value under section 773(a) of the Act. The Department bases NV on the FOPs because the presence of government controls on various aspects of NMEs renders price comparisons and the calculation of production costs invalid under the Department's normal methodologies.

Factor Valuations

In accordance with 19 CFR 351.408(c)(1), the Department will normally use publicly available information to value the FOPs, but when a producer sources an input from a market economy (''ME'') country and pays for it in an ME currency, the Department may value the factor using the actual price paid for the input. During the POR, both Ningbo Dafa and Cixi Santai reported that they purchased certain inputs from an ME supplier and paid for the inputs in an ME currency. *See* Ningbo Dafa Section C & D Questionnaire Response, dated December 3, 2010, at D–7–8 and Exhibit D–3; and Cixi Santai's Section C & D Questionnaire Response, dated

[7] *See, e.g.,* Ningbo Dafa's Section A Questionnaire Response at 2–10; Cixi Santai's Section A Questionnaire Response at 1–11; Hangzhou Sanxin Co., Ltd.'s Separate Rate Certification, dated September 27, 2010, at 6–7; Zhaoqing Tifo New Fibre Co., Ltd.'s Separate Rate Certification, dated September 27, 2010, at 6–7; Zhejiang Waysun Chemical Fiber Co. Ltd.'s Separate Rate Certification, dated September 27, 2010, at 5–6; and Huvis Sichuan Co. Ltd.'s Separate Rate Application, dated September 27, 2010, at 15–23. Therefore, the Department preliminarily finds that Ningbo Dafa, Cixi Santai, and the Separate-Rate Applicants have established that they qualify for a separate rate under the criteria established by Silicon Carbide and Sparklers.

[8] *See, e.g., Wooden Bedroom Furniture From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review, Preliminary Results of New Shipper Review and Partial Rescission of Administrative Review,* 73 FR 8273 (February 13, 2008) (unchanged in *Wooden Bedroom Furniture From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and New Shipper Review,* 73 FR 49162 (August 20, 2008).

[9] *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value and Negative Final Determination of Critical Circumstances: Certain Frozen and Canned Warmwater Shrimp from Thailand,* 69 FR 76918 (December 23, 2004) and accompanying Issues and Decision Memorandum at Comment 10.

December 3, 2010, at Exhibit D–3. The Department confirmed that these inputs were produced in ME countries through supplemental questionnaires and again at verification. The Department has a rebuttable presumption that ME input prices are the best available information for valuing an input when the total volume of the input purchased from all ME sources during the period of investigation or review exceeds 33 percent of the total volume of the input purchased from all sources during the period. *See Antidumping Methodologies: Market Economy Inputs, Expected Non-Market Economy Wages, Duty Drawback; and Request for Comments,* 71 FR 61716, 61717–18 (October 19, 2006) (''*Antidumping Methodologies*'').

In these cases, unless case-specific facts provide adequate grounds to rebut the Department's presumption, the Department will use the weighted-average ME purchase price to value the input. Alternatively, when the volume of an NME firm's purchases of an input from ME suppliers during the period is below 33 percent of its total volume of purchases of the input during the period, but where these purchases are otherwise valid and there is no reason to disregard the prices, the Department will weight-average the ME purchase price with an appropriate SV according to their respective shares of the total volume of purchases, unless case-specific facts provide adequate grounds to rebut the presumption. *See Antidumping Methodologies.* When a firm has made ME input purchases that may have been dumped or subsidized, are not *bona fide,* or are otherwise not acceptable for use in a dumping calculation, the Department will exclude them from the numerator of the ratio to ensure a fair determination of whether valid ME purchases meet the 33-percent threshold. *See Antidumping Methodologies.*

In accordance with section 773(c) of the Act, for subject merchandise produced by Ningbo Dafa and Cixi Santai, the Department calculated NV based on the FOPs reported by Ningbo Dafa and Cixi Santai for the POR. The Department used Indian import data and other publicly available Indian sources in order to calculate surrogate values for Ningbo Dafa and Cixi Santai's FOPs. To calculate NV, the Department multiplied the reported per-unit factor quantities by publicly available Indian surrogate values. The Department's practice when selecting the best available information for valuing FOPs is to select, to the extent practicable, surrogate values which are product-specific, representative of a broad-market average, publicly available, contemporaneous with the POR and exclusive of taxes and duties. *See, e.g., Electrolytic Manganese Dioxide From the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 73 FR 48195 (August 18, 2008) and accompanying Issues and Decision Memorandum at Comment 2. The record shows that data in the Indian Import Statistics, as well as those from the other Indian sources, are contemporaneous with the POR, product-specific, and tax-exclusive. *See* Memorandum to the File through Scot T. Fullerton, Program Manager, Office 9 from Jerry Huang, International Trade Analyst: Antidumping Duty Administrative Review of Certain Polyester Staple Fiber from the People's Republic of China (''PRC''): Surrogate Values for the Preliminary Results (''Prelim Surrogate Value Memo'') dated June 30, 2011. In those instances where the Department could not obtain publicly available information contemporaneous to the POR with which to value factors, the Department adjusted the SVs using, where appropriate, the Indian Wholesale Price Index (''WPI'') as published in the International Financial Statistics of the International Monetary Fund, a printout of which is attached to the Prelim Surrogate Value Memo at Attachment 3. Where necessary, the Department adjusted SVs for inflation and exchange rates, taxes, and the Department converted all applicable items to a per-kilogram basis.

As appropriate, the Department adjusted input prices by including freight costs to render them delivered prices. Specifically, the Department added to Indian import surrogate values a surrogate freight cost using the shorter of the reported distance from the domestic supplier to the factory or the distance from the nearest seaport to the factory where we relied on an import value. This adjustment is in accordance with the decision of the *Federal Circuit in Sigma Corp.* v. *United States,* 117 F.3d 1401, 1408 (Fed. Cir. 1997).

The Department used Indian import data from the Global Trade Atlas (''GTA'') published by Global Trade Information Services, Inc. (''GTIS''), which is sourced from the Directorate General of Commercial Intelligence & Statistics, Indian Ministry of Commerce, to determine the surrogate values for certain raw materials, by-products, and packing material inputs. The Department has disregarded statistics from NMEs, countries with generally available export subsidies, and countries listed as ''unidentified'' in GTA in calculating the average value. In accordance with the *OTCA 1988* legislative history, the Department continues to apply its long-standing practice of disregarding SVs if it has a reason to believe or suspect the source data may be subsidized.[10] In this regard, the Department has previously found that it is appropriate to disregard such prices from India, Indonesia, South Korea and Thailand because we have determined that these countries maintain broadly available, non-industry specific export subsidies.[11] Based on the existence of these subsidy programs that were generally available to all exporters and producers in these countries at the time of the POR, the Department finds that it is reasonable to infer that all exporters from Indonesia, South Korea and Thailand may have benefitted from these subsidies. For a detailed description of all SVs used for Ningbo Dafa and Cixi Santai, *see* Prelim Surrogate Value Memo.

The Department valued electricity using the updated electricity price data for small, medium, and large industries, as published by the Central Electricity Authority, an administrative body of the Government of India, in its publication titled *Electricity Tariff & Duty and Average Rates of Electricity Supply in India,* dated March 2008. These electricity rates represent actual country-wide, publicly-available information on tax-exclusive electricity rates charged to small, medium, and large industries in India. We did not inflate this value because utility rates represent current rates, as indicated by the effective dates listed for each of the rates provided.

The Department valued water using data from the Maharashtra Industrial Development Corporation (''MIDC'') as it includes a wide range of industrial water tariffs. To value water, we used the average rate for industrial use from MIDC water rates at *http://www.midcindia.org.* Section 733(c) of the Act provides that the Department will value the FOPs in NME cases using the best available information regarding

[10] Omnibus Trade and Competitiveness Act of 1988, Conf. Report to Accompany H.R. 3, H.R. Rep. No. 576, 100th Cong., 2nd Sess. (1988) (''*OTCA 1988*'') at 590.

[11] *See e.g., Expedited Sunset Review of the Countervailing Duty Order on Carbazole Violet Pigment 23 from India,* 75 FR 13257 (March 19, 2010) and accompanying Issues and Decision Memorandum at 4–5; *Expedited Sunset Review of the Countervailing Duty Order on Certain Cut-to-Length Carbon Quality Steel Plate from Indonesia,* 70 FR 45692 (August 8, 2005) and accompanying Issues and Decision Memorandum at 4; *see Certain Hot-Rolled Carbon Steel Flat Products from Thailand: Final Results of Countervailing Duty Determination,* 66 FR 50410 (October 3, 2001) and accompanying Issues and Decision Memorandum at 23.

the value of such factors in a ME country or countries considered to be appropriate by the administering authority. The Act requires that when valuing FOP, the Department utilize, to the extent possible, the prices or costs of factors of production in one or more ME countries that are (1) at a comparable level of economic development and (2) significant producers of comparable merchandise. *See* section 773(c)(4) of the Act.

Previously, the Department used regression-based wages that captured the worldwide relationship between per capita Gross National Income (''GNI'') and hourly manufacturing wages, pursuant to 19 CFR 351.408(c)(3), to value the respondent's cost of labor. However, on May 14, 2010, the Court of Appeals for the Federal Circuit (''CAFC''), in *Dorbest Ltd.* v. *United States,* 604 F.3d 1363, 1372 (Fed. Cir. 2010) (''*Dorbest*''), invalidated 19 CFR 351.408(c)(3). As a consequence of the CAFC's ruling in *Dorbest,* the Department no longer relies on the regression-based wage rate methodology described in its regulations. On February 18, 2011, the Department published in the **Federal Register** a request for public comment on the interim methodology, and the data sources. *See Antidumping Methodologies in Proceedings Involving Non-Market Economies: Valuing the Factor of Production: Labor, Request for Comment,* 76 FR 9544 (Feb. 18, 2011).

On June 21, 2011, the Department revised its methodology for valuing the labor input in NME antidumping proceedings. *See Antidumping Methodologies in Proceedings Involving Non-Market Economies: Valuing the Factor of Production: Labor,* 76 FR 36092 (June 21, 2011) (''*Labor Methodologies*''). In *Labor Methodologies,* the Department determined that the best methodology to value the labor input is to use industry-specific labor rates from the primary surrogate country. Additionally, the Department determined that the best data source for industry-specific labor rates is Chapter 6A: Labor Cost in Manufacturing, from the International Labor Organization (ILO) Yearbook of Labor Statistics (''Yearbook'').

In these preliminary results, the Department calculated the labor input using the wage method described in *Labor Methodologies.* To value the mandatory respondents' labor input, the Department relied on data reported by India to the ILO in Chapter 6A of the Yearbook. The Department further finds the two-digit description under ISIC–Revision 3 (''Manufacture of chemicals and chemical products'') to be the best available information on the record because it is specific to the industry being examined, and is therefore derived from industries that produce comparable merchandise. The explanatory notes for this sub-classification state that this sub-classification includes the manufacture of man-made fibers. Accordingly, relying on Chapter 6A of the Yearbook, the Department calculated the labor input using labor data reported by India to the ILO under Sub-Classification 24 of the ISIC–Revision 3 standard, in accordance with Section 773(c)(4) of the Act. For these preliminary results, the calculated industry-specific wage rate is Rs. 74.58. A more detailed description of the wage rate calculation methodology is provided in the Prelim Surrogate Value Memo.

As stated above, the Department used Indian ILO data reported under Chapter 6A of Yearbook, which reflects all costs related to labor, including wages, benefits, housing, training, etc. Since the financial statement used to calculate the surrogate financial ratios includes itemized detail of indirect labor costs, the Department made adjustments to the surrogate financial ratios. *See Labor Methodologies; see also Prelim Surrogate Value Memo.*

The Department valued truck freight expenses using a per-unit average rate calculated from data on the Infobanc Web site: *http://www.infobanc.com/logistics/logtruck.htm.* The logistics section of this Web site contains inland freight truck rates between many large Indian cities. Since this value is not contemporaneous with the POR, the Department deflated the rate using WPI.

The Department valued brokerage and handling using a price list of export procedures necessary to export a standardized cargo of goods in India. The price list is compiled based on a survey case study of the procedural requirements for trading a standard shipment of goods by ocean transport in India that is published in *Doing Business 2010: India,* by the World Bank. The study assumes that payment is secured by letters of credit (''LC''), and the time and cost for issuing and securing a LC is included in the value. As Ningbo Dafa and Cixi Santai do not export using LC, we have accordingly deducted the necessary costs of securing LC based on the schedule of charges published by the Bank of India. *See* Prelim Surrogate Value Memo.

To value factory overhead, selling, general, and administrative (''SG&A'') expenses, and profit, the Department used the audited financial statements of Ganesh Polytex Limited.

We are preliminarily granting a by-product offset to Ningbo Dafa for waste paper and waste bottle hood. We are also preliminarily granting a by-product offset to Ningbo Dafa for waste fiber based on its production of waste fiber, as opposed to its POR reintroduction of waste fiber. Similarly, we are preliminarily granting a by-product offset to Cixi Santai for polypropylene (''PP'') waste and polyethylene terephthalate (''PET'') waste.

Currency Conversion

Where necessary, the Department made currency conversions into U.S. dollars, in accordance with section 773A(a) of the Act, based on the exchange rates in effect on the dates of the U.S. sales, as certified by the Federal Reserve Bank. We relied on the daily exchange rates posted on the Import Administration Web site (*http://www.trade.gov/ia/*). *See* Prelim Surrogate Value Memo.

Notice of Intent To Revoke Order, in Part

On June 28, 2010, Ningbo Dafa and Cixi Santai requested revocation of the antidumping duty order with respect to their sales of subject merchandise, pursuant to 19 CFR 351.222(e). These requests were accompanied by certifications, pursuant to 19 CFR 351.222(e)(1) that: (1) Ningbo Dafa and Cixi Santai have sold the subject merchandise at not less than NV for at least three consecutive years and that they will not sell the merchandise at less than NV in the future; and (2) Ningbo Dafa and Cixi Santai sold subject merchandise to the United States in commercial quantities for a period of at least three consecutive years. Ningbo Dafa and Cixi Santai also agreed to immediate reinstatement of the antidumping duty order, as long as any exporter or producer is subject to the order, if the Department concludes that, subsequent to its revocation, they sold the subject merchandise at less than NV.

Pursuant to section 751(d) of the Act, the Department ''may revoke, in whole or in part'' an antidumping duty order upon completion of a review under section 751(a) of the Act. In determining whether to revoke an antidumping duty order in part, the Department considers: (1) Whether the company in question has sold subject merchandise at not less than NV for a period of at least three consecutive years; (2) whether during each of the three consecutive years for which the company sold the merchandise at not less than normal value, it sold the merchandise to the United States in commercial quantities;

and (3) the company has agreed in writing to its immediate reinstatement in the order, as long as any exporter or producer is subject to the order, if the Department concludes that the company, subsequent to revocation, sold the subject merchandise at less than NV.[12] We have preliminarily determined that the request from both Ningbo Dafa and Cixi Santai meets all of the criteria under 19 CFR 351.222(e)(1). Our preliminary margin calculation confirms that Ningbo Dafa and Cixi Santai sold subject merchandise at not less than NV during the current review period. *See* the ''Preliminary Results of the Review'' section below. In addition, we have confirmed that Ningbo Dafa and Cixi Santai sold subject merchandise at not less than NV in the two previous administrative reviews in which they were individually examined (*i.e.,* their dumping margins were zero or *de minimis*).[13]

Based on our examination of the sales data submitted by Ningbo Dafa and Cixi Santai, we preliminarily determine that they both sold the subject merchandise in the United States in commercial quantities in each of the consecutive years cited by Ningbo Dafa and Cixi Santai to support their requests for revocation.[14] Thus, we preliminarily find that Ningbo Dafa and Cixi Santai had zero or *de minimis* dumping margins for the last three years and sold subject merchandise in commercial quantities in each of these years. Also, we preliminarily determine, pursuant to section 751(d) of the Act and 19 CFR 351.222(b)(2), that the application of the antidumping duty order with respect to Ningbo Dafa and Cixi Santai is no longer warranted for the following reasons: (1) The companies had a zero or *de minimis* margin for a period of at least three consecutive years; (2) the companies have agreed to immediate reinstatement of the order if the Department finds that it has resumed making sales at less than NV; and, (3) the continued application of the order is not otherwise necessary to offset dumping. Therefore, we preliminarily determine that subject merchandise produced and exported by Ningbo Dafa and Cixi Santai qualify for revocation from the antidumping duty order on certain polyester staple fiber from the PRC and that the order with respect to such merchandise should be revoked. If these preliminary findings are affirmed in our final results, we will revoke this order, in part, with respect to certain polyester staple fiber produced and exported by Ningbo Dafa and Cixi Santai and, in accordance with 19 CFR 351.222(f)(3), terminate the suspension of liquidation for any of the merchandise in question that is entered, or withdrawn from warehouse, for consumption on or after June 1, 2010, and instruct CBP to release any cash deposits for such entries.

Preliminary Results of Review

The Department preliminarily determines that the following weighted-average dumping margins exist:

Manufacturer/exporter	Weighted-Average Margin (percent)
Ningbo Dafa Chemical Fiber Co., Ltd	0.00
Cixi Santai Chemical Fiber Co	0.00
Hangzhou Sanxin Paper Co., Ltd	4.44
Zhaoqing Tifo New Fiber Co., Ltd	4.44
Huvis Sichuan Chemical Fiber Corporation	4.44
Zhejiang Waysun Chemical Fiber Co., Ltd	4.44

The Department will disclose to parties the calculations performed in connection with these preliminary results within five days of the date of publication of this notice. *See* 19 CFR 351.224(b). In accordance with 19 CFR 351.301(c)(3)(ii), for the final results of this administrative review, interested parties may submit publicly available information to value the factors of production within 20 days after the date of publication of these preliminary results. Interested parties must provide the Department with supporting documentation for the publicly available information to value each FOP. Additionally, in accordance with 19 CFR 351.301(c)(1), for the final results of this administrative review, interested parties may submit factual information to rebut, clarify, or correct factual information submitted by an interested party less than ten days before, on, or after, the applicable deadline for submission of such factual information. However, the Department notes that 19 CFR 351.301(c)(1) permits new information only insofar as it rebuts, clarifies, or corrects information recently placed on the record. The Department generally cannot accept the submission of additional, previously absent-from-the-record alternative SV information pursuant to 19 CFR 351.301(c)(1). *See Glycine From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Rescission, in Part,* 72 FR 58809 (October 17, 2007) and accompanying Issues and Decision Memorandum at Comment 2.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, Room 1117, within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. *Id.* Issues raised in the hearing will be limited to those raised in the respective case briefs. Case briefs from interested parties may be submitted not later than 30 days of the date of publication of this notice, pursuant to 19 CFR 351.309(c). Rebuttal briefs, limited to issues raised in the case briefs, will be due five days later, pursuant to 19 CFR 351.309(d). Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. *See* 19 CFR 351.309(c) and (d).

The Department will issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by these reviews. The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review. In accordance with 19 CFR 351.212(b)(1), we calculated exporter/importer (or customer)-specific assessment rates for the merchandise subject to this review. Where the respondent has reported reliable entered values, we calculated importer (or customer)-specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to each importer (or customer) and

[12] *See* 19 CFR 351.222(e)(1).

[13] *See Certain Polyester Staple Fiber From the People's Republic of China: Final Results and Partial Rescission of Second Antidumping Duty Administrative Review,* 76 FR 2886 (January 18, 2011); *First Administrative Review of Certain Polyester Staple Fiber From the People's Republic of China: Final Results of Antidumping Duty Administrative Review*, 75 FR 1336 (January 11, 2010).

[14] *See* Memorandum to the File entitled, ''Analysis of Commercial Quantities for Ningbo Dafa Chemical Fiber Co. Ltd.'s Request for Revocation,'' dated June 30, 2011; Memorandum to the File entitled, ''Analysis of Commercial Quantities for Cixi Santai Chemical Fiber Co. Ltd.'s Request for Revocation,'' also dated June 30, 2011.

dividing this amount by the total entered value of the sales to each importer (or customer). *See* 19 CFR 351.212(b)(1). Where an importer (or customer)-specific *ad valorem* rate is greater than *de minimis,* we will apply the assessment rate to the entered value of the importers'/customers' entries during the POR. *See* 19 CFR 351.212(b)(1).

Where we do not have entered values for all U.S. sales, we calculated a per-unit assessment rate by aggregating the antidumping duties due for all U.S. sales to each importer (or customer) and dividing this amount by the total quantity sold to that importer (or customer). *See* 19 CFR 351.212(b)(1). To determine whether the duty assessment rates are *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated importer (or customer)-specific *ad valorem* ratios based on the estimated entered value. Where an importer (or customer)-specific *ad valorem* rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties. *See* 19 CFR 351.106(c)(2).

For the companies receiving a separate rate that were not selected for individual review, the assessment rate will be based on the rate listed above.

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 the separate rate companies listed above, the cash deposit rate will be established in the final results of this review (except, if the rate is zero or *de minimis, i.e.*, less than 0.5 percent, no cash deposit will be required for that company); (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 44.3 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. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary 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 double antidumping duties.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: June 30, 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–17207 Filed 7–7–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Seats for the Florida Keys National Marine Sanctuary Advisory Council

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice and request for applications.

SUMMARY: The ONMS is seeking applications for the following vacant positions on the Florida Keys National Marine Sanctuary Advisory Council: Boating Industry (alternate), Citizen at Large—Lower Keys (member), Citizen at Large—Lower Keys (alternate), Conservation and Environment [1 of 2] (member), Conservation and Environment [1 of 2] (alternate), Diving—Lower Keys (member), Diving—Lower Keys (alternate), Fishing—Commercial—Marine/Tropical (member), Fishing—Commercial—Marine/Tropical (alternate), Fishing—Charter Fishing F1ats Guide (member), Fishing—Charter Fishing Flats Guide (alternate), South Florida Ecosystem Restoration (member), and South Florida Ecosystem Restoration (alternate). Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; philosophy regarding the protection and management of marine resources; and possibly the length of residence in the area affected by the sanctuary. Applicants who are chosen as members should expect to serve 3-year terms, pursuant to the council's Charter.

DATES: Applications are due by August 5, 2011.

ADDRESSES: Application kits may be obtained from Lilli Ferguson, Florida Keys National Marine Sanctuary, 33 East Quay Rd., Key West, FL, 33040. Completed applications should be sent to the same address.

FOR FURTHER INFORMATION CONTACT: Lilli Ferguson, Florida Keys National Marine Sanctuary, 33 East Quay Rd., Key West, FL 33040; (305) 292–0311 x245; *Lilli.Ferguson@noaa.gov.*

SUPPLEMENTARY INFORMATION: Per the council's Charter, if necessary, terms of appointment may be changed to provide for staggered expiration dates or member resignation mid term.

Authority: 16 U.S.C. 1431, *et seq.*

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: June 8, 2011.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2011–17195 Filed 7–7–11; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XA434

Fisheries of the Exclusive Economic Zone Off Alaska; Prohibited Species Donation Program

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

ACTION: Notice; selection of an authorized distributor.

SUMMARY: NMFS announces the renewal of permits to SeaShare authorizing this organization to distribute Pacific salmon and Pacific halibut to economically disadvantaged individuals under the prohibited species donation (PSD) program. Salmon and halibut are caught incidentally during directed fishing for groundfish with trawl gear off Alaska. This action is necessary to comply with

provisions of the PSD program and is intended to promote the goals and objectives of the North Pacific Fishery Management Council.

DATES: The permits are effective from July 8, 2011 through July 8, 2014.

ADDRESSES: Electronic copies of the PSD permits for salmon and halibut prepared for this action may be obtained from the Alaska Region Web site at *http://www.alaskafisheries.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Sarah Ellgen, 907–586–7228.

SUPPLEMENTARY INFORMATION:

Background

Fishing for groundfish by U.S. vessels in the exclusive economic zone of the Bering Sea and Aleutian Islands management area (BSAI) and Gulf of Alaska (GOA) is managed by NMFS in accordance with the Fishery Management Plan for Groundfish of the BSAI and the Fishery Management Plan for Groundfish of the GOA (FMPs). These FMPs were prepared by the North Pacific Fishery Management Council under the Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.* Regulations governing the Alaska groundfish fisheries and implementing the FMPs appear at 50 CFR parts 600 and 679. Fishing for halibut in waters in and off Alaska is governed by the Convention between the United States and Canada for the Preservation of the Halibut Fishery of the North Pacific Ocean and Bering Sea (Convention). The International Pacific Halibut Commission (IPHC) promulgates regulations pursuant to the Convention. The IPHC's regulations are subject to approval by the Secretary of State with concurrence from the Secretary of Commerce. After approval by the Secretary of State and the Secretary of Commerce, the IPHC regulations are published in the **Federal Register** as annual management measures pursuant to 50 CFR 300.62.

Amendments 26 and 29 to the BSAI and GOA FMPs, respectively, authorize a salmon donation program and were approved by NMFS on July 10, 1996; a final rule implementing this program was published in the **Federal Register** on July 24, 1996 (61 FR 38358). The salmon donation program was expanded to include halibut as part of the PSD program under Amendments 50 and 50 to the FMPs that were approved by NMFS on May 6, 1998. A final rule implementing Amendments 50 and 50 was published in the **Federal Register** on June 12, 1998 (63 FR 32144). Although that final rule contained a sunset provision for the halibut PSD program of December 31, 2000, the halibut PSD program was permanently extended under a final rule published in the **Federal Register** on December 14, 2000 (65 FR 78119). A full description of, and background information on, the PSD program may be found in the preambles to the proposed rules for Amendments 26 and 29, and Amendments 50 and 50 (61 FR 24750, May 16, 1996, and 63 FR 10583, March 4, 1998, respectively).

Regulations at § 679.26 authorize the voluntary distribution of salmon and halibut taken incidentally in the groundfish trawl fisheries off Alaska to economically disadvantaged individuals by tax-exempt organizations through an authorized distributor. The Administrator, Alaska Region, NMFS (Regional Administrator), may select one or more tax-exempt organizations to be authorized distributors, as defined by § 679.2, based on the information submitted by applicants under § 679.26. After review of qualified applicants, NMFS must announce the selection each authorized distributor in the **Federal Register** and issue one or more PSD permits to each selected distributor.

Currently, SeaShare, a tax-exempt organization, is the sole authorized distributor of salmon and halibut taken incidentally in the groundfish trawl fisheries off Alaska. The salmon and halibut PSD permits became effective August 15, 2008 and authorize SeaShare to participate in the PSD program through August 15, 2011 (73 FR 35659, June 24, 2008).

On May 9, 2011, the Regional Administrator received two applications from SeaShare to renew its salmon and halibut PSD permits. Revisions to the applications were received on May 10, 2011. The Regional Administrator reviewed the applications and determined that they are complete and that SeaShare continues to meet the requirements for an authorized distributor under the PSD program. As required by § 679.26(b)(2), the Regional Administrator based his selection on the following criteria:

1. *The number and qualifications of applicants for PSD permits.* Seashare is the only applicant for PSD permits at this time. NMFS has previously approved applications submitted by SeaShare. As of the date of this notice, no other applications have been approved by NMFS. SeaShare has been coordinating the distribution of salmon taken incidentally in trawl fisheries since 1993, and of halibut taken incidentally in trawl fisheries since 1998, under exempted fishing permits from 1993 to 1996, and under the PSD program since 1996. SeaShare employs independent seafood quality control experts to ensure product quality is maintained by cold storage facilities and common carriers servicing the areas where salmon and halibut donations will take place.

2. *The number of harvesters and the quantity of fish that applicants can effectively administer.* Five shoreside processors and 87 catcher vessels delivering to shoreside processors, 17 catcher/processors, and two motherships and 11 catcher vessels delivering to motherships currently participate in the salmon donation program administered by SeaShare. Five shoreside processors and 87 catcher vessels participate in the halibut donation program administered by SeaShare. SeaShare has the capacity to receive and distribute salmon and halibut from up to 40 processors and the associated catcher vessels. Therefore, it is anticipated that SeaShare has more than adequate capacity for any foreseeable expansion of donations.

In 2008, 2009, and 2010, SeaShare recovered and donated 72,237 pounds, 59,233 pounds, and 52,262 pounds, respectively, of steaked salmon to food bank organizations. During these same years, SeaShare recovered and donated 17,716 pounds, 23,911 pounds, and 10,360 pounds, respectively, of steaked halibut to food bank organizations. The donations came from the BSAI trawl fisheries. NMFS does not have information to convert accurately the net weights of salmon and halibut to numbers of salmon and numbers of halibut.

3. *The anticipated level of salmon and halibut incidental catch based on salmon and halibut incidental catch from previous years.* The incidental catch of salmon and incidental catch mortality of halibut in the GOA and BSAI trawl fisheries are shown in the following table:

Area fishery	2009	2010
BSAI Trawl Chinook Salmon Incidental Catch	12,415 fish	9,734 fish.
BSAI Trawl Other Salmon Incidental Catch	47,497 fish	14,965 fish.
GOA Trawl Chinook Salmon Incidental Catch	7,898 fish	54,178 fish.

Area fishery	2009	2010
GOA Trawl Other Salmon Incidental Catch	2,355 fish	1,857 fish.
BSAI Trawl Halibut Mortality	2,802 mt	2,736 mt.
GOA Trawl Halibut Mortality	1,818 mt	1,637 mt.

mt = metric tons.

Halibut incidental catch amounts are constrained by an annual prohibited species catch limit in the BSAI and GOA. Future halibut incidental catch levels likely will be similar to those experienced in 2009 and 2010. Chinook salmon prohibited species catch (PSC) limits are established for the BS pollock fisheries that when attained, result in the closure of pollock fishing. The Chinook salmon PSC limits for the Bering Sea pollock fishery were established by Amendment 91 to the FMP for Groundfish of the BSAI FMP (75 FR 53026, August 30, 2010). Salmon incidental catch limits are not yet established for the GOA. In general, salmon incidental catch amounts tend to be variable between years, making accurate prediction of future incidental take amounts difficult.

4. *Number of vessels and processors participating in the PSD program.* For the 2011 permit renewal, participation in the PSD program is being expanded beyond the BSAI to include GOA processors and vessels. Shoreside processors will increase from 5 to 15, and vessels delivering to shoreside processors will increase from 87 vessels to 166, with 31 of the 166 vessels participating in both the BSAI and GOA. Catcher processors participating in the PSD program for salmon will drop slightly from 17 to 16 under the 2011 permit renewal. Catcher vessels delivering to motherships will remain at 11 vessels.

NMFS issues PSD permits to SeaShare for a 3-year period unless the permits are suspended or revoked under § 679.26. The permits may not be transferred; however, they may be renewed following the application procedures in § 679.26.

If the authorized distributor modifies the list of participants in the PSD program or delivery locations, the authorized distributor must submit a modified list of participants or a modified list of delivery locations to the Regional Administrator.

These permits may be suspended, modified, or revoked under 15 CFR part 904 for violation of § 679.26 or other regulations in 50 CFR part 679.

Classification

This action is taken under § 679.26.

Authority: 16 U.S.C. 773 *et seq.;* 1801 *et seq.;* 3631 *et seq.;* Pub. L. 108–447.

Dated: July 1, 2011.

Margo Schulze-Haugen,

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

[FR Doc. 2011–17203 Filed 7–7–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RIN 0648–XA545]

Marine Mammals; Photography Permit No. 16360

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

ACTION: Notice; issuance of permit.

SUMMARY: Notice is hereby given that a permit has been issued to Oceanic Nature Film Productions (Responsible Party: Dieter Paulmann), P.O. Box 301 722, Albany 0752, Auckland, New Zealand to conduct commercial/educational photography of cetaceans off Hawaii.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment in the following offices:

Permits, Conservation and Education 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

Pacific Islands Region, NMFS, 1601 Kapiolani Blvd., Rm 1110, Honolulu, HI 96814–4700; phone (808) 944–2200; fax (808) 973–2941.

FOR FURTHER INFORMATION CONTACT: Carrie Hubard or Laura Morse, (301) 427–8401.

SUPPLEMENTARY INFORMATION: On May 11, 2011, notice was published in the **Federal Register** (76 FR 27307) that a request for a permit to conduct commercial/educational photography on 12 cetacean species had been submitted by the above-named applicant. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216). Section 104(c)(6) provides for photography for educational or commercial purposes involving non-endangered and non-threatened marine mammals in the wild.

Oceanic Nature Film Productions is authorized to film cetaceans in the waters off Kona, Hawaii. Using one or two sailing catamarans as a base, filmmakers can conduct surface and underwater photography. Additionally, a passive acoustic array may be towed to obtain marine mammal vocalizations. Twelve species of cetaceans may be approached for filming. The permit does not authorize approaches of species listed as threatened or endangered. Up to 50 animals from each species may be harassed as a result of filming. Footage will be used in a feature film intended to educate the public about marine mammal conservation issues, as well as the importance of the Pacific Islands to the oceans. The permit expires on October 31, 2011.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: July 1, 2011.

P. Michael Payne,

Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2011–17194 Filed 7–7–11; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

National Estuarine Research Reserve System

AGENCY: Estuarine Reserves Division, Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Notice of Approval and Availability for Revised Management Plans for ACE Basin, SC National Estuarine Research Reserve and Old

Woman Creek, OH National Estuarine Research Reserve.

SUMMARY: The Estuarine Reserves Division, Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce has approved the ACE Basin, SC National Estuarine Research Reserve and Old Woman Creek, OH National Estuarine Research Reserve Management Plan Revisions.

The revised management plan for the ACE Basin, SC National Estuarine Research Reserve outlines the administrative structure; the education, training, stewardship, and research programs of the reserve; and the plans for future land acquisition and facility development to support reserve operations. The objectives described in this plan address the most critical coastal issues in ACE Basin related to habitat conservation, water quality, community resilience, and public access. Since the last approved management plan in 1992, the reserve has become fully staffed; added a Coastal Training Program that delivers science-based information to key decision makers; and added significant monitoring of emergent marsh vegetation, water quality, and invasive species. In addition to programmatic and staffing advances, the reserve has constructed an interpretive center that houses educational exhibits, classrooms, offices, conference space, trails and dock with public access. A field station with lab facilities, research dock, and accommodations for visiting researchers has also been constructed.

This management plan amends the boundary to include 4,687 acres of the Botany Bay Plantation located adjacent to the northeastern corner of Edisto Island in lower Charleston County, SC. South Carolina Budget and Control Board is the property owner and has a cooperative partnership with South Carolina Department of Natural Resources to manage the Botany Bay Plantation as a Wildlife Management Area and Heritage Preserve property. The undeveloped coastal habitats of the plantation include maritime forest, coastal shrub, wetlands, tidal marshes and sand beaches. The property provides important habitat for numerous wildlife species, including critical nesting habitat for the Federally threatened loggerhead sea turtle and the state threatened least tern. The lands contain significant cultural resources and list several sites on the National Register of Historic Places. This management plan amends the boundary by also removing 40,089 acres of private lands previously counted in error. In total, the ACE Basin Reserve includes 99,308 acres designated for long term research, education and stewardship. The revised management plan is available at: *http://www.dnr.sc.gov/marine/NERR/index.html.*

The revised management plan for the Old Woman Creek, OH National Estuarine Research Reserve contains the collective vision, mission, goals, and objectives of the reserve; updates the reserve boundary; as well as outlines plans for facility use and development to support reserve operations. The objectives described in this plan address the most critical coastal issues of the reserve related to water quality (non-point source pollution), invasive species, habitat loss and regional ecosystem impacts of climate change. Since the last approved management plan in 2000, the reserve has all core staff; added a Coastal Training Program that delivers science-based information to key decision makers; and developed partnerships to continue to restore and protect land and waters in the Old Woman Creek watershed. In addition to programmatic and staffing advances, the reserve has completed construction of a new dormitory, boathouse, and administrative spaces.

This management plan includes a boundary expansion of 2.2 acres. This land was incorporated with the state nature preserve in 2004 and is subject to all protection afforded by Ohio laws governing state nature preserves. The additional parcel is adjacent to the reserve's southwestern boundary and consists of early successional habitat (e.g., various Cornus sp.) and will become an area dominated by mixed hardwoods. Incorporating these lands increases the size of the reserve to 573 acres. The revised management plan is available at: *http://www.oldwomancreek.org.*

FOR FURTHER INFORMATION CONTACT: Tina O'Connell at (301) 563–7107 or Laurie McGilvray at (301) 563–1158 of NOAA's National Ocean Service, Estuarine Reserves Division, 1305 East-West Highway, N/ORM5, 10th floor, Silver Spring, MD 20910.

Dated: June 24, 2011.

Donna Wieting,

Director, Office of Ocean and Coastal Resource Management, National Oceanic and Atmospheric Administration.

[FR Doc. 2011–16971 Filed 7–7–11; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Patent Prosecution Highway (PPH) Program

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before September 6, 2011.

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

- *E-mail: InformationCollection@uspto.gov.* Include ''0651–0058 comment'' in the subject line of the message.
- *Mail:* Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.
- *Federal Rulemaking Portal: http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Magdalen Greenlief, Office of the Associate Commissioner for Patent Examination Policy, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–8850; or by e-mail to *Magdalen.Greenlief@uspto.gov.* Additional information about this collection is also available at *http://www.reginfo.gov* under ''Information Collection Review.''

SUPPLEMENTARY INFORMATION:

I. Abstract

The Patent Prosecution Highway (PPH) pilot program was originally established between the United States Patent and Trademark Office (USPTO) and the Japan Patent Office (JPO) on July 3, 2006. The USPTO and the JPO agreed at the November 2007 Trilateral Conference to fully implement the PPH program on a permanent basis starting on January 4, 2008.

The USPTO entered into a PPH pilot program with the United Kingdom Intellectual Property Office (UKIPO) on September 4, 2007. Since then, additional PPH pilot programs have

been established between the USPTO and the intellectual property offices of several other countries. Some of the pilot programs, such as those with Japan, Canada, and South Korea, have become permanent.

The PPH program allows applicants whose claims are determined to be patentable in the office of first filing to have the corresponding application that is filed in the office of second filing be advanced out of turn for examination. At the same time, the PPH program allows the office of second filing to exploit the search and examination results of the office of first filing, which increases examination efficiency and improves patent quality. The PCT–PPH pilot program is an expansion to the PPH program based on the framework of the Patent Cooperation Treaty (PCT). Information collected for the PCT is approved under OMB control number 0651–0021.

PPH agreements streamline the patent system by allowing patent examiners to avail themselves of the work product from other participating patent offices. Originally, the PPH program was limited to the utilization of search and examination results of national applications between cross filings under the Paris Convention. The newer PCT–PPH agreements have greatly expanded the potential of the PPH program by permitting participating patent offices to draw upon the positive results of the PCT work product from another participating office. The PCT–PPH pilot program uses international written opinions and international preliminary examination reports developed within the framework of the PCT, thereby making the PPH program available to a larger number of applicants.

The forms in this collection allow participants to file a request in a corresponding U.S. application and petition to make the U.S. application special under the PPH or PCT–PPH program. The PPH forms collect similar data; however, there is a unique form for each participant. This collection includes forms for these current PPH programs with the USPTO: Japan Patent Office (JPO), United Kingdom Intellectual Property Office (UKIPO), Canadian Intellectual Property Office (CIPO), Danish Patent and Trademark Office (DKPTO), European Patent Office (EPO), Korean Intellectual Property Office (KIPO), Intellectual Property Office of Australia (IPAU), Intellectual Property Office of Singapore (IPOS), German Patent and Trade Mark Office (DPMA), National Board of Patents and Registration of Finland (NBPR), Russian Patent Office (ROSPATENT), Hungarian Patent Office (HPO), Spanish Patent and Trademark Office (SPTO), Austrian Patent Office (APO), and the Mexican Institute of Industrial Property (IMPI). This collection also includes forms for these upcoming PPH programs that are being planned with the USPTO: Israeli Patent Office, State Intellectual Property Office of the P.R.C. (SIPO), Instituto Nacional da Propriedade Industrial (INPI), and the Taiwan Intellectual Property Office (TIPO).

This collection includes forms for these current PCT–PPH pilot programs with the USPTO: EPO, JPO, KIPO, APO, ROSPATENT, SPTO, IPAU, NBPR, the Swedish Patent and Registration Office (PRV), and in U.S. applications where the USPTO was the International Searching Authority (ISA) or International Preliminary Examining Authority (IPEA). This collection also includes forms for these upcoming PCT–PPH pilot programs that are being planned with the USPTO: CIPO, SIPO, and the Nordic Patent Institute (NPI).

II. Method of Collection

Requests to participate in the PPH programs must be submitted online using EFS-Web, the USPTO's Web-based electronic filing system.

III. Data

OMB Number: 0651–0058.

Form Number(s): PTO/SB/20AT/AU/BR/CA/CN/DE/DK, PTO/SB/20EP/ES/FI/HU/IL/JP/KR/MX/RU/SG/TW/UK, and PTO/SB/20PCT–AT/PCT–AU/PCT–CA/PCT–CN/PCT–EP/PCT–ES/PCT–FI/PCT–JP/PCT–KR/PCT–RU/PCT–SE/PCT–US/PCT–XN.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households; businesses or other for-profits; and not-for-profit institutions.

Estimated Number of Respondents: 3,700 responses per year. The USPTO estimates that approximately 10% of these responses will be from small entities.

Estimated Time per Response: The USPTO estimates that it will take the public approximately two hours to gather the necessary information, prepare the appropriate form, and submit a completed request to the USPTO.

Estimated Total Annual Respondent Burden Hours: 7,400 hours.

Estimated Total Annual Respondent Cost Burden: $2,405,000. The USPTO expects that the information in this collection will be prepared by attorneys. Using the professional rate of $325 per hour for attorneys in private firms, the USPTO estimates that the total annual respondent cost burden for this collection will be approximately $2,405,000 per year.

Item	Estimated time for response (hours)	Estimated annual responses	Estimated annual burden hours
Request for Participation in the PPH Program Between the JPO and the USPTO (PTO/SB/20JP)	2	500	1,000
Request for Participation in the PPH Pilot Program Between the UKIPO and the USPTO (PTO/SB/20UK)	2	100	200
Request for Participation in the PPH Program Between the CIPO and the USPTO (PTO/SB/20CA)	2	100	200
Request for Participation in the PPH Program Between the KIPO and the USPTO (PTO/SB/20KR)	2	200	400
Request for Participation in the PPH Pilot Program Between the IPAU and the USPTO (PTO/SB/20AU)	2	100	200
Request for Participation in the PPH Pilot Program Between the EPO and the USPTO (PTO/SB/20EP)	2	100	200
Request for Participation in the PPH Pilot Program Between the DKPTO and the USPTO (PTO/SB/20DK)	2	100	200
Request for Participation in the PPH Pilot Program Between the IPOS and the USPTO (PTO/SB/20SG)	2	100	200
Request for Participation in the PPH Pilot Program Between the DPMA and the USPTO (PTO/SB/20DE)	2	100	200

Item	Estimated time for response (hours)	Estimated annual responses	Estimated annual burden hours
Request for Participation in the PPH Pilot Program Between the NBFR and the USPTO (PTO/SB/20FI)	2	100	200
Request for Participation in the PPH Pilot Program Between ROSPATENT and the USPTO (PTO/SB/20RU)	2	100	200
Request for Participation in the PPH Pilot Program Between the HPO and the USPTO (PTO/SB/20HU)	2	100	200
Request for Participation in the PPH Pilot Program Between the SPTO and the USPTO (PTO/SB/20ES)	2	100	200
Request for Participation in the PPH Pilot Program Between the APO and the USPTO (PTO/SB/20AT)	2	100	200
Request for Participation in the PPH Pilot Program Between the Israeli Patent Office and the USPTO (PTO/SB/20IL)	2	100	200
Request for Participation in the PPH Pilot Program Between the IMPI and the USPTO (PTO/SB/20MX)	2	100	200
Request for Participation in the PPH Pilot Program Between the SIPO and the USPTO (PTO/SB/20CN)	2	100	200
Request for Participation in the PPH Pilot Program Between the INPI and the USPTO (PTO/SB/20BR)	2	100	200
Request for Participation in the PPH Pilot Program Between the TIPO and the USPTO (PTO/SB/20TW)	2	100	200
Request for Participation in the PCT–PPH Pilot Program Between the EPO and the USPTO (PTO/SB/20PCT–EP)	2	100	200
Request for Participation in the PCT–PPH Pilot Program Between the JPO and the USPTO (PTO/SB/20PCT–JP)	2	100	200
Request for Participation in the PCT–PPH Pilot Program Between the KIPO and the USPTO (PTO/SB/20PCT–KR)	2	100	200
Request for Participation in the PCT–PPH Pilot Program Between the APO and the USPTO (PTO/SB/20PCT–AT)	2	100	200
Request for Participation in the PCT–PPH Pilot Program Between the ROSPATENT and the USPTO (PTO/SB/20PCT–RU)	2	100	200
Request for Participation in the PCT–PPH Pilot Program Between the SPTO and the USPTO (PTO/SB/20PCT–ES)	2	100	200
Request for Participation in the PCT–PPH Pilot Program Between the IPAU and the USPTO (PTO/SB/20PCT–AU)	2	100	200
Request for Participation in the PCT–PPH Pilot Program Between the CIPO and the USPTO (PTO/SB/20PCT–CA)	2	100	200
Request for Participation in the PCT–PPH Pilot Program Between the NBPR and the USPTO (PTO/SB/20PCT–FI)	2	100	200
Request for Participation in the PCT–PPH Pilot Program Between the PRV and the USPTO (PTO/SB/20PCT–SE)	2	100	200
Request for Participation in the PCT–PPH Pilot Program Between the NPI and the USPTO (PTO/SB/20PCT–XN)	2	100	200
Request for Participation in the PCT–PPH Pilot Program Between the SIPO and the USPTO (PTO/SB/20PCT–CN)	2	100	200
Request for Participation in the PCT–PPH Pilot Program in a U.S. Application Where the USPTO was the ISA or IPEA (PTO/SB/20PCT–US)	2	100	200
Totals	.....	3,700	7,400

Estimated Total Annual Non-hour Respondent Cost Burden: $0. There are no capital start-up, maintenance, or postage costs associated with this collection. This collection also has no filing fees or recordkeeping costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, *e.g.,* the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: July 1, 2011.

Susan K. Fawcett,

Records Officer, USPTO, Office of the Chief Information Officer.

[FR Doc. 2011–17077 Filed 7–7–11; 8:45 am]

BILLING CODE 3510–16–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Effective Date:* 8/8/2011.

ADDRESS: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 4/29/2011 (76 FR 23998); 5/6/2011 (76 FR 26279); and 5/13/2011 (76 FR 28000–28001), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and services and impact of the additions on the current or most recent contractors, the Committee has determined that the products and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. The action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products and services are added to the Procurement List:

Products

NSN: 7530–00–NIB–1028—Dated 18-Month Paper Wall Planner, 24″ x 37″.

NSN: 7530–00–NIB–1029—Dated 12-Month 2-Sided Laminated Wall Planner, 24″ x 37″.

NPA: The Chicago Lighthouse for People Who Are Blind or Visually Impaired, Chicago, IL.

Contracting Activity: General Services Administration, Household and Industrial Furniture, Arlington, VA.

Coverage: A-List for the Total Government Requirement as aggregated by the General Services Administration.

Services

Service Type/Location: Custodial Service, USDA APHIS—Plant Protection and Quarantine, & Veterinary Services, 8100 NW. 15th Place, Gainesville, FL.

NPA: The Arc of Bradford County, Starke, FL.

Contracting Activity: Dept. of Agriculture, Animal and Plant Health Inspection Service, Minneapolis, MN.

Service Type/Location: Custodial and Grounds Services, White Sands Missile Range, NM.

NPA: Tresco, Inc., Las Cruces, NM.

Contracting Activity: Dept. of the Army, W6QM White Sands DOC, White Sands Missile Range, NM.

Service Type/Location: Janitorial/Custodial Service, San Francisco Maritime National Historical Park, Building E, Lower Fort Mason, San Francisco, CA.

NPA: Toolworks, Inc., San Francisco, CA.

Contracting Activity: Dept. of the Interior, National Park Service, Pacific West Region, Oakland, CA.

Service Type/Locations: Janitorial Services, Mustang Armed Force Reserve Center (AFRC), Mustang, OK. Norman Armed Force Reserve Center (AFRC), Norman, OK.

NPA: Dale Rogers Training Center, Inc., Oklahoma City, OK.

Contracting Activity: Dept. of the Army, W7NV USPFO Activity OK ARNG, Oklahoma City, OK.

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2011–17147 Filed 7–7–11; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to and Deletions from the Procurement List.

SUMMARY: The Committee is proposing to add products and a service to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products and a service previously furnished by such agencies.

DATES: *Comments must be Received on or Before:* 8/8/2011.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION OR TO SUBMIT COMMENTS CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products and service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and service to the Government.

2. If approved, the action will result in authorizing small entities to furnish the products and service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and service proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following products and service are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Products

NSN: M.R. 1001—Towels, Dish, Kitchen Gourmet, Black, 2pc.

NSN: M.R. 1002—Towels, Dish, Kitchen Gourmet, Red, 2pc.

NSN: M.R. 1003—Towels, Dish, Kitchen Gourmet, Green, 2pc.

NSN: M.R. 1005—Cloth, Dish, Kitchen

Gourmet, Black, 2pc.
NSN: M.R. 1006—Cloth, Dish, Kitchen Gourmet, Red, 2pc.
NSN: M.R. 1007—Cloth, Dish, Kitchen Gourmet, Green, 2pc.
NSN: M.R. 1021—Holder, Pot, Deluxe, Black.
NSN: M.R. 1022—Holder, Pot, Deluxe, Red.
NSN: M.R. 1023—Holder, Pot, Deluxe, Green.
NPA: New York City Industries for the Blind, Inc., Brooklyn, NY.
Contracting Activity: Military Resale-Defense Commissary Agency, Fort Lee, VA.
Coverage: C-List for the requirements of military commissaries and exchanges as aggregated by the Defense Commissary Agency.

Service

Service Type/Location: Janitorial Service, Naval Operations Support Center (NOSC), Bldgs. 245 and 247, 5609 Randall Ave., Cheyenne, WY.
NPA: Skils'kin, Spokane, WA.
Contracting Activity: Dept. of the Navy, NAVFAC Northwest, Silverdale, WA.

Deletions

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.
2. If approved, the action may result in authorizing small entities to furnish the products and service to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and service proposed for deletion from the Procurement List.

End of Certification

The following products and service are proposed for deletion from the Procurement List:

Products

NSN: 7530–00–281–4844—Envelope, Wallet.
NPA: L.C. Industries for the Blind, Inc., Durham, NC.
Contracting Activity: General Services Administration, New York, NY.
NSN: 7290–00–130–3271—Cover, Ironing Board.
NPA: Lions Services, Inc., Charlotte, NC.
Contracting Activity: General Services Administration, Fort Worth, TX.

Service

Service Type/Location: Janitorial/Custodial, Veterans Affairs Medical Center, 1540 Spring Valley Drive, Huntington, WV.
NPA: Goodwill Industries of KYOWVA Area, Inc., Huntington, WV.
Contracting Activity: Department of Veterans Affairs, NAC, Hines, IL.

Barry S. Lineback,
Director, Business Operations.

[FR Doc. 2011–17146 Filed 7–7–11; 8:45 am]
BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID USA–2011–0017]

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DoD.

ACTION: Notice to amend a system of records.

SUMMARY: The Department of the Army is proposing to amend a system of records notice in its existing inventory of records systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: The changes will be effective on August 8, 2011 unless comments are received that would result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and/Regulatory Information Number (RIN) and title, by any of the following methods:

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

* *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mr. Leroy Jones, Department of the Army, Privacy Office, U.S. Army Records Management and Declassification Agency, 7701 Telegraph Road, Casey Building, Suite 144, Alexandria, VA 22325–3905, at (703) 428–6185.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the records systems being amended are set forth below followed by the notices, as amended, published in their entirety. The proposed amendments are not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: July 1, 2011.

Aaron Siegel,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

A0027–1k DAJA

SYSTEM NAME:

Judge Advocate General Professional Conduct Files (June 27, 2011, 76 FR 37329).

* * * * *

CHANGES:

RETENTION AND DISPOSAL:

Delete entry and replace with ''Professional conduct inquiry founded files maintained at the United States Army Office of The Judge Advocate General, Professional Responsibility Branch are destroyed by shredding paper copies and erasure off computers in the local office 5 years after the Judge Advocate Legal Service (JALS) member leaves the JALS or 5 years after the case is closed for non-JALS members, unless the non-JALS member is the subject of another monitoring, open, or founded case, then 5 years after the latest case is closed.

Legal office mismanagement inquiry founded files maintained at the United States Army Office of The Judge Advocate General, Professional Responsibility Branch are destroyed by shredding paper copies and erasure off computers 5 years after the Judge Advocate Legal Service (JALS) member leaves the JALS or 5 years after the case is closed unless the JALS member is the subject of another monitoring, open, or founded case, then 5 years after the latest case is closed, whichever is applicable.

Professional conduct inquiry and legal office mismanagement inquiry unfounded files or inquiry-not-warranted files maintained at the United States Army Office of The Judge Advocate General, Professional Responsibility Branch are destroyed 3 years after the case is closed.

Professional conduct inquiry founded, and unfounded or inquiry-not-warranted files, and legal office mismanagement inquiry founded, and unfounded or inquiry-not-warranted files, maintained in other Judge

Advocates General (JAG) offices are destroyed by shredding paper copies and erasure off computers in those offices 3 years after the case is closed.''

* * * * *

A0027–1k DAJA

SYSTEM NAME:

Judge Advocate General Professional Conduct Files.

SYSTEM LOCATION:

Primary location: United States Army Office of The Judge Advocate General, Professional Responsibility Branch, 2200 Army Pentagon, Room 2B517, Washington, DC 20310–2200.

Secondary locations: Offices of The Judge Advocate General at Army Commands, Army Service Component Commands, Direct Reporting Units, field operating agencies, installations and activities Army-wide. Official mailing addresses are published as an appendix to the Army's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Judge Advocates, civilian attorneys of the Judge Advocate Legal Service, and civilian attorneys subject to the disciplinary authority of The Judge Advocate General who have been the subject of a complaint related to their impairment, professional conduct or mismanagement or when a court has convicted, diverted, or sanctioned the attorney, or has found contempt or an ethics violation, or the attorney has been disciplined elsewhere.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records include subject's name, current mailing address, complaints with substantiating documents, tasking memoranda, preliminary screening inquiry (PSI) reports and mismanagement inquiry reports (containing sensitive personal information pertaining to the underlying allegations of personal and professional misconduct in witness statements and other documents, and inquiry officers' findings and recommendations), supervisory Judge Advocate recommendations and actions, staff memoranda to Judge Advocate General's Corps leadership, Professional Responsibility Committee opinions, memoranda related to disciplinary actions, responses from subjects, and correspondence with Governmental agencies and professional licensing authorities.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3013, Secretary of the Army; 10 U.S.C. 3037, Judge Advocate General, Deputy Judge Advocate General, and general officers of Judge Advocate General's Corps: appointment; duties; Rules for Courts-Martial (RCM) Rule 109, Manual for Courts-Martial United States (2008 Edition); Army Regulation 690–300, Civilian Personnel Employment; Army Regulation 27–1, Legal Services, Judge Advocate Legal Services; and Army Regulation 27–26, Rules of Professional Conduct for Lawyers.

PURPOSE(S):

To protect the integrity of the Army and government legal profession; to assist The Judge Advocate General in the evaluation, management, administration, and regulation of, and inquiry into, the delivery of legal services by offices and personnel under his jurisdiction; to document founded violations of the rules of professional responsibility and mismanagement; to take adverse action and appropriate disciplinary action against those found to have violated the rules of professional responsibility or committed mismanagement; to record disposition of professional responsibility and mismanagement complaints; and to report founded violations of the rules of professional responsibility to professional licensing authorities and to current and prospective government employers.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, records contained within this system may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To professional licensing authorities (for example, state and federal disciplinary agencies); and to current and prospective government employers.

The DoD 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of systems of records notices shall also apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper records in file folders and electronic computer records.

RETRIEVABILITY:

By subject's name.

SAFEGUARDS:

Records are maintained in locked offices and/or in locked file cabinets in secured buildings or on military installations protected by police patrols. All information is maintained in secured areas accessible only to designated individuals having official need therefore in the performance of official duties. Computer stored information is password protected.

RETENTION AND DISPOSAL:

Professional conduct inquiry founded files maintained at the United States Army Office of The Judge Advocate General, Professional Responsibility Branch are destroyed by shredding paper copies and erasure off computers in the local office 5 years after the Judge Advocate Legal Service (JALS) member leaves the JALS or 5 years after the case is closed for non-JALS members, unless the non-JALS member is the subject of another monitoring, open, or founded case, then 5 years after the latest case is closed.

Legal office mismanagement inquiry founded files maintained at the United States Army Office of The Judge Advocate General, Professional Responsibility Branch are destroyed by shredding paper copies and erasure off computers 5 years after the Judge Advocate Legal Service (JALS) member leaves the JALS or 5 years after the case is closed unless the JALS member is the subject of another monitoring, open, or founded case, then 5 years after the latest case is closed, whichever is applicable.

Professional conduct inquiry and legal office mismanagement inquiry unfounded files or inquiry-not-warranted files maintained at the United States Army Office of The Judge Advocate General, Professional Responsibility Branch are destroyed 3 years after the case is closed.

Professional conduct inquiry founded, and unfounded or inquiry-not-warranted files, and legal office mismanagement inquiry founded, and unfounded or inquiry-not-warranted files, maintained in other Judge Advocates General (JAG) offices are destroyed by shredding paper copies and erasure off computers in those offices 3 years after the case is closed.

SYSTEM MANAGER(S) AND ADDRESS:

United States Army Office of The Judge Advocate General, Professional Responsibility Branch, 2200 Army Pentagon, Room 2B517, Washington, DC 20310–2200.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the United States Army Office of The Judge

Advocate General, Professional Responsibility Branch, 2200 Army Pentagon, Room 2B517, Washington, DC 20310–2200.

All written inquiries should provide the full name and current mailing address and any details which may assist in locating records, and their signature.

IN ADDITION, THE REQUESTER MUST PROVIDE A NOTARIZED STATEMENT OR AN UNSWORN DECLARATION MADE IN ACCORDANCE WITH 28 U.S.C. 1746, IN THE FOLLOWING FORMAT:

If executed outside the United States: 'I declare (or certify, verify, or state) under penalty of perjury under the laws of the United State of America that the foregoing is true and correct. Executed on (date). (Signature)'.

If executed within the United States, its territories, possessions, or commonwealths: 'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)'.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves should address written inquiries to the United States Army Office of The Judge Advocate General, Professional Responsibility Branch, 2200 Army Pentagon, Room 2B517, Washington, DC 20310–2200.

All written inquiries should provide the full name, and current mailing address and any details which may assist in locating records, and their signature.

IN ADDITION, THE REQUESTER MUST PROVIDE A NOTARIZED STATEMENT OR AN UNSWORN DECLARATION MADE IN ACCORDANCE WITH 28 U.S.C. 1746, IN THE FOLLOWING FORMAT:

If executed outside the United States: 'I declare (or certify, verify, or state) under penalty of perjury under the laws of the United State of America that the foregoing is true and correct. Executed on (date). (Signature)'.

If executed within the United States, its territories, possessions, or commonwealths: 'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)'.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, and for contesting contents and appealing initial agency determinations are contained in Army Regulation 340–21; 32 CFR Part 505; or may be obtained from the system manager.

RECORDS SOURCES CATEGORIES:

Information is received from individuals as well as from federal, state, and local authorities, and includes preliminary screening inquiry reports and other Army and military records, state bar records and other attorney licensing authority records, law enforcement records, educational institution records, and any other relevant records or information.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2011–17158 Filed 7–7–11; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Information on Surplus Land at a Military Installation Designated for Disposal: Naval Station Pascagoula, Mississippi

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: This notice provides information on withdrawal of surplus property at Naval Station Pascagoula, Mississippi, Lakeside Manor Housing Area.

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Kesler, Director, Base Realignment and Closure Program Management Office, 1455 Frazee Road, San Diego, CA 92108–4310, telephone 619–532–0993; or Mr. James E. Anderson, Director, Base Realignment and Closure Program Management Office, Southeast, 4130 Faber Place Drive, Suite 202, North Charleston, SC 29405, telephone 843–743–2147.

SUPPLEMENTARY INFORMATION: In 2005, Naval Station Pascagoula, including the Lakeside Manor, was designated for closure under the authority of the Defense Base Closure and Realignment Act of 1990, Public Law 101–510, as amended (the Act). On May 10, 2006, Navy published a Notice in the **Federal Register** (71 FR 27237 and 27238) that land and facilities at this installation were declared surplus to the needs of the Federal Government. Land and facilities previously reported as surplus are now required by the Federal Government to satisfy military housing requirements in the Gulf Coast region.

Notice of Surplus Property. Pursuant to paragraph (7)(B) of Section 2905(b) of the Act, as amended by the Base Closure Community Redevelopment and Homeless Assistance Act of 1994, the following information regarding the withdrawal of previously reported surplus property at Naval Station Pascagoula, Mississippi, is provided.

Withdrawn Property Description. The surplus determination for the following land and facilities at Naval Station Pascagoula, Mississippi, is withdrawn.

a. Land. Naval Station Pascagoula, Mississippi, Lakeside Manor consists of approximately 33 acres of improved fee simple land located within Jackson County and the City of Pascagoula.

b. Buildings. The following is a summary of the buildings and other improvements located on the above-described land that will also be withdrawn.

(1) Bachelor quarters housing (2 structures).

Comments: Approximately 186,400 square feet.

(2) Maintenance facility (1 structure).

Comments: Approximately 2,500 square feet.

(3) Miscellaneous facilities (4 structures).

Comments: Approximately 2,000 square feet. Includes guard shack, auto hobby shop, wash rack and restroom.

(4) Paved areas. *Comments:* Approximately 13,300 square yards of roads, parking lots, sidewalks, etc.

(5) Recreational facilities include ball fields, playgrounds, and indoor recreation areas.

Dated: July 1, 2011.

D.J. Werner,

Lieutenant Commander, Office of the Judge Advocate General, U.S. Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 2011–17148 Filed 7–7–11; 8:45 am]

BILLING CODE 3810–FF–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:

Docket Numbers: RP11–2191–000.

Applicants: CenterPoint Energy—Mississippi River Transmission, LLC.

Description: CenterPoint Energy—Mississippi River Transmission, LLC submits tariff filing per 154.204: Non-Conforming ITS TSA between MRT and Trigen to be effective 7/16/2011.

Filed Date: 06/15/2011.

Accession Number: 20110615–5042.

Comment Date: 5 p.m. Eastern Time on Monday, June 27, 2011.

Docket Numbers: RP11–2192–000. RP11–2192–001.

Applicants: Big Sandy Pipeline, LLC.

Description: Big Sandy Pipeline, LLC submits tariff filing per 154.601: Changes to Big Sandy Negotiated Rate Service Agreements to be effective 6/1/2011.

Filed Date: 06/15/2011.
Accession Number: 20110615–5092.
Comment Date: 5 p.m. Eastern Time on Monday, June 27, 2011.

Docket Numbers: RP11–2193–000.
Applicants: Northern Natural Gas Company.
Description: Northern Natural Gas Company submits tariff filing per 154.204: 20110615–1 MUD Non-conforming to be effective 7/16/2011.
Filed Date: 06/15/2011.
Accession Number: 20110615–5093.
Comment Date: 5:00 p.m. Eastern Time on Monday, June 27, 2011.

Docket Numbers: RP11–2194–000.
Applicants: Northern Natural Gas Company.
Description: Northern Natural Gas Company submits tariff filing per 154.204: 20110615–2 Denver City—Golden Spread Non-conforming to be effective 7/16/2011.
Filed Date: 06/15/2011.
Accession Number: 20110615–5119.
Comment Date: 5 p.m. Eastern Time on Monday, June 27, 2011.

Docket Numbers: RP11–2195–000.
Applicants: El Paso Natural Gas Company.
Description: El Paso Natural Gas Company submits tariff filing per 154.204: HEEN Enhancement to be effective 8/1/2011.
Filed Date: 06/16/2011.
Accession Number: 20110616–5028.
Comment Date: 5 p.m. Eastern Time on Tuesday, June 28, 2011.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

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 St., NE., Washington, DC 20426.

The filings in the above proceedings 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 e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 16, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–17133 Filed 7–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings No. 2

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP10–21–006.
Applicants: Florida Gas Transmission Company, LLC.
Description: Florida Gas Transmission Company, LLC submits its Refund Report pursuant to Article VI, Section 4 of the Stipulation and Agreement.
Filed Date: 06/27/2011.
Accession Number: 20110628–0201.
Comment Date: 5 p.m. Eastern Time on Monday, July 11, 2011.

Docket Numbers: RP10–1197–001.
Applicants: Mojave Pipeline Company, LLC.
Description: Mojave Pipeline Company, LLC submits tariff filing per 154.203: Order 587–U Compliance FDD Diversion IT to be effective 8/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5128.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–1566–004.
Applicants: Tennessee Gas Pipeline Company.
Description: Tennessee Gas Pipeline Company submits tariff filing per 154.203: Compliance Motion Rate Case Sheets—Tech Conference to be effective 6/1/2011.

Filed Date: 06/30/2011.

Accession Number: 20110630–5227.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2174–001.

Applicants: High Island Offshore System, LLC.

Description: High Island Offshore System, LLC submits tariff filing per 154.501: Refund Report—RP09–487 to be effective N/A.

Filed Date: 06/30/2011.

Accession Number: 20110630–5141.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed on or before 5 p.m. Eastern time on the specified comment date. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 1, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–17135 Filed 7–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings No. 1

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP11–2220–000.
Applicants: Rockies Express Pipeline LLC.
Description: Rockies Express Pipeline LLC submits tariff filing per 154.204: Negotiated Rate 2011–06–29 BP and Johnstown to be effective 7/1/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5043.
Comment Date: 5 p.m. Eastern Time on Monday, July 11, 2011.

Docket Numbers: RP11–2221–000.
Applicants: Kinder Morgan Interstate Gas Transmission LLC.
Description: Kinder Morgan Interstate Gas Transmission LLC submits tariff filing per 154.204: Negotiated Rate 2011–06–29 Mieco, Concord to be effective 7/1/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5081.
Comment Date: 5 p.m. Eastern Time on Monday, July 11, 2011.

Docket Numbers: RP11–2222–000.
Applicants: Panhandle Eastern Pipe Line Company, LP.
Description: Panhandle Eastern Pipe Line Company, LP submits tariff filing per 154.204: Negotiated Rates—1 to be effective 7/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5053.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2223–000.
Applicants: Trunkline Gas Company, LLC.
Description: Trunkline Gas Company, LLC submits tariff filing per 154.204: Negotiated Rates Filing—11 to be effective 7/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5054.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2224–000.
Applicants: Trunkline LNG Company, LLC.
Description: Trunkline LNG Company, LLC submits tariff filing per 154.203: Misc. Revenue Surcharge Report 6–30–11 to be effective N/A.
Filed Date: 06/30/2011.
Accession Number: 20110630–5055.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2225–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: Devon 34694–32 Amendment to Negotiated Rate Agreement Filing to be effective 7/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5081.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2226–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: ONEOK 34951 to BP 38951 Capacity Release Negotiated Rate Agreement Filing to be effective 7/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5084.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2227–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: HK 37731 to BP 38952 Capacity Release Negotiated Rate Agreement Filing to be effective 7/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5087.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2228–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: HK 37731 to Texla 38953 Capacity Release Negotiated Rate Agreement Filing to be effective 7/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5090.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2229–000.
Applicants: El Paso Natural Gas Company.
Description: El Paso Natural Gas Company submits tariff filing per 154.203: Order 587–U Compliance FDD IT to be effective 8/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5109.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2230–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: Gulf Crossing Pipeline Company LLC submits tariff filing per 154.204: Devon K10–8 Amendment to Negotiated Rate Agreement Filing to be effective 7/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5112.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2231–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: Gulf Crossing Pipeline Company LLC submits tariff filing per 154.204: Antero 2 to Tenaska K204 Capacity Release Negotiated Rate Agreement Filing to be effective 7/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5113.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2232–000.
Applicants: Alliance Pipeline L.P.
Description: Alliance Pipeline L.P. submits tariff filing per 154.204: ACE & PAL Services to be effective 8/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5127.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2233–000.
Applicants: ANR Pipeline Company.
Description: ANR Pipeline Company submits tariff filing per 154.203: Operational Purchases and Sales Report Refiling to be effective N/A.
Filed Date: 06/30/2011.
Accession Number: 20110630–5145.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2234–000.
Applicants: Texas Eastern Transmission, LP.
Description: Texas Eastern Transmission, LP submits tariff filing per 154.403: EPC Aug 2011 Filing to be effective 8/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5167.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2235–000.
Applicants: Gulfstream Natural Gas System, LLC.
Description: Gulfstream Natural Gas System, LLC submits tariff filing per 154.204: GNGS July 1, 2011, Negotiated Rate Agreements to be effective 7/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5177.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2236–000.
Applicants: Natural Gas Pipeline Company of America LLC.
Description: Natural Gas Pipeline Company of America LLC submits tariff filing per 154.204: Negotiated Rate Filing—EDF Trading to be effective 7/1/2011.
Filed Date: 06/30/2011.

Accession Number: 20110630–5179.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2237–000.
Applicants: Wyoming Interstate Company, LLC.
Description: Wyoming Interstate Company, LLC submits tariff filing per 154.204: Agreement Update for Anadarko TSA Nos. 41147 and 41153 to be effective 8/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5190.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2238–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Algonquin Gas Transmission, LLC submits tariff filing per 154.204: ConEd 2011–07–01 Releases to be effective 7/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5221.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2239–000.
Applicants: Equitrans, L.P.
Description: Equitrans, L.P. submits tariff filing per 154.204: Negotiated Rate Service Agreement Filing to be effective 7/1/2011.
Filed Date: 06/30/2011.
Accession Number: 20110630–5231.
Comment Date: 5 p.m. Eastern Time on Tuesday, July 12, 2011.

Docket Numbers: RP11–2240–000.
Applicants: Guardian Pipeline, LLC.
Description: Guardian Pipeline, LLC submits tariff filing per 154.204: Chevron Amended Agreements to be effective 7/1/2011.
Filed Date: 07/01/2011.
Accession Number: 20110701–5001.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 13, 2011.

Docket Numbers: RP11–2241–000.
Applicants: Gulf States Transmission LLC.
Description: Gulf States Transmission LLC submits tariff filing per 154.204: Gulf States Transmission LLC Miscellaneous Revisions to Tariff to be effective 8/1/2011.
Filed Date: 07/01/2011.
Accession Number: 20110701–5002.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 13, 2011.

Docket Numbers: RP11–2242–000.
Applicants: Petal Gas Storage, LLC.
Description: Petal Gas Storage, LLC submits tariff filing per 154.203: Proxy Group Compliance to be effective 11/2/2010.
Filed Date: 07/01/2011.
Accession Number: 20110701–5038.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 13, 2011.

Docket Numbers: RP11–2243–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: Algonquin Gas Transmission, LLC submits tariff filing per 154.204: ConEd 07–01–2011 Release to DTE to be effective 7/1/2011.
Filed Date: 07/01/2011.
Accession Number: 20110701–5048.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 13, 2011.

Docket Numbers: RP11–2244–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: Gulf Crossing Pipeline Company LLC submits tariff filing per 154.204: BP Energy K37–5 Amendment to Negotiated Rate Agreement Filing to be effective 7/1/2011.
Filed Date: 07/01/2011.
Accession Number: 20110701–5066.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 13, 2011.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

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 St. NE., Washington, DC 20426.

The filings in the above proceedings 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 e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 1, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–17137 Filed 7–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings No. 1

June 21, 2011.

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP11–2196–000.
Applicants: Ruby Pipeline, LLC.
Description: Ruby Pipeline, LLC submits tariff filing per 154.203: Tariff Implementation & Compliance to be effective 12/31/9998.
Filed Date: 06/16/2011.
Accession Number: 20110616–5101.
Comment Date: 5 p.m. Eastern Time on Tuesday, June 28, 2011.

Docket Numbers: RP11–2197–000.
Applicants: Rockies Express Pipeline LLC.
Description: Rockies Express Pipeline LLC submits tariff filing per 154.204: Negotiated Rate 2011–06–17 Encana to be effective 6/18/2011.
Filed Date: 06/17/2011.
Accession Number: 20110617–5103.
Comment Date: 5 p.m. Eastern Time on Wednesday, June 29, 2011.

Docket Numbers: RP11–2198–000.
Applicants: Portland Natural Gas Transmission System.
Description: Request for Waiver of Portland Natural Gas Transmission System.
Filed Date: 06/17/2011.
Accession Number: 20110617–5160.
Comment Date: 5 p.m. Eastern Time on Wednesday, June 29, 2011.

Docket Numbers: RP11–2199–000.
Applicants: Transcontinental Gas Pipe Line Company.
Description: Transcontinental Gas Pipe Line Company, LLC submits tariff filing per 154.203: First Revised Vol. 2 Baseline Tariff Filing and Amendment

to Rate Schedule X–275 to be effective 7/20/2011.

Filed Date: 06/20/2011.

Accession Number: 20110620–5028.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 05, 2011.

Docket Numbers: RP11–2200–000.

Applicants: Rockies Express Pipeline LLC.

Description: Rockies Express Pipeline LLC submits tariff filing per 154.204: Negotiated Rate 2011–0617 Johnstown to be effective 6/21/2011.

Filed Date: 06/20/2011.

Accession Number: 20110620–5086.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 05, 2011.

Docket Numbers: RP11–2201–000.

Applicants: Pine Prairie Energy Center, LLC.

Description: Pine Prairie Energy Center, LLC submits tariff filing per 154.203: Filing of Revised GT&C Section 3.1 in Compliance with Docket No. CP11–1–000 to be effective 7/20/2011.

Filed Date: 06/20/2011.

Accession Number: 20110620–5101.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 05, 2011.

Docket Numbers: RP11–2202–000.

Applicants: Northern Natural Gas Company.

Description: Northern Natural Gas Company submits tariff filing per 154.204: 20110620 Flint Hills Negotiated Rate to be effective 6/21/2011.

Filed Date: 06/20/2011.

Accession Number: 20110620–5112.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 05, 2011.

Docket Numbers: RP11–2203–000.

Applicants: Texas Gas Transmission, LLC.

Description: Texas Gas Transmission, LLC submits tariff filing per 154.204: NICOR 27652 Negotiated Rate Agreement Filing to be effective 7/1/2011.

Filed Date: 06/21/2011.

Accession Number: 20110621–5027.

Comment Date: 5 p.m. Eastern Time on Tuesday, July 05, 2011.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

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.

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Dated: June 21, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–17138 Filed 7–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings No. 2

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP11–2006–001.

Applicants: Equitrans, L.P.

Description: Equitrans, L.P. submits tariff filing per 154.203: Removal of Non-Conforming Agreement Compliance Filing to be effective 7/9/2011.

Filed Date: 06/09/2011.

Accession Number: 20110609–5105.

Comment Date: 5 p.m. Eastern Time on Friday, June 24, 2011.

Docket Numbers: RP10–713–002.

Applicants: Enbridge Offshore Pipelines (UTOS) LLC.

Description: Enbridge Offshore Pipelines (UTOS) LLC submits tariff filing per 154.203: Resubmittal in Compliance with Order to be effective 6/5/2010.

Filed Date: 06/16/2011.

Accession Number: 20110616–5071.

Comment Date: 5 p.m. Eastern Time on Tuesday, June 28, 2011.

Docket Numbers: RP11–2177–001.

Applicants: Texas Gas Transmission, LLC.

Description: Texas Gas Transmission, LLC submits tariff filing per 154.205(b): RP11–2177–000 Amendment Filing to be effective 7/7/2011.

Filed Date: 06/16/2011.

Accession Number: 20110616–5057.

Comment Date: 5 p.m. Eastern Time on Tuesday, June 28, 2011.

Docket Numbers: CP05–357–010.

Applicants: Cheniere Creole Trail Pipeline, L.P.

Description: Cheniere Creole Trail Pipeline, L.P. submits Cost and Revenue Study.

Filed Date: 06/17/2011.

Accession Number: 20110617–5178.

Comment Date: 5 p.m. Eastern Time on Tuesday, June 28, 2011.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed on or before 5 p.m. Eastern time on the specified comment date. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC

Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 21, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–17136 Filed 7–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG11–98–000.
Applicants: Shiloh III Wind Project, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Shiloh III Wind Project, LLC.
Filed Date: 06/29/2011.
Accession Number: 20110629–5131.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1476–001.
Applicants: Tampa Electric Company.
Description: Updated Market Power Analysis for Southeast Region of Tampa Electric Company.
Filed Date: 06/29/2011.
Accession Number: 20110629–5184.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER10–1586–001; ER10–1595–001; ER10–1598–001; ER10–1618–001; ER11–2610–001; ER10–1626–001; ER10–1630–001.
Applicants: Big Sandy Peaker Plant, LLC, Tenaska Power Services Co., Wolf Hills Energy, LLC, Lincoln Generating Facility, LLC, Rolling Hills Generating, LLC, Tenaska Virginia Partners, L.P., Crete Energy Venture, LLC.
Description: Updated Market Power Analysis and Notification of Change in Status of Big Sandy Peaker Plant, LLC, *et al.* under ER10–1586, *et al.*
Filed Date: 06/29/2011.
Accession Number: 20110629–5178.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER10–2238–002; ER10–2239–002; ER10–2237–001.
Applicants: Indigo Generation LLC, Larkspur Energy LLC, Wildflower Energy LP.
Description: Notification of Non-Material Change in Status of Indigo Generation LLC, *et al.*
Filed Date: 06/29/2011.
Accession Number: 20110629–5181.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER10–2253–003; ER10–3319–004.
Applicants: Astoria Energy LLC, Astoria Energy II LLC.
Description: Astoria Energy LLC and Astoria Energy II LLC Submit Triennial Order 697 Filing.
Filed Date: 06/29/2011.
Accession Number: 20110629–5063.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER10–2923–003.
Applicants: Sunbury Generation LP.
Description: Updated Market Power Filing and Request to be Classified as a Category 1 Seller.
Filed Date: 06/29/2011.
Accession Number: 20110629–5046.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER10–3124–002; ER10–3127–002; ER10–3129–002; ER10–3130–002; ER10–3132–002; ER10–3134–002; ER10–3137–002.
Applicants: Noble Altona Windpark, LLC, Noble Bellmont Windpark, LLC, Noble Bliss Windpark, LLC, Noble Chateaugay Windpark, LLC, Noble Clinton Windpark I, LLC, Noble Ellenburg Windpark, LLC, Noble Wethersfield Windpark, LLC.
Description: Triennial Market Power Analysis of Noble Altona Windpark, LLC, *et al.*
Filed Date: 06/29/2011.
Accession Number: 20110629–5176.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER10–3139–001; ER10–2964–001; ER11–2041–002; ER11–2042–002; ER10–2924–002.
Applicants: Kleen Energy Systems, LLC, Selkirk Cogen Partners, L.P., Innovative Energy Systems, LLC, Seneca Energy II, LLC, Black River Generation, LLC.
Description: Triennial Order 697 Submission (Joint)—Black River.
Filed Date: 06/29/2011.
Accession Number: 20110629–5174.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER10–3253–001; ER10–3237–001; ER10–3240–001; ER10–3230–001; ER10–3239–001.
Applicants: Wheelabrator Portsmouth Inc., Wheelabrator Westchester L.P.,Wheelabrator Bridgeport, L.P., Wheelabrator Frackville Energy Co., Inc., Wheelabrator North Andover Inc.
Description: Updated Market Power Analysis for the Northeast Region of Wheelabrator Bridgeport, L.P., *et al.* under ER10–3253, *et al.*
Filed Date: 06/29/2011.
Accession Number: 20110629–5094.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER11–3677–000; ER11–3734–000; ER11–3720–000; ER11–3718–000; ER11–3717–000; ER11–3716–000; ER11–3715–000; ER11–3714–000; ER10–2631–001; ER10–2632–001.
Applicants: CP Energy Marketing (US) Inc.; CPI Energy Services (US) LLC, CPI USA North Carolina LLC, CPIDC, Inc., Frederickson Power, L.P., Manchief Power Company, LLC, Morris Cogeneration, LLC, Bridgeport Energy LLC, Rumford Power Inc., Tiverton Power Inc.
Description: Capital Power Companies' Amendment to Notice of Change in Status Regarding Market-Based Rate Authority.
Filed Date: 06/29/2011.
Accession Number: 20110629–5173.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3914–000.
Applicants: Pacific Gas and Electric Company.
Description: Pacific Gas and Electric Company submits tariff filing per 35.13(a)(2)(iii: Kirkwood Meadows Public Utility District Engineering Agreement, to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5000.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3915–000.
Applicants: New York Independent System Operator, Inc., National Grid
Description: Notice of Termination of Large Generator Interconnection Service Agreement of New York Independent System Operator, Inc., *et al.*
Filed Date: 06/29/2011.
Accession Number: 20110629–5029.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3916–000.
Applicants: ISO New England Inc., Fitchburg Gas and Electric Light Company, New England Power Pool Participants Committee, The United Illuminating Company, Central Maine Power Company.
Description: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii: Jt. Filing of Clean-up Revisions to the ISO NE Trans., Mkts., and Srv. Tariff to be effective 7/1/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5055.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3917–000.

Applicants: Mojave Solar LLC.
Description: Mojave Solar LLC submits tariff filing per 35.12: MBR Application to be effective 7/1/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5065.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3918–000.
Applicants: Black Hills/Colorado Electric Utility Co.
Description: Black Hills/Colorado Electric Utility Company, LP submits tariff filing per 35.1: Black Hills/Colorado Electric Utility Company, LP, WestConnect Participation to be effective 7/1/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5067.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3919–000.
Applicants: PJM Interconnection, LLC.
Description: PJM Interconnection, LLC submits tariff filing per 35.13(a)(2)(iii: Original Service Agreement Nos. 2807 and 2808 to be effective 6/1/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5107.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3920–000.
Applicants: Oasis Power Partners, LLC.
Description: Oasis Power Partners, LLC submits tariff filing per 35: Seller Category Compliance Filing to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5139.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3921–000.
Applicants: Shiloh Wind Project 2, LLC.
Description: Shiloh Wind Project 2, LLC submits tariff filing per 35: Shiloh Seller Category Compliance Filing to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5146.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3922–000.
Applicants: Public Service Company of Colorado.
Description: Public Service Company of Colorado submits tariff filing per 35.13(a)(2)(iii: 2011_6_29_306-PSCo_Holy Cross Const Agrmt to be effective 6/29/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5147.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3923–000.
Applicants: CP Power Sales Nineteen, LLC.
Description: CP Power Sales Nineteen, LLC submits tariff filing per 35.37: CP Power Sales Nineteen, LLC Triennial MBR Update for the NR Region to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5148.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER11–3924–000.
Applicants: Sempra Energy Trading LLC.
Description: Sempra Energy Trading LLC submits tariff filing per 35.37: Sempra Energy Trading LLC Second Revised MBR to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5149.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3925–000.
Applicants: EME Homer City Generation, L.P.
Description: EME Homer City Generation, L.P. submits tariff filing per 35.37: EME Homer City Generation, L.P. Triennial MBR Update for the NE Region to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5150.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER11–3926–000.
Applicants: Arizona Public Service Company.
Description: Arizona Public Service Company submits tariff filing per 35.13(a)(2)(i): Rate Schedule No. 182 update to O&M adder to be effective 9/1/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5151.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3927–000.
Applicants: Chanarambie Power Partners, LLC.
Description: Chanarambie Power Partners, LLC submits tariff filing per 35: Chanarambie Seller Category Compliance Filing to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5152.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3928–000.
Applicants: Midwest Generation LLC.
Description: Midwest Generation LLC submits tariff filing per 35.37: Midwest Generation, LLC Triennial Market-Based Rate Update for the NE Region to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5153.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER11–3929–000.
Applicants: Lookout WindPower LLC.
Description: Lookout WindPower LLC submits tariff filing per 35.37: Lookout WindPower LLC's Triennial Market-Based Rate Update for the NE Region to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5154.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER11–3930–000.
Applicants: Big Sky Wind, LLC.
Description: Big Sky Wind, LLC submits tariff filing per 35.37: Big Sky Wind, LLC Triennial Market-Based Rate Update for the NE Region to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5155.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER11–3931–000.
Applicants: Forward WindPower LLC.
Description: Forward WindPower LLC submits tariff filing per 35.37: Forward Wind Power, LLC Triennial MBR Update for the NE Region to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5156.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER11–3932–000.
Applicants: Edison Mission Solutions, LLC.
Description: Edison Mission Solutions, LLC submits tariff filing per 35.37: Edison Mission Solutions, LLC Triennial MBR Update for the NE Region to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5157.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER11–3933–000.
Applicants: Fenton Power Partners I, LLC.
Description: Fenton Power Partners I, LLC submits tariff filing per 35: Fenton Seller Category Compliance Filing to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5158.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3934–000.
Applicants: Edison Mission Marketing & Trading, Inc.
Description: Edison Mission Marketing & Trading, Inc. submits tariff filing per 35.37: Edison Mission Marketing and Trading, Inc. Triennial MBR Update NE Region to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5159.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER11–3935–000.
Applicants: CL Power Sales Eight, LLC.
Description: CL Power Sales Eight, LLC submits tariff filing per 35.37: CL Power Sales Eight, LLC Triennial MBR Update for the NE Region to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5160.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER11–3936–000.
Applicants: CP Power Sales Twenty, LLC.
Description: CP Power Sales Twenty, LLC submits tariff filing per 35.37: CP Power Sales Twenty, LLC Triennial MBR Update for the NE Region to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5161.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER11–3937–000.
Applicants: CP Power Sales Seventeen, LLC.
Description: CP Power Sales Seventeen, LLC submits tariff filing per 35.37: CP Power Sales Seventeen, LLC Triennial MBR Update for the NE Region to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5162.
Comment Date: 5 p.m. Eastern Time on Monday, August 29, 2011.

Docket Numbers: ER11–3938–000.
Applicants: Hoosier Wind Project, LLC.
Description: Hoosier Wind Project, LLC submits tariff filing per 35: Hoosier Seller Category Compliance Filing to be effective 6/30/2011.
Filed Date: 06/29/2011.
Accession Number: 20110629–5163.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Docket Numbers: ER11–3944–000.
Applicants: Pacific Gas and Electric Company.
Description: Request for Tariff Waiver of Pacific Gas and Electric Company in ER11–3944.
Filed Date: 06/29/2011.
Accession Number: 20110629–5182.
Comment Date: 5 p.m. Eastern Time on Wednesday, July 20, 2011.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RD11–8–000.
Applicants: North American Electric Reliability Corporation.
Description: Petition of the North American Electric Reliability Corporation for Approval of Proposed NPCC Regional Reliability Standard PRC–002–NPCC–01—Disturbance Monitoring.
Filed Date: 05/31/2011.
Accession Number: 20110531–5064.
Comment Date: 5 p.m. Eastern Time on Monday, August 1, 2011.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

As it relates to any qualifying facility filings, the notices of self-certification [or self-recertification] listed above, do not institute a proceeding regarding qualifying facility status. A notice of self-certification [or self-recertification] simply provides notification that the entity making the filing has determined the facility named in the notice meets the applicable criteria to be a qualifying facility. Intervention and/or protest do not lie in dockets that are qualifying facility self-certifications or self-recertifications. Any person seeking to challenge such qualifying facility status may do so by filing a motion pursuant to 18 CFR 292.207(d)(iii). Intervention and protests may be filed in response to notices of qualifying facility dockets other than self-certifications and self-recertifications.

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 St., NE., Washington, DC 20426.

The filings in the above proceedings 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 e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 30, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–17134 Filed 7–7–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration; Amended Record of Decision: Site-Wide Environmental Impact Statement for the Continued Operation of Los Alamos National Laboratory, Los Alamos, NM

AGENCY: National Nuclear Security Administration, U.S. Department of Energy.

ACTION: Amended Record of Decision.

SUMMARY: The National Nuclear Security Administration (NNSA), a semi-autonomous agency within the U.S. Department of Energy (DOE), is amending its September 26, 2008 Record of Decision (ROD) issued pursuant to the *Site-Wide Environmental Impact Statement for the Continued Operation of Los Alamos National Laboratory, Los Alamos, New Mexico* (LANL SWEIS; DOE/EIS–0380). That ROD announced NNSA's decision, among other things, to continue and expand support for the Global Threat Reduction Initiative (GTRI) Off-Site Source Recovery Project (OSRP). These activities include the recovery, storage, and disposal of certain high-activity sealed sources to minimize risks to national security and public health and safety. The LANL SWEIS and subsequent ROD did not address shipment of sealed sources through the global commons and the use of a commercial facility in managing these sealed sources as part of the GTRI program's recovery of sealed sources. In April, 2011, NNSA prepared a *Supplement Analysis for the Transport and Storage of High-Activity Sealed Sources from Uruguay and Other Locations* (DOE/EIS–0380–SA–02) to analyze the potential impacts of these

actions. Based on the LANL SWEIS and the Supplement Analysis, NNSA is amending the ROD for the LANL SWEIS to announce its decision that these actions can be expected to take place as part of the ongoing GTRI program.

FOR FURTHER INFORMATION CONTACT: For further information about the GTRI OSRP, contact: Ms. Abigail Cuthbertson; phone: 202–586–2391; email: *Abigail.Cuthbertson@nnsa.doe.gov.*

For general information concerning the DOE NEPA process, contact: Ms. Carol M. Borgstrom, Director, Office of NEPA Policy and Compliance (GC–54), U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585; (202) 586–4600; leave a message at (800) 472–2756; or send an e-mail to ask *NEPA@hq.energy.gov.* Additional information regarding DOE NEPA activities and access to many DOE NEPA documents, including those referenced in this ROD, are available on the Internet through the DOE NEPA Web site at *http://nepa.energy.gov.*

SUPPLEMENTARY INFORMATION:

Background

The GTRI mission includes the effort to reduce and protect vulnerable nuclear and radiological materials located at civilian sites worldwide. Part of the GTRI mission is implemented through OSRP, an ongoing effort (since 1979) that involves the recovery, storage, and, when appropriate, disposition of disused (excess, unwanted) radiological sources that present national security or public health and safety concerns. GTRI OSRP recovers sealed sources domestically and, in coordination with the U.S. Department of State and the International Atomic Energy Agency (IAEA), from foreign countries.

Some of the sources recovered through OSRP are high-activity beta/gamma sealed sources used in medical devices (e.g., teletherapy units) and for research. These contain cobalt-60, cesium-137, radium-226, or strontium-90. OSRP may recover sources from approximately 20 locations annually. Most would be recovered from locations within the United States; others would come from locations in foreign countries, such as Uruguay.

The specific actions analyzed in DOE/EIS–0380–SA–02 include packaging the sealed sources (sometimes with a part of the larger device within which they are contained), transporting the packages to a secure storage facility with the capability to safely handle the sources, then transporting the sealed sources to their country of origin or disposing of the sealed sources as low-level radioactive waste at the Nevada National Security Site (NNSS) in southern Nevada if the sources meet the NNSS waste acceptance criteria. DOE accepts ownership of the sealed sources prior to transport or, for sources recovered from foreign countries, upon arrival in the United States.

Basis for Decision

In addition, DOE/EIS–0380–SA–02 activities associated with the recovery of high-activity sealed sources are analyzed in the *Site-Wide Environmental Impact Statement for the Continued Operation of Los Alamos National Laboratory, Los Alamos, New Mexico* (DOE/EIS–0380). NNSA published a ROD based on the LANL SWEIS announcing its decision, among other things, to continue and expand support for GTRI OSRP activities (73 FR 55833; September 26, 2008). The disposal of low-level radioactive waste, including sealed sources, is analyzed in the *Final Environmental Impact Statement for the Nevada Test Site and Off-Site Locations in the State of Nevada* (DOE/EIS–0243). This EIS resulted in a ROD stating that NNSS is available to DOE sites for disposal of low-level radioactive waste that meets the NNSS waste acceptance criteria (61 FR 65551, December 13, 1996). Certain sealed sources meeting NNSS low-level waste acceptance criteria have been disposed of at the NNSS.

Environmental Impacts Associated With the Decision

In the Supplement Analysis, NNSA analyzes potential impacts associated with actions involving high activity sealed sources including transporting sealed sources by commercial cargo aircraft and by truck; handling such as loading and offloading associated with transportation; storage; opening and repackaging containers to inspect sealed sources; and intentional destructive acts. Estimates of potential impacts are comparable to those for similar activities analyzed in the LANL SWEIS and other DOE NEPA documents. The dose estimates and associated risks are small. For example, the highest dose estimate in the Supplement Analysis associated with incident-free commercial truck transport of sealed sources is approximately 78 millirem to an individual crewmember, which equates to a fatal cancer risk of approximately 1 chance in 25,000.

For air transport of sealed sources, which was not analyzed in the LANL SWEIS, the Supplement Analysis estimates potential impacts associated with incident-free operations and accidents. For a 12-hour flight transporting three containers with sealed sources, the estimated dose to a crew of four is 0.0065 person-rem, which equates to a chance of one in approximately 250,000 of a latent cancer fatality among the crew. For other transportation scenarios, this estimate would vary according to factors such as flight time and the number of containers of sealed sources. However, the variability would not change the overall conclusion that potential impacts are small and similar to those estimated for transportation of radioactive material in other DOE NEPA documents.

The air transport accident analysis assumed a low probability crash from a landing stall and subsequent fire. For purposes of analysis, NNSA assumed failure of all transport packages, though this is a very unlikely scenario. If such an accident were to occur, the Supplement Analysis estimates a chance of a latent cancer fatality of about one in 100,000 among the population surrounding the accident location (approximately five million people within 50 miles). When the probability of the accident (4.5×10^{-6}) is considered, the risk of a latent cancer fatality is about one chance in 20 billion.

Amended Decision

Consistent with the decisions announced in the ROD issued pursuant to the LANL SWEIS (73 FR 55833; September 26, 2008), NNSA will continue implementing the GTRI OSRP program, including the recovery, storage and disposition of high-activity beta/gamma sealed sources. This program includes the recovery of sealed sources from foreign countries, and NNSA has decided that transport of high-activity sealed sources through the global commons via commercial cargo aircraft may be utilized as part of the ongoing GTRI OSRP program.

Mitigation Measures

NNSA will use all practicable means to avoid or minimize environmental harm when implementing the actions described in this ROD. NNSA operates pursuant to a number of Federal laws including environmental laws, DOE Orders, and Federal, State, and local controls, and agreements. Also, the commercial storage and transportation activities associated with the recovery of high-activity sealed sources are regulated by the Nuclear Regulatory Commission (and states granted certain authorities by the Commission) and the Department of Transportation. Many of these requirements mandate actions that may serve to mitigate potential adverse environmental impacts.

Issued in Washington, DC, on June 27, 2011.

Thomas P. D'Agostino,

Administrator, National Nuclear Security Administration.

[FR Doc. 2011–17161 Filed 7–7–11; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

[DOE/EIS–0462]

Notice of Cancellation of Environmental Impact Statement for the Proposed Crowned Ridge Wind Energy Center Project, Codington and Grant Counties, SD

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of Cancellation of Environmental Impact Statement.

SUMMARY: The U.S. Department of Energy (DOE), Western Area Power Administration (Western) is issuing this notice to advise the public that it is cancelling the preparation of an environmental impact statement (EIS) under the National Environmental Policy Act (NEPA) on an interconnection request by NextEra Energy Resources (NextEra).

DATES: This cancellation is effective on July 8, 2011.

FOR FURTHER INFORMATION CONTACT: For additional information on the cancellation of this EIS process, contact Matt Marsh, NEPA Document Manager, Upper Great Plains Regional Office, Western Area Power Administration, P.O. Box 35800, Billings, MT 59107–5800, e-mail *MMarsh@wapa.gov,* telephone (800) 358–3415. For general information on DOE's NEPA review process, contact Carol M. Borgstrom, Director of NEPA Policy and Compliance, GC–54, Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585–0119, telephone (202) 586–4600 or (800) 472–2756, facsimile (202) 586–7031.

SUPPLEMENTARY INFORMATION: NextEra proposed to design, construct, operate, and maintain a 150-megawatt Crowned Ridge Wind Energy Center Project (Project) in Codington and Grant counties, South Dakota, and interconnect that Project with Western's transmission system. NextEra's interconnection request caused Western to initiate a NEPA review of its action to allow the interconnection. Western published a Notice of Intent for the EIS in the **Federal Register** on November 30, 2010 (75 FR 74040), and started the EIS process. A public scoping meeting was held subsequent to the Notice of Intent, but a Draft EIS was not produced because NextEra decided to suspend further action on its proposed Project. NextEra notified Western of the decision, and Western is now terminating the NEPA review process on its interconnection decision and NextEra's proposed Project. NextEra could decide to reinitiate the proposed Project at some future date. In that event Western would issue a new Notice of Intent, and would start an entirely new NEPA process.

The Assistant Secretary, Environment, Safety and Health granted approval authority to Western's Administrator for EISs related to integrating major new sources of generation in a October 4, 1999, memorandum. Under the authority granted by that memorandum, I have terminated the NEPA process for NextEra's proposed Crowned Ridge Wind Energy Center Project with the publication of this notice.

Dated: June 29, 2011.

Timothy J. Meeks,

Administrator.

[FR Doc. 2011–17157 Filed 7–7–11; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–8997–8]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–1399 or *http://www.epa.gov/compliance/nepa/*

Weekly receipt of Environmental Impact Statements

Filed 06/27/2011 Through 07/01/2011

Pursuant to 40 CFR 1506.9.

Notice

In accordance with Section 309(a) of the Clean Air Act, EPA is required to make its comments on EISs issued by other Federal agencies public. Historically, EPA met this mandate by publishing weekly notices of availability of EPA comments, which includes a brief summary of EPA's comment letters, in the **Federal Register**. Since February 2008, EPA has included its comment letters on EISs on its Web site at: *http://www.epa.gov/compliance/nepa/eisdata.html.* Including the entire EIS comment letters on the Web site satisfies the Section 309(a) requirement to make EPA's comments on EISs available to the public. Accordingly, on March 31, 2010, EPA discontinued the publication of the notice of availability of EPA comments in the **Federal Register**.

EIS No. 20110210, Final EIS, USFS, NM, McKinley County Easement—Forest Roads 191 and 191D, Implementation, Cibola National Forest, McKinley County, NM, Review Period Ends: 08/08/2011, Contact: Keith Baker 505–346–3820.

EIS No. 20110211, Draft EIS, USFS, AK, Ketchikan—Misty Fiords Outfitter and Guide Management Plan, Authorizes Outfitter and Guide Operations through the Issuance of Special-Use-Permits, Tongass National Forest, Ketchikan-Misty Ranger District, Ketchikan, AK, *Comment Period Ends:* 08/22/2011, Contact: Susan Jennings 907–723–0477.

EIS No. 20110212, Draft EIS, BLM, CA, Ocotillo Express Wind Energy Project, Proposing to Develop a 465–Megawatt Wind Energy Facility, Implementation, Imperial County, CA, *Comment Period Ends:* 10/05/2011, Contact: Cedric Perry 951–697–5388.

EIS No. 20110213, Final EIS, FAA, RI, Theodore Francis Green Airport Improvement Program, Proposing Improvements to Enhance Safety and the Efficiency of the Airport and the New England Regional Airport System, City of Warwick, Kent County, RI, *Review Period Ends:* 08/08/2011, Contact: Richard Doucette 781–238–7613.

EIS No. 20110214, Draft Supplement, USFS, ND, North Billings County Allotment Management Plan Revisions, Updated Information, Proposes to Continue to Permit Livestock Grazing on 43 Allotments, Medora Ranger District, Dakota Prairie Grasslands, Billings County, ND, *Comment Period Ends:* 08/22/2011, Contact: Nickole Dahl 701–227–7800.

EIS No. 20110215, Final EIS, FHWA, WI, Wisconsin Highway Project, Mobility Motorized and Nonmotorized Travel Enhancements, Updated Information on New Alternatives, and Evaluates a Staged Improvement, US18/151 (Verona Road) and the US 12/14 (Beltine) Corridors, Dane County, WI, *Review Period Ends:* 08/08/2011, Contact: George R. Poirier 608–829–7500.

EIS No. 20110216, Final EIS, FHWA, UT, Hyde Park/North Logan Corridor Project, Proposed 200 East Transportation Corridor between North Logan City and Hyde Park, Funding, Right-of-Way Acquisitions and US Army COE Section 404 Permit, Cache County, UT, *Review Period Ends:* 08/08/2011, Contact: Paul C. Ziman 801–955–3525.

Amended Notices

EIS No. 20110149, Draft EIS, USFS, MT, Troy Mine Revised Reclamation Plan, Proposed Revision is to Return Lands Disturbed by Mining to a Condition Appropriate for Subsequent Use of the Area, Kootenai National Forest, MT, *Comment Period Ends:* 08/05/2011, Contact: Bobbie Loaklen 406–283–7681.

Revision to FR Notice Published 05/20/2011: Extending Comment Period from 07/05/2011 to 08/05/2011.

Dated: July 5, 2011.

Aimee S. Hessert,

Deputy Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2011–17199 Filed 7–7–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9431–7]

Science Advisory Board Staff Office; Notification of a Public Meeting of the Science Advisory Board Panel for the Review of Great Lakes Restoration Initiative Action Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) Science Advisory Board (SAB) Staff Office announces a change in meeting location for a public face-to-face meeting of the SAB panel to review the interagency *Great Lakes Restoration Initiative (GLRI) Action Plan (FY 2010–FY 2014)* that describes restoration priorities, goals, objectives, measurable ecological targets, and specific actions for the Great Lakes.

DATES: The meeting will be held on July 12, 2011 from 9 a.m. to 5:30 p.m. and July 13, 2011 from 8 a.m. to 5 p.m. (Central Time).

ADDRESSES: The Panel meeting will be held at the EPA Region 5 Offices, The Lake Michigan Room in the Ralph H. Metcalfe Federal Building, 77 West Jackson Boulevard, Chicago, IL 60604.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this meeting may contact Mr. Thomas Carpenter, Designated Federal Officer (DFO), SAB Staff Office, by telephone/voice mail at (202) 564–4885; by fax at (202) 565–2098 or via e-mail at *carpenter.thomas@epa.gov.* General information concerning the EPA Science Advisory Board can be found at the EPA SAB Web site at *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION:

Background: The SAB Staff Office requested public nominations of experts to serve on a review panel to advise the Agency on scientific and technical issues related to the GRLI Action Plan (75 FR 185 58383–58385). EPA subsequently announced on June 15, 2011 a public meeting of the panel for July 12 and 13, 2011. That notice provided instructions to submit written comments or provide oral statements and accommodations for individuals with disabilities (76 FR 115 34977–34978). This notice announces a change in the location of the public meeting.

Dated: July 1, 2011.

Vanessa T. Vu,

Director, EPA Science Advisory Staff Office.

[FR Doc. 2011–17258 Filed 7–7–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9431–1; EPA–HQ–OW–2008–0238]

Modification to 2008 National Pollutant Discharge Elimination System (NPDES) General Permit for Stormwater Discharges Associated With Construction Activities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA Regions 1, 2, 3, 5, 6, 7, 8, 9, and 10 are modifying the 2008 National Pollutant Discharge Elimination System (NPDES) general permits for stormwater discharges associated with construction activity in order to extend until February 15, 2012 the expiration date of the permit. Hereinafter, these NPDES general permits will be referred to as ''permit'' or ''2008 construction general permit'' or ''2008 CGP.'' This modification will extend the three-year permit so that it expires on February 15, 2012 instead of June 30, 2011. Prior to this extension, EPA modified the 2008 CGP in January 2010 to extend the permit by one year, thus making it a three-year permit. By Federal law, no NPDES permit may be issued for a period that exceeds five years.

DATES: EPA is finalizing a modification to its 2008 CGP that extends the permit until February 15, 2012. The 2008 CGP will now expire on midnight, February 15, 2012, instead of June 30, 2011.

FOR FURTHER INFORMATION CONTACT: Greg Schaner, Water Permits Division, Office of Wastewater Management (Mail Code: 4203M), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., EPA East, Washington, DC 20460; telephone number: (202) 564–0721; fax number: (202) 564–6431; e-mail address: *schaner.greg@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

If a discharger chooses to apply for coverage under the 2008 CGP, the permit provides specific requirements for preventing contamination of waterbodies from stormwater discharges from the following construction activities:

Category	Examples of affected entities	North American Industry Classification System (NAICS) Code
Industry	Construction site operators disturbing 1 or more acres of land, or less than 1 acre but part of a larger common plan of development or sale if the larger common plan will ultimately disturb 1 acre or more, and performing the following activities:	
	Building, Developing and General Contracting	236
	Heavy Construction	237

EPA does not intend the preceding table to be exhaustive, but provides it as a guide for readers regarding entities likely to be regulated by this action. This table lists the types of activities that EPA is now aware of that could

potentially be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your facility is affected by this action, you should carefully examine the definition of ''construction activity'' and ''small construction activity'' in existing EPA regulations at 40 CFR 122.26(b)(14)(x) and 122.26(b)(15), respectively. If you have questions regarding the applicability of this action to a particular entity, consult the person listed for technical information in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Eligibility for coverage under the 2008 CGP is limited to operators of ''new projects'' or ''unpermitted ongoing projects.'' A ''new project'' is one that commences after the effective date of the 2008 CGP. An ''unpermitted ongoing project'' is one that commenced prior to the effective date of the 2008 CGP, yet never received authorization to discharge under the 2003 CGP or any other NPDES permit covering its construction-related stormwater discharges. Construction sites that originally obtained permit coverage under the 2003 CGP will continue to be covered under that permit. The 2008 CGP is effective only in those areas where EPA is the permitting authority. A list of eligible areas is included in Appendix B of the 2008 CGP.

B. How can I get copies of this document and other related information?

1. Docket. EPA has established an official public docket for this action under Docket ID No. EPA–HQ–OW–2008–0238. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20460. Although all documents in the docket are listed in an index, some information is not publicly available, *i.e.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Publicly available docket materials are available electronically through *http://www.regulations.gov* and in hard copy at the EPA Docket Center Public Reading Room, 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 Water Docket is (202) 566–2426.

2. Electronic Access. You may access this **Federal Register** document electronically through the EPA Internet under the ''Federal Register'' listings at *http://www.epa.gov/fedrgstr/*. Electronic versions of the final permit and fact sheet are available at EPA's stormwater Web site *http://www.epa.gov/npdes/stormwater.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.regulations.gov/fdmspublic/component/main* to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search'', then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Section I.B.1.

C. Who are the EPA regional contacts for this permit?

For EPA Region 1, contact Jessica Hing at tel.: (617) 918–1560 or e-mail at *hing.jessica@epa.gov.*

For EPA Region 2, contact Stephen Venezia at tel.: (212) 637–3856 or e-mail at *venezia.stephen@epa.gov,* or for Puerto Rico, contact Sergio Bosques at tel.: (787) 977–5838 or e-mail at *bosques.sergio@epa.gov.*

For EPA Region 3, contact Chuck Schadel at tel.: (215) 814–5761 or e-mail at *schadel.chuck@epa.gov.*

For EPA Region 5, contact Brian Bell at tel.: (312) 886–0981 or e-mail at *bell.brianc@epa.gov.*

For EPA Region 6, contact Suzanna Perea at tel.: (214) 665–7217 or e-mail at: *perea.suzanna@epa.gov.*

For EPA Region 7, contact Tanya Nix at tel.: (913) 551–7170 or e-mail at: *nix.tanya@epa.gov.*

For EPA Region 8, contact Amy Clark at tel.: (303) 312–7014 or e-mail at: *clark.amy@epa.gov.*

For EPA Region 9, contact Eugene Bromley at tel.: (415) 972–3510 or e-mail at *bromley.eugene@epa.gov.*

For EPA Region 10, contact Misha Vakoc at tel.: (206) 553–6650 or e-mail at *vakoc.misha@epa.gov.*

II. Background of Permit

A. Statutory and Regulatory History

Section 402(p) of the Clean Water Act (CWA) directs EPA to develop a phased approach to regulate stormwater discharges under the National Pollutant Discharge Elimination System (NPDES) program. 33 U.S.C. 1342(p). EPA published two regulations, on November 16, 1990 (the ''Phase I rule'', see 55 FR 47990) and on December 8, 1999 (the ''Phase II rule'', see 64 FR 68722), which resulted in requiring NPDES permits for discharges from construction sites disturbing at least one acre, including sites that are less than one acre but are part of a larger common plan of development or sale that will ultimately disturb at least one acre. See 40 CFR 122.26(b)(14)(x) and 122.26(b)(15)(i).

B. The Relevance of EPA's ''C&D Rule'' to the 2008 CGP

NPDES permits issued for construction stormwater discharges are required under Section 402(a)(1) of the CWA to include conditions for meeting technology-based effluent limits established under Section 301 and, where applicable, Section 306 of the CWA. Once an effluent limitations guideline or new source performance standard is promulgated in accordance with these sections, NPDES permits issued by the NPDES permitting authorities must incorporate requirements based on such limitations and standards. See 40 CFR 122.44(a)(1). Prior to the promulgation of national effluent limitations guidelines or new source performance standards, permitting authorities incorporate technology-based effluent limitations on a best professional judgment basis. CWA section 402(a)(1)(B); 40 CFR 125.3(a)(2)(ii)(B).

On December 1, 2009, EPA published final regulations establishing technology-based Effluent Limitations Guidelines (ELGs) and New Source Performance Standards (NSPS) for the Construction & Development (C&D) point source category. See 40 CFR Part 450, and 74 FR 62996 (December 1, 2009). The Construction & Development Rule, or ''C&D rule'', became effective on February 1, 2010; therefore, all NPDES construction permits issued by EPA or states after this date must incorporate the C&D rule requirements.

Because EPA issued the 2008 CGP prior to the effective date of the C&D rule, the Agency is not required by the

CWA and 40 CFR 122.44(a)(1) to incorporate the C&D rule requirements into the current permit. However, EPA is required to incorporate the C&D rule requirements into the next, reissued CGP, which the Agency expects to issue by February 15, 2012. EPA published for public comment on April 25, 2011 a draft of the new CGP, which includes new requirements implementing the C&D rule. For more information, see 76 FR 22882.

C. Stay of the C&D Rule Numeric Limit

The C&D rule included non-numeric requirements for erosion and sediment control, stabilization, and pollution prevention (see 40 CFR 450.21(a) thru (f)), and, for the first time, a numeric limitation on the discharge of turbidity from active construction sites (see 40 CFR 450.22). Since its promulgation, EPA discovered that the data used to calculate the numeric limit for turbidity were misinterpreted, and that it was necessary to recalculate the numeric limit.

On August 12, 2010, EPA filed a motion with the U.S. Court of Appeals for the Seventh Circuit, requesting that the court issue an order vacating and remanding to the Agency limited portions of the final C&D rule. On August 24, 2010, the U.S. Court of Appeals for the Seventh Circuit remanded the matter to EPA but did not vacate the numeric limit. On September 9, 2010, the National Association of Home Builders (NAHB) filed a motion for clarification (which EPA did not oppose) asking the court to (1) vacate the limit and (2) hold the case in abeyance until February 15, 2012 instead of remanding the matter to EPA. On September 20, 2010, the court granted the motion in part by ruling to hold the matter in abeyance pending EPA consideration of the numeric limit and the other remand issues, but the court did not vacate the numeric limit. Instead, the court stated that ''EPA may make any changes to the limit it deems appropriate, as authorized by law.''

EPA issued a direct final rule staying the numeric limit and a companion proposed rule proposing a stay, and the stay took effect on January 4, 2011, resulting in an indefinite postponement of the implementation of the 280 NTU limit. The Agency is currently developing a proposed rule proposing the recalculated limit. If the numeric limit becomes effective prior to the issuance of the final CGP, EPA must by law incorporate the applicable numeric limit into the final CGP.

D. Summary of 2008 CGP

EPA announced the issuance of the 2008 CGP on July 14, 2008. See 73 FR 40338. Construction operators choosing to be covered by the 2008 CGP must certify in their notice of intent (NOI) that they meet the requisite eligibility requirements described in Part 1.3 of the permit. If eligible, operators are authorized to discharge under this permit in accordance with Part 2. Permittees must install and implement control measures to meet the effluent limits applicable to all dischargers in Part 3, and must inspect such stormwater controls and repair or modify them in accordance with Part 4. The permit in Part 5 requires all construction operators to prepare a stormwater pollution prevention plan (SWPPP) that identifies all sources of pollution, and describes control measures used to minimize pollutants discharged from the construction site. Part 6 details the requirements for terminating coverage under the permit.

The 2008 CGP permit provides coverage for discharges from construction sites in areas where EPA is the permitting authority. The geographic coverage and scope of the 2008 CGP is listed in Appendix B of the permit.

III. Extension of 2008 CGP Expiration Date

A. What Is EPA's rationale for the modification of the 2008 CGP for an extension of the expiration date?

As stated above, EPA is modifying the 2008 CGP by extending to February 15, 2012, the expiration date of the permit. This extension is necessary in order to provide sufficient time to finalize the new CGP, which will incorporate for the first time new effluent limitations guidelines and new source performance standards, which EPA promulgated in December 2009. Additional time beyond the previous June 30, 2011 expiration date of the 2008 CGP is necessary in order to make up for a delay of several months in the permit issuance process caused by the initial uncertainty surrounding the error in calculating the 280 NTU limit and the appropriate way for EPA to address it. This delay made it a near certainty that, given even the most optimistic timeframe for finalizing the new CGP, EPA would not have been able to finalize the new CGP by the June 30, 2011 expiration date of the 2008 CGP.

EPA was unaware of the need to extend the expiration date of the 2008 CGP when it first modified the 2008 CGP's expiration date in January 2010 by one year to June 30, 2011. At that time, EPA was under the impression that the June 30, 2011 date provided sufficient time to finalize a new permit incorporating all of the new C&D rule requirements. However, with the setback of time related to the stay of the 280 NTU limit, EPA now needs additional time to complete the permit issuance process as explained above. EPA believes that the proposed extension of the current permit to February 15, 2012 will provide the Agency with sufficient time to finalize the new CGP.

EPA believes it is imperative that EPA has sufficient time to incorporate the C&D rule requirements into the new CGP and issue the new CGP prior to the existing permit's expiration date. If EPA does not issue the new CGP before expiration of the existing permit, no new construction projects may be permitted under the CGP, leaving individual NPDES permits as the only available option for permitting new projects. The sole reliance on individual permits would mean that discharge authorizations would almost certainly be delayed due to the greater amount of time and Agency resources that are required for developing and issuing individual permits. In turn, construction projects that need to begin construction activity on or after midnight June 30, 2011 would be delayed for an uncertain amount of time until EPA could review their individual permit applications and issue the necessary permits. Rather than risk detrimental delays to new construction projects, EPA has decided that it is advisable to instead propose a modification to the 2008 CGP to extend the expiration date until February 15, 2012.

In addition, EPA notes that the February 15, 2012 expiration date is a modification from the proposal to extend the date to January 31, 2012. See 79 FR 22891 (April 25, 2011). As discussed below in Section III.C, commenters pointed out that EPA had earlier requested that the Seventh Circuit Court of Appeals hold in abeyance until February 15, 2012 any further court proceedings in the challenge to the C&D rule's numeric turbidity limit. Changing the expiration date of the 2008 CGP to February 15, 2012 date is consistent with its motion to the court.

B. EPA's Authority to Modify NPDES Permits

EPA regulations establish when the permitting authority may make modifications to existing NPDES permits. In relevant part, EPA regulations state that ''[w]hen the Director receives any information * * * he or she may determine whether or not

one or more of the causes listed in paragraph (a) * * * of this section for modification * * * exist. If cause exists, the Director may modify * * * the permit accordingly, subject to the limitations of 40 CFR 124.5(c).'' 40 CFR 122.62. For the purposes of this **Federal Register** notice, the relevant cause for modification is at 40 CFR 122.62(a)(2), which states that a permit may be modified when ''[t]he Director has received new information'' and that information ''was not available at the time of permit issuance * * * and would have justified the application of different permit conditions at the time of issuance.'' Pursuant to EPA regulations, ''[w]hen a permit is modified, only the conditions subject to the modification are reopened.'' 40 CFR 122.62.

In the case of the 2008 CGP, a permit modification is justified based on the new information EPA received since it issued the 2008 CGP, and more specifically, since it modified the 2008 CGP in January 2010, in terms of the delay to the permit process associated with the discovery of the error in the numeric turbidity limit and the Agency's decision to stay to the numeric turbidity limit. If this information was available at the time of issuance of the 2008 CGP, and more specifically in January 2010 when EPA extended the expiration date to June 30, 2011, it would have supported establishing an expiration date for the 2008 CGP that was later than June 30, 2011. As a result, cause exists under EPA regulations to justify modification of the 2008 CGP to extend the expiration date of the permit from midnight June 30, 2011 to midnight February 15, 2012.

EPA notes that, by law, NPDES permits cannot be extended beyond 5 years. 40 CFR 122.46. The proposed extension of the 2008 CGP complies with this restriction. The 2008 CGP was first issued on June 30, 2008. With the new expiration date set as February 15, 2012, the permit will still have been in effect for less than the 5-year limit.

C. Response to Comments

EPA received 4 comments in response to the proposed extension of the 2008 CGP expiration date. All of the commenters were supportive of an extension to the expiration date of the 2008 CGP, however, each comment stated that the proposed extension period was inadequate. Several of the commenters recommended extending the permit to June 30, 2013, making it a full 5-year permit. The following is a summary of the concerns raised by the commenters and EPA's responses:

• *EPA requires additional time to streamline the permitting process.* According to one commenter, EPA should take the period of time remaining in the 5-year permit term to focus on ways to streamline the existing permitting process under the CGP. This commenter specifically recommended that the Agency consider the development of a ''Single Lot Permit'' for small residential construction projects, with streamlined authorization procedures and best management practice (BMP) requirements, either within the new CGP or as a stand-alone permit. The commenter also urged EPA to modify the draft CGP to incorporate ''Qualified Local Program'' (QLP) provisions.

EPA appreciates the suggestion by the commenter that the Agency take the time to adequately consider ways to streamline the permitting process so that it better accommodates small-scale, single lot construction projects. EPA invites the commenter and other members of the public to provide more specific suggestions in their comments on the draft new CGP as to how the permit can be streamlined to better address the types of requirements that are appropriate for single-lot residential construction sites. At the same time, however, EPA does not agree that additional time beyond February 15, 2012 is needed to address this issue, and is confident that it can consider such streamlining recommendations within this timeframe.

Similarly, EPA does not agree that additional time is needed to incorporate QLP provisions into the permit. For background, the NPDES regulations at 40 CFR 122.44(s) enable EPA to incorporate by reference qualifying State, Tribal, or local program requirements applicable to small construction sites so that these requirements replace corresponding provisions in the CGP. To effectuate QLP requirements in the CGP, EPA would need to propose the addition of the QLP provisions for public comment. To date, EPA has not been approached by a State, Tribe, or local program to include any such requirements in the CGP, despite previous encouragement by the Agency to do so. For that reason, EPA does not find it necessary to further delay the issuance of the new CGP to address the inclusion of QLP requirements. Having said this, EPA notes that it will consider any request by affected states, Tribes, or local governments to include QLP requirements in the CGP.

• *The proposed extension does not account for the amount of time needed to complete the rulemaking process to correct the numeric turbidity limit.* Some commenters questioned how EPA could issue a new permit by the proposed January 31, 2012 expiration date incorporating both the (future) numeric and non-numeric requirements of the C&D rule given the realistic amount of time that is needed to complete the rulemaking for correcting the C&D rule's numeric turbidity limit. These commenters noted that since EPA has not yet proposed a correction to the numeric limit, and because the Agency will need to allow for an adequate public comment period and sufficient time to review and respond to comments it receives, it appears unlikely that the correction rule will be completed prior to the proposed expiration date of the 2008 CGP. The commenters also noted that the public should be given an opportunity to review the draft CGP's sampling protocols with the final turbidity limit in mind. In addition, a few of the commenters remarked that the proposed January 31, 2012 date is out of step with the Agency's own request to the Seventh Circuit Court of Appeals to hold the lawsuit challenging the validity of the numeric turbidity limit in abeyance until February 15, 2012. For these reasons, these commenters requested that EPA modify the proposed extension so that the 2008 CGP would instead expire on June 30, 2013, making it a full 5-year permit.

The commenters are correct that EPA asked the Seventh Circuit Court of Appeals to hold the litigation challenging the numeric turbidity limit (*Wisconsin Builders Association et. al.* v. *U.S. EPA,* No. 09–4113) in abeyance until February 15, 2012. See *EPA's Unopposed Motion for Partial Vacature of the Final Rule, Remand of the Record, To Vacate Briefing Schedule, and to Hold Case in Abeyance,* No. 09–4113 (consolidated with Nos. 10–1247 and 10–1876) (August 12, 2010). EPA agrees that, in retrospect, the use of February 15, 2012 would have been an appropriate date for the expiration of the current permit since it is consistent with the timeframe that was presented to the court. For this reason, EPA has decided to further extend the 2008 CGP so that it expires on February 15, 2012 instead of January 31, 2012.

EPA does not agree with the commenter that a longer extension of the 2008 CGP is needed or appropriate. If the final numeric effluent limit is completed prior to the February 15, 2012 expiration date of the 2008 CGP, EPA intends to include the final, corrected turbidity limit in the new permit. As the commenters noted, the Agency proposed in the draft permit a

placeholder for the final turbidity limit along with a draft set of sampling requirements (see Part 3.3 of the draft CGP), so that if the numeric limit is finalized by February 15, 2012, the numeric limit and the final sampling requirements would be included in the final permit. EPA believes that providing a draft permit with all of the provisions necessary to implement the final limit, even though the final numeric limit is not yet known, provides the public with an adequate opportunity to review and provide comment on sampling requirements that the Agency believes are appropriate for implementing a numeric turbidity limit.

EPA also does not agree with the commenter's suggestion that additional time is needed so that the public may review the draft CGP's sampling requirements with the specific turbidity limit in mind. The specific turbidity limit value will undergo a separate Agency rulemaking effort, including a public notice and comment process dedicated to that rulemaking, which is the proper venue for conducting public review of that limit. As stated previously, EPA would be required to incorporate the final numeric limit in its new permit if it is finalized before EPA's new CGP is issued. See 40 CFR 122.44(a)(1). EPA anticipates that the final value of the turbidity limit can be directly inserted into the CGP without the need to translate the limit further, thus making it unnecessary to have a specific public review of the use of the limit in the permit.

Furthermore, in developing the new CGP's draft sampling requirements, EPA put forward for comment provisions for conducting turbidity monitoring that the Agency views as workable regardless of the value of the final numeric turbidity limit. The sampling requirements in the draft permit reflect EPA's research into the types of requirements that will likely result in measurements that are ''representative of the monitored activity'' (see 40 CFR 122.41(j)), are reflective of the types of requirements imposed in other similar permits, and were envisioned by EPA in the C&D rule. See III.XIX.A of the preamble to the C&D rule, 74 FR 63047 (December 1, 2009). Although the draft requirements are still undergoing public review, it is important to note that it was EPA's judgment when it issued the draft permit that the draft sampling provisions are appropriate regardless of the final effluent limit. Through the public comment process, EPA will revisit these sampling requirements, as well as the Agency's initial assumptions discussed above, based on comments received. However, at this time, EPA does not believe that additional time is necessary for the public to review the draft sampling requirements based on the as yet unknown final value of the numeric turbidity limit.

• *The 2008 CGP should be extended further to allow for the Seventh Circuit litigation to play out in full prior to implementing the C&D rule in the new permit.* A few of the commenters suggested that EPA provide for an extension of the 2008 CGP to June 30, 2013 in order to allow for the litigation to come to a final outcome so that the new CGP would presumably reflect any final decision regarding the C&D rule.

EPA does not agree that it is necessary or appropriate to extend the 2008 CGP further to account for the timeline of litigation on the C&D rule. It is difficult to anticipate with any degree of certainty how long this litigation will take, and what the outcome will be, and EPA does not agree that it is appropriate to base its permitting timeline on such a process. EPA believes it is important to issue the new CGP as quickly as possible independent of any litigation schedule. Among other reasons, EPA is interested in issuing the permit in a timely manner so that regulated construction sites, state permitting authorities, and the general public are given the opportunity to see in the near term how the Agency intends to implement its own rule. In EPA's judgment, the February 15, 2012 date for the expiration of the 2008 CGP provides EPA with a sufficient window of time within which to issue the new permit and accomplish this objective.

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

Dated: June 28, 2011.

H. Curtis Spalding,

Regional Administrator, EPA Region 1.

Dated: June 29, 2011.

Kevin Bricke,

Acting Director, Division of Environmental Planning & Protection, EPA Region 2.

Dated: June 28, 2011.

Carl-Axel P. Soderberg,

Division Director, Caribbean Environmental Protection Division, EPA Region 2.

Dated: June 28, 2011.

Jon M. Capacasa,

Director, Water Protection Division, EPA Region 3.

Dated: June 28, 2011.

Tinka G. Hyde,

Director, Water Division, EPA Region 5.

Dated: June 28, 2011.

Miguel I. Flores,

Director, Water Quality Protection Division, EPA Region 6.

Dated: June 27, 2011.

Karen Flournoy,

Acting Director, Water, Wetlands and Pesticides Division, EPA Region 7.

Dated: June 28, 2011.

Stephen S. Tuber,

Assistant Regional Administrator, EPA Region 8.

Dated: June 27, 2011.

Alexis Strauss,

Director, Water Division, EPA Region 9.

Dated: June 28, 2011.

Christine Psyk,

Associate Director, Office of Water and Watersheds, EPA Region 10.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–1017; FRL–8878–7]

Product Cancellation Order for Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations, voluntarily requested by the registrants and accepted by the Agency, of the products listed in Tables 1, 2, and 3 of Unit II., pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This cancellation order follows a May 4, 2011 **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 4 of Unit II. to voluntarily cancel these product registrations. In the May

4, 2011 notice, EPA indicated that it would issue an order implementing the cancellations, unless the Agency received substantive comments within the 30-day comment period that would merit its further review of these requests, or unless the registrants withdrew their requests. The Agency did not receive any comments on the notice. Further, the registrants did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations are effective July 8, 2011.

FOR FURTHER INFORMATION CONTACT: Maia Tatinclaux, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–0123; fax number: (703) 308–8090; e-mail address: *tatinclaux.maia@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get copies of this document and other related information?

EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–1017. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

II. What action is the agency taking?

This notice announces the cancellation, as requested by registrants, of 124 products registered under FIFRA section 3. These registrations are listed in sequence by registration number in Tables 1, 2, and 3 of this unit.

TABLE 1—PRODUCT CANCELLATIONS

EPA registration No.	Product name	Chemical name
000056–00056	J.T. Eaton Answer for Mice Feeder Box	Chlorophacinone.
000056–00069	J.T. Eaton Answer for Rats Feeder Box	Chlorophacinone.
01020–00008	Oakite Steri-Det	Alkyl * dimethyl benzyl ammonium chloride *(60% C_{14}, 30% C_{16}, 5% C_{18}, 5% C_{12}).
		Alkyl * dimethyl ethyl ammonium chloride *(50% C_{12}, 30% C_{14}, 17% C_{16}, 3% C_{18}).
001022–00523	Cunapsol-2	Copper naphthenate.
001448–00054	Nabe-M	Carbamodithioic acid, methyl-monopotassium salt.
		Carbamodithioic acid, cyano-disodium salt.
005481–00551	Ambush 4E Insecticide	Permethrin.
006836–00057	Barquat 42Z–10	Alkyl * dimethyl benzyl ammonium chloride *(60% C_{14}, 30% C_{16}, 5% C_{18}, 5% C_{12}).
		Alkyl * dimethyl ethylbenzyl ammonium chloride *(68% C_{12}, 32% C_{14}).
006836–00270	Barquat 42Z–10F	Alkyl * dimethyl benzyl ammonium chloride *(60% C_{14}, 30% C_{16}, 5% C_{18}, 5% C_{12}).
		Alkyl * dimethyl ethylbenzyl ammonium chloride *(68% C_{12}, 32% C_{14}).
007792–00005	Roebic Root Endz	Copper sulfate pentahydrate.
009688–00070	Chemsico Roach Control System I	Tralomethrin.
009688–00078	Chemsico Tralomethrin Indoor Fogger	Tralomethrin.
009688–00080	Chemsico Home Insect Control A	Tralomethrin.
009688–00081	Chemsico Home Insect Control B	Tralomethrin.
009688–00082	Chemsico Tralomethrin Flea Killer	Tralomethrin.
009688–00087	Chemsico Home Insect Control D	Tralomethrin.
009688–00091	Chemsico Home Insect Control Refill	Tralomethrin.
009688–00098	Chemsico Home Insect Control E	Tralomethrin.
009688–00101	Chemsico Home Insect Control E Refill	Tralomethrin.
009688–00113	Chemsico Tralomethrin Insecticide D	Tralomethrin.
009688–00119	Green Thumb Home Insect Fogger	Tralomethrin.
009688–00144	Dethmor 3.75% EC	Tralomethrin.
009688–00147	Chemsico Indoor Fogger G	Tralomethrin.
009688–00152	Saga WP Insecticide 228	Tralomethrin.
009688–00153	Saga Multi-purpose Home Pest Control Insecticide	Tralomethrin.
009688–00166	Chemsico Insect Control CP	Tralomethrin.
009688–00167	Aerosol Insecticide IT–B	Imiprothrin.
		Tralomethrin.
009688–00170	Chemsico Aerosol Insecticide IT–D	Imiprothrin.
		Tralomethrin.
009688–00171	Chemsico Aerosol Insecticide IT–C	Imiprothrin.
		Tralomethrin.
009688–00172	Chemsico Insect Granules Formula T	Tralomethrin.

TABLE 1—PRODUCT CANCELLATIONS—Continued

EPA registration No.	Product name	Chemical name
009688–00185	Chemsico Tralomethrin Insecticide C	Prallethrin. Tralomethrin.
009688–00194	Chemsico Wasp & Hornet Killer TE	Prallethrin. Tralomethrin.
009688–00204	Chemsico Insecticide Concentrate T	Tralomethrin.
009688–00275	Chemsico Insecticide RTU OP–M	Pyrethrins.
047000–00139	Permethrin Dust 0.25%	Permethrin.
047371–00137	Formulation RTU–6075	Alkyl * dimethyl benzyl ammonium chloride *(60% C_{14}, 30% C_{16}, 5% C_{18}, 5% C_{12}). Alkyl * dimethyl ethylbenzyl ammonium chloride *(50% C_{12}, 30% C_{14}, 17% C_{16}, 3% C_{18}).
048273–00023	Marman Malathion	Malathion.
048273–00026	Marman Malathion 56 EC	Malathion.
062719–00308	Vista	Fluroxypyr 1-methylheptyl ester.

TABLE 2—CANCELLATIONS OF REGISTRATIONS CONTAINING METHYL BROMIDE

EPA registration number	Product name	Chemical name
003377–00009	Methyl Bromide Technical	Methyl bromide.
005785–00023	Terr-O-Gas 45	Chloropicrin. Methyl bromide.
008622–00040	57–43 Preplant Soil Fumigant	Methyl bromide. Chloropicrin.
008622–00044	80–20 Preplant Soil Fumigant	Methyl bromide. Chloropicrin.

Table 3 contains a list of registrations for which companies paying at one of the maintenance fee caps requested cancellation in the FY 2011 maintenance fee billing cycle. Because maintaining these registrations as active would require no additional fee, the Agency is treating these requests as voluntary cancellations under 6(f)(1).

TABLE 3—CANCELLATIONS OF PRODUCTS DUE TO NON-PAYMENT OF MAINTENANCE FEES

EPA registration No.	Product name	Chemical name
000400–00069	B-Nine	Daminozide.
000400–00500	Floramite Ls	Bifenazate.
000400–00501	Floramite GN	Bifenazate.
006836–00022	Lonza Disinfectant Cleaner (30–3)	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride.
006836–00027	Lonza Disinfectant Cleaner (47–5)	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride.
006836–00034	Lonza Formulation 71–30	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride. 1-Octanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. 1-Decanaminium, *N,N*-dimethyl-*N*-octyl-, chloride.
006836–00037	Lonza Formulation 68–16	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride. 1-Octanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. 1-Decanaminium, *N,N*-dimethyl-*N*-octyl-, chloride.
006836–00072	Lonza Formulation S–37	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride. 1-Octanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. 1-Decanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
006836–00099	Formulation 100a	Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
006836–00100	Formulation DC 100b	Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
006836–00101	Formulation DC 100C	Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
006836–00102	Formulation 100 D	Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
006836–00105	Rohm and Haas DC–100 G	Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
006836–00137	Lonza Formulation S–37f	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride. 1-Octanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. 1-Decanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).

TABLE 3—CANCELLATIONS OF PRODUCTS DUE TO NON-PAYMENT OF MAINTENANCE FEES—Continued

EPA registration No.	Product name	Chemical name
006836–00141	Lonza Formulation 70–12f	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride, 1-Octanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. 1-Decanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
006836–00158	Bio Guard Swimming Pool Algicide 28–10	Alkyl* dimethyl benzyl ammonium chloride *(58%C_{14}, 28%C_{16}, 14%C_{12}).
006836–00178	Bio-Guard M–38 Disinfectant, Cleaner, Deodorant	Alkyl* dimethyl benzyl ammonium chloride *(58%C_{14}, 28%C_{16}, 14%C_{12}).
006836–00179	Bio-Guard L–38	Alkyl* dimethyl benzyl ammonium chloride *(58%C_{14}, 28%C_{16}, 14%C_{12}).
006836–00181	Lonza Formulation LS–22	Alkyl* dimethyl benzyl ammonium chloride *(58%C_{14}, 28%C_{16}, 14%C_{12}).
006836–00185	Bio-Guard L–76	Alkyl* dimethyl benzyl ammonium chloride *(58%C_{14}, 28%C_{16}, 14%C_{12}).
006836–00215	Barquat Molluscicide 80	Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
006836–00222	Bath Master	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride 1-Octanaminium, *N*,N-dimethyl-*N*-octyl-, chloride. 1-Decanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
006836–00223	Bath Master (refill)	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride 1-Octanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. 1-Decanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
006836–00224	Smart AB	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride. 1-Octanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. 1-Decanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
006836–00225	Smart AB Refill	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride. 1-Octanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. 1-Decanaminium, *N,N*-dimethyl-*N*-octyl-, chloride. Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
006836–00232	Bardac 22–50	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride.
006836–00246	Lonza Barquat 1552–5%	Dialkyl* methyl benzyl ammonium chloride *(60% C_{14}, 30% C_{16}, 5% C_{18}, 5% C_{12}). Alkyl* dimethyl benzyl ammonium chloride *(60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}).
006836–00260	Barquat WP 50	Alkyl* dimethyl benzyl ammonium chloride *(67%C_{12}, 25%C_{14}, 7%C_{16}, 1%C_{18}).
043813–00033	Bethoguard Technical	Bethoxazin.
043813–00034	Bethoguard Biocide	Bethoxazin.
043813–00035	Bethoguard 300 SC	Bethoxazin.
047371–00002	Formulation HS–64Q	Alkyl* dimethyl benzyl ammonium chloride *(60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}). Alkyl* dimethyl ethylbenzyl ammonium chloride *(50%C_{12}, 30%C_{14}, 17%C_{16}, 3%C_{18}).
047371–00007	Formulation HS–821Q	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride. Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
047371–00008	Formulation HS–256Q	Alkyl* dimethyl benzyl ammonium chloride *(60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}). Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C_{12}, 32%C_{14}).
047371–00009	Quanto A Germicidal Detergent	Alkyl* dimethyl benzyl ammonium chloride *(60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}). Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C_{12}, 32%C_{14}).
047371–00029	Formulation HI–69d	Alkyl* dimethyl benzyl ammonium chloride *(60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}). Tributyltin oxide.
047371–00038	HS–Q Germicidal Concentrate	Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
047371–00041	Formulation HS–56P	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C_{12}, 32%C_{14}). Alkyl* dimethyl benzyl ammonium chloride *(60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}).

TABLE 3—CANCELLATIONS OF PRODUCTS DUE TO NON-PAYMENT OF MAINTENANCE FEES—Continued

EPA registration No.	Product name	Chemical name
047371–00048	Formulation AE–3328	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C_{12}, 32%C_{14}). Alkyl* dimethyl benzyl ammonium chloride *(60%C_{14}, 30%C_{16}, 5% 5%C_{18}, 5%C_{12}).
047371–00054	Formulation HS 210–37	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride.
047371–00056	HS–1210 Swimming Pool Algaecide	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride. Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
047371–00074	Pow-256 Powdered Germicidal Detergent	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C_{12}, 32%C_{14}). Alkyl* dimethyl benzyl ammonium chloride *(60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}).
047371–00077	Formulation HTA–64 Disinfectant	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C_{12}, 32%C_{14}). Alkyl* dimethyl benzyl ammonium chloride *(60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}).
047371–00098	HS–451 Swimming Pool Algaecide	Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
047371–00141	Formulation HH–652 Q	Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}). 1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride.
047371–00142	Formulation HTA–96	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C_{12}, 32%C_{14}). Alkyl* dimethyl benzyl ammonium chloride *(60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}).
047371–00143	HS–96 Disinfectant Bowl Cleaner	Alkyl* dimethyl ethylbenzyl ammonium chloride *(50%C_{12}, 30%C_{14}, 17%C_{16}, 3%C_{18}). Alkyl* dimethyl benzyl ammonium chloride *(60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}).
047371–00145	HS–210 Laundry Mildew and Bacteriostat (10%)	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride.
047371–00150	TB–910 Disinfectant Bowl Cleaner & Deodorant	Hydrochloric acid. 1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride.
047371–00155	Formulation RTU–6075a	Alkyl* dimethyl ethylbenzyl ammonium chloride *(50%C_{12}, 30%C_{14}, 17%C_{16}, 3%C_{18}). Alkyl* dimethyl benzyl ammonium chloride *(60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}).
047371–00157	Formulation RTU–6075(la)	Alkyl* dimethyl ethylbenzyl ammonium chloride *(50%C_{12}, 30%C_{14}, 17%C_{16}, 3%C_{18}). Alkyl* dimethyl benzyl ammonium chloride *(60%C_{14}, 30%C_{16}, 5%C_{18}, 5%C_{12}).
047371–00165	HS–451 Waterbed Microbiocide	Alkyl* dimethyl benzyl ammonium chloride *(50%C_{14}, 40%C_{12}, 10%C_{16}).
047371–00172	TB–A165 Disinfectant Bowl Cleaner	Hydrochloric acid. 1-Decanaminium, *N*-decyl-*N*,N-dimethyl-, chloride.
047371–00184	HS–210 Sap Stain Control	1-Decanaminium, *N*-decyl-*N,N*-dimethyl-, chloride.
073049–00360	Tralex FA 3.75% EC	Tralomethrin.
073049–00401	Tralex MUP	Tralomethrin.
073049–00459	Ultra TEC DS Yard and Patio Spray	S–Bioallethrin. Deltamethrin.
CA780167	Comite Agricultural Miticide	Propargite.
CA940008	Omite-30WS Agricultural Miticide	Propargite.
DE040003	Acramite 50WS	Bifenazate.
ID070010	Acramite-4SC	Bifenazate.
ID070013	Acramite-4SC	Bifenazate.
ID910015	Comite Agricultural Miticide	Propargite.
ID940011	Comite Agricultural Miticide	Propargite.
ID910015	Comite Agricultural Miticide	Propargite.
KS950001	Comite II	Progargite.
MT900001	Comite Agricultural Miticide	Propargite.
ND050005	Dimilin 2l	Diflubenzuron.
NV870009	Comite Agricultural Miticide	Propargite.
OR080010	Comite Agricultural Miticide	Propargite.
OR080015	Comite	Propargite.
OR080029	Acramite-4SC	Bifenazate.
OR080030	Acramite-4SC	Bifenazate.
SC910003	Comite Agricultural Miticide	Propargite.
TN080006	Temprano	Abamectin.
TX940006	Comite II	Propargite.
UT960006	Comite Agricultural Miticide	Propargite.
WA040020	Comite—Potato SLN	Propargite.
WA080009	Acramite-4SC	Bifenazate.

TABLE 3—CANCELLATIONS OF PRODUCTS DUE TO NON-PAYMENT OF MAINTENANCE FEES—Continued

EPA registration No.	Product name	Chemical name
WA080011	Acramite-4SC	Bifenazate.
WA870029	Comite Agricultural Miticide	Propargite.
WA910033	Comite Agricultural Miticide	Propargite.

Table 4 of this unit includes the names and addresses of record for all registrants of the products in Tables 1, 2, and 3 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Tables 1, 2, and 3 of this unit.

TABLE 4—REGISTRANTS OF CANCELLED PRODUCTS

EPA Company No.	Company name and address
56	Eaton JT and Company Inc, 1393 E. Highland Road, Twinsburg, OH 44087.
400	Chemtura Corp., Attn: Crop Registration, 199 Benson Road, Middlebury, CT 06749.
1020	Chemetall US, Inc., 675 Central Avenue, New Providence, NJ 07974–0007.
1022	IBC Manufacturing Co., 416 E. Brooks Rd, Memphis, TN 38109.
1448	Buckman Laboratories Inc., 1256 North Mclean Blvd, Memphis, TN 38108.
3377	Albermarle Corporation, 451 Florida Street, Baton Rouge, LA 70801–1765.
5481	Amvac Chemical Corporation, 4695 MacArthur Court, Suite 1250, Newport Beach, CA 92660.
5785	Great Lakes Chemical Corporation, Agent: Chemtura Corporation, 1801 Highway 52 West, West Lafayette, IN 47906.
6836	Lonza Inc., 90 Boroline Rd., Allendale, NJ 07401.
7792	Roebic Laboratories, Inc., Agent: Landis International, Inc., 3185 Madison Highway,, P.O. Box 5126, Valdosta, GA 31605–5126.
8622	ICL–IP America, Inc., 95 MacCorkle Avenue, Southwest, South Charleston, WV 25303.
9688	Chemsico, Div of United Industries Corp, P.O. Box 142642, St Louis, MO 63114–0642.
43813	Janssen PMP Janssen Pharmaceutica NV, 1125 Trenton-Harbourton Road, Titusville, NJ 08560–0200.
47000	Chem-Tech, LTD., 4515 Fleur Dr., #303, Des Moines, Iowa 50321.
47371	H & S Chemicals Division, c/o Lonza Inc., 90 Boroline Road, Allendale, NJ 07401.
48273	Marman USA Inc., Agent: Nufarm Inc., 150 Harvester Drive, Suite 200, Burr Ridge, IL 60527.
62719	Dow Agrosciences LLC, 9330 Zionsville Rd, 308/2E, Indianapolis, IN 46268–1054.
73049	Valent Biosciences Corp., 870 Technology Way, Suite 100, Libertyville, IL 60048–6316.
CA780167; CA940008; DE040003; ID070010; ID070013; ID910015; ID940011; ID970015; KS950001; MT900001; ND050005; NV870009; OR080010; OR080015; OR080029; OR080030; SC910003; TN080006; TX940006; UT960006; WA040020; WA070009; WA070011; WA870029; WA910033.	Chemtura Corp., Attn: Crop Registration, 199 Benson Road (2–5), Middlebury CT 06749.

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period provided, EPA received no comments in response to the May 4, 2011 **Federal Register** notice announcing the Agency's receipt of the requests for voluntary cancellations of products listed in Tables 1, 2, and 3 of Unit II.

IV. Cancellation Order

Pursuant to FIFRA section 6(f), EPA hereby approves the requested cancellations of the registrations identified in Tables 1, 2, and 3 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Tables 1, 2, and 3 of Unit II are cancelled. The effective date of the cancellations that are the subject of this notice is July 8, 2011. Any distribution, sale, or use of existing stocks of the products identified in Tables 1, 2, and 3 of Unit II. in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI. will be a violation of FIFRA.

V. What is the agency's authority for taking this action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be cancelled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment in the **Federal Register** of May 4, 2011 (76 FR 25334) (FRL–8870–5). The comment period closed on June 3, 2011.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. The existing stocks provisions for the products subject to this order are as follows:

A. Registrations Listed in Table 1 of Unit II Except Nos. 000056–00056 and 000056–00069

The Agency anticipates allowing registrants to sell and distribute existing stocks of these products until July 9, 2012. Thereafter, registrants will be

prohibited from selling or distributing the pesticides identified in Table 1 of Unit II., except for export consistent with FIFRA section 17 or for proper disposal. Persons other than registrants are allowed to sell, distribute, or use existing stocks until such stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the cancelled products.

B. Registration Nos. 000056–00056 and 000056–00069

All sale or distribution of existing stocks by the registrants is prohibited after July 8, 2011, except for export consistent with FIFRA section 17 or for proper disposal. Persons other than registrants are allowed to sell, distribute, or use existing stocks until such stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the cancelled products.

C. Registrations Listed in Table 2 of Unit II

All sale or distribution of existing stocks by the registrants is prohibited after July 8, 2011, unless that sale or distribution is solely for the purpose of facilitating disposal or export of the products.

Existing stocks may be sold and distributed by persons other than the registrant until November 7, 2011. Existing stocks may be used until exhausted, provided that such use complies with the EPA-approved label and labeling of the products.

D. Registrations Listed in Table 3 of Unit II

Registrants are allowed to sell and distribute existing stocks of these products until January 15, 2012, 1 year after the date on which the maintenance fee was due. Thereafter, registrants will be prohibited from selling or distributing the pesticides identified in Table 3 of Unit II., except for export consistent with FIFRA section 17 or for proper disposal. Persons other than registrants are allowed to sell, distribute, or use existing stocks until such stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the cancelled products.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: June 29, 2011.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2011–17089 Filed 7–7–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 10:50 a.m. on Wednesday, July 6, 2011, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation's supervision, corporate, and resolution activities.

In calling the meeting, the Board determined, on motion of Vice Chairman Martin J. Gruenberg, seconded by Director John E. Bowman (Acting Director, Office of Thrift Supervision), concurred in by Director Thomas J. Curry (Appointive), Director John G. Walsh (Acting Comptroller of the Currency), and Chairman Sheila C. Bair, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550—17th Street, NW., Washington, DC.

Dated: July 6, 2011.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2011–17370 Filed 7–6–11; 4:15 pm]

BILLING CODE P

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

TIME AND DATE: July 13, 2011—10 a.m.

PLACE: 800 North Capitol Street, NW., First Floor Hearing Room, Washington, DC.

STATUS: Part of the meeting will be in Open Session and the remainder of the meeting will be in Closed Session.

Matters To Be Considered

Open Session

1. Update from Commissioner Cordero on the Congress of Latin American Ports and Peru Discussions.
2. Options for Passenger Vessel Financial Responsibility Requirements (Performance).

Closed Session

1. Discussion of Transpacific Stabilization Agreement and Westbound Transpacific Stabilization Agreement Transcript Filing Requirement.
2. Staff Briefing and Discussion of Proposed PierPass Traffic Mitigation Fee Increase.
3. Docket No. 09–08: SSA Terminals, LLC and SSA Terminals (Oakland), *LLC* v. *The City of Oakland.*
4. Staff Briefing and Discussion of the Reconstruction Proceedings and Chapter 15 Bankruptcy Petition of The Containership Company A/S.

CONTACT PERSON FOR MORE INFORMATION: Karen V. Gregory, Secretary, (202) 523–5725.

Karen V. Gregory,

Secretary.

[FR Doc. 2011–17348 Filed 7–6–11; 4:15 pm]

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 July 21, 2011.

A. Federal Reserve Bank of Philadelphia (William Lang, Senior Vice

President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521:

1. *Patriot Financial Partners, GP, L.P.; Patriot Financial Partners, L.P.; Patriot Financial Partners Parallel, L.P.; Patriot Financial Partners, GP, LLC; Patriot Financial Managers, L.P.; and Ira M. Lubert, W. Kirk Wycoff, and James J. Lynch,* all of Philadelphia, Pennsylvania, to acquire voting shares of Heritage Oakes Bancorp, and thereby indirectly acquire voting shares of Heritage Bank, both in Paso Robles, California.

Board of Governors of the Federal Reserve System, July 1, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–17086 Filed 7–7–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 1, 2011.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Acting Vice President) 1000 Peachtree Street, NE., Atlanta, Georgia 30309:

1. *Bankia, S.A.,* Valencia, Spain; to become a bank holding company by acquiring 100 percent of the voting shares of Caja Madrid Cibeles, S.A., Madrid, Spain, CM Florida Holdings, Inc., Coral Gables, Florida, and City National Bank of Florida, Miami, Florida.

Board of Governors of the Federal Reserve System, July 1, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–17085 Filed 7–7–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 4, 2011.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) P.O. Box 55882, Boston, Massachusetts 02106–2204:

1. *Provident Bancorp and Provident Bancorp, Inc.,* both in Amesbury, Massachusetts, to acquire The Provident Bank, Amesbury, Massachusetts. In connection with this application, Provident Bancorp, Inc., has applied to become a bank holding company.

Board of Governors of the Federal Reserve System, July 5, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–17153 Filed 7–7–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies That Are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 4, 2011.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Acting Vice President), 1000 Peachtree Street, NE., Atlanta, Georgia 30309:

1. *CenterState Banks, Inc.,* Davenport, Florida; to acquire 100 percent of the voting shares of Federal Trust Corporation, and indirectly acquire Federal Trust Bank, both in Winter Park, Florida, and thereby engage in operating a savings association, pursuant to section 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, July 5, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–17152 Filed 7–7–11; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0022; Docket 2011–0079; Sequence 11]

Federal Acquisition Regulation; Submission for OMB Review; Duty-Free Entry

AGENCIES: 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 (44 U.S.C. chapter 35), the Regulatory Secretariat (MVCB) 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 duty-free entry.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the 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 August 8, 2011.

ADDRESSES: Submit comments identified by Information Collection 9000–0022, Duty-Free Entry by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by inputting ''Information Collection 9000–0022, Duty-Free Entry,'' under the heading ''Enter Keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0022, Duty-Free Entry.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0022, Duty-Free Entry,'' 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 9000–0022, Duty-Free Entry.

Instructions: Please submit comments only and cite Information Collection 9000–0022, Duty-Free Entry, 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: Cecelia Davis, Procurement Analyst, Acquisition Policy Division, GSA (202) 219–0202 or e-mail *Cecelia.davis@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

United States laws impose duties on foreign supplies imported into the customs territory of the United States. Certain exemptions from these duties are available to Government agencies. These exemptions are used whenever the anticipated savings outweigh the administrative costs associated with processing required documentation. When a Government contractor purchases foreign supplies, it must notify the contracting officer to determine whether the supplies should be duty-free. In addition, all shipping documents and containers must specify certain information to assure the duty-free entry of the supplies.

The contracting officer analyzes the information submitted by the contractor to determine whether or not supplies should enter the country duty-free. The information, the contracting officer's determination, and the U.S. Customs forms are placed in the contract file.

B. Annual Reporting Burden

Respondents: 1,330.

Responses per Respondent: 10.

Total Responses: 13,300.

Hours per Response: .5.

Total Burden Hours: 6,650.

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. 9000–0022, Duty-Free Entry, in all correspondence.

Dated: July 1, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy Division.

[FR Doc. 2011–17213 Filed 7–7–11; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0141; Docket 2011–0079; Sequence 15]

Federal Acquisition Regulation; Information Collection; Buy American Act—Construction

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), the Regulatory Secretariat (MVCB) 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 the Buy American Act—Construction (Grimberg Decision).

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the 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 September 6, 2011.

FOR FURTHER INFORMATION CONTACT: Ms. Cecelia Davis, Procurement Analyst, Acquisition Policy Division, GSA (202) 219–0202 or *Cecelia.davis@gsa.gov.*

ADDRESSES: Submit comments identified by Information Collection 9000–0141, American Act—Construction (Grimberg Decision), by any of the following methods:

• *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by inputting ''Information Collection 9000–0141,'' American Act—Construction (Grimberg Decision), under the heading ''Enter Keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0141,'' American Act—Construction (Grimberg Decision). Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0141,'' American Act—Construction (Grimberg Decision), 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 9000–0141, American Act—Construction (Grimberg Decision).

Instructions: Please submit comments only and cite Information Collection 9000–0141, American Act—Construction (Grimberg Decision), 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.

SUPPLEMENTARY INFORMATION:

A. Purpose

The clauses at FAR 52.225–9, Buy American Act—Construction Materials, and FAR 52.225–11, Buy American Act—Construction Materials under Trade Agreements, provide that offerors/contractors requesting to use foreign construction material, other than construction material eligible under a trade agreement, shall provide adequate information for Government evaluation of the request.

These regulations implement the Buy American Act for construction (41 U.S.C. 10a–10d).

B. Annual Reporting Burden

Respondents: 500.
Responses per Respondent: 2.
Annual Responses: 1,000.
Hours per Response: 2.5.
Total Burden Hours: 2,500.

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. 9000–0141, Buy American Act—Construction (Grimberg Decision), in all correspondence.

Dated: July 1, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy.

[FR Doc. 2011–17216 Filed 7–7–11; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0134; Docket 2011–0079; Sequence 6]

Federal Acquisition Regulation; Submission for OMB Review; Environmentally Sound Products

AGENCIES: 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 (44 U.S.C. chapter 35), the Regulatory Secretariat (MVCB) 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 environmentally sound products.

DATES: Submit comments on or before August 8, 2011.

ADDRESSES: Submit comments identified by Information Collection 9000–0134, Environmentally Sound Products, by any of the following methods:

• *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by inputting ''Information Collection 9000–0134, Environmentally Sound Products'', under the heading ''Enter Keyword or ID'' and selecting ''Search''. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0134, Environmentally Sound Products''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0134, Environmentally Sound Products'' 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 9000–0134, Environmentally Sound Products.

Instructions: Please submit comments only and cite Information Collection 9000–0134, Environmentally Sound Products, 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. William Clark, Procurement Analyst, Contract Policy Branch, GSA, (202) 219–1813 or *william.clark@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

This information collection complies with Section 6002 of the Resource Conservation and Recovery Act (RCRA) (42 U.S.C. 6962). RCRA requires the Environmental Protection Agency (EPA) to designate items which are or can be produced with recovered materials. RCRA further requires agencies to develop affirmative procurement programs to ensure that items composed of recovered materials will be purchased to the maximum extent practicable. Affirmative procurement programs required under RCRA must contain, as a minimum (1) a recovered materials preference program and an agency promotion program for the preference program; (2) a program for requiring estimates of the total percentage of recovered materials used in the performance of a contract, certification of minimum recovered material content actually used, where appropriate, and reasonable verification procedures for estimates and certifications; and (3) annual review and monitoring of the effectiveness of an agency's affirmative procurement program.

The items for which EPA has designated minimum recovered material content standards are grouped into eight categories: (1) Construction products, (2) landscaping products, (3) nonpaper office products, (4) paper and paper products, (5) park and recreation products, (6) transportation products, (7) vehicular products, and (8) miscellaneous products. The FAR rule also permits agencies to obtain pre-award information from offerors regarding the content of items which the agency has designated as requiring minimum percentages of recovered materials.

In accordance with RCRA, the information collection applies to acquisitions requiring minimum percentages of recovered materials,

when the price of the item exceeds $10,000 or when the aggregate amount paid for the item or functionally equivalent items in the preceding fiscal year was $10,000 or more.

Contracting officers use the information to verify offeror/contractor compliance with solicitation and contract requirements regarding the use of recovered materials. Additionally, agencies use the information in the annual review and monitoring of the effectiveness of the affirmative procurement programs required by RCRA.

B. Annual Reporting Burden

Respondents: 64,350.
Responses per Respondent: 1.
Annual Responses: 64,350.
Hours per Response: .325.
Total Burden Hours: 20,914.
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 20405, telephone (202) 501–4755. Please cite OMB control No. 9000–0134, Environmentally Sound Products, in all correspondence.

Dated: July 1, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy.

[FR Doc. 2011–17218 Filed 7–7–11; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10388, CMS–10252, CMS–R–235, CMS–304 and CMS–304a, CMS–368 and CMS–R–144, CMS–10123 and CMS–10124]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Section 1115 Demonstration HIV and AIDS Application Template; *Use:* Section 1115 of the Social Security Act (the Act) allows the Secretary of the Department of Health and Human Services (the Secretary) to waive selected provisions of section 1902 of the Act for experimental, pilot, or demonstration projects (demonstrations), and to provide Federal Financial Participation (FFP) for demonstration costs which would not otherwise be considered as expenditures under the Medicaid State plan, when the Secretary finds that the demonstrations are likely to assist in promoting the objectives of Medicaid. While some States have applied for section 1115 demonstrations, many have not because the process is long and often tenuous. The purpose of the application template is to streamline the process by collecting the minimally acceptable amount of information required to appropriately review a demonstration request. The template will minimize the amount of time the State spends preparing a demonstration request and it should shorten the review process because the required information should be present. *Form Number:* CMS–10388 (OMB#: 0938–NEW); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Governments; N*umber of Respondents:* 56; *Total Annual Responses:* 6; *Total Annual Hours:* 270; (For policy questions regarding this collection contact Robin Preston at 410–786–3420. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Certificate of Destruction for Data Acquired from the Centers for Medicare and Medicaid Services; *Use:* The Certificate of Destruction is used by recipients of CMS data to certify that they have destroyed the data they have received through a CMS Data Use Agreement (DUA). The DUA requires the destruction of the data at the completion of the project/expiration of the DUA. The DUA addresses the conditions under which CMS will disclose and the User will maintain CMS data that are protected by the Privacy Act of 1974, § 552a and the Health Insurance Portability Accountability Act of 1996. CMS has developed policies and procedures for such disclosures that are based on the Privacy Act and the Health Insurance Portability Act (HIPAA). The Certificate of Destruction is required to close out the DUA and to ensure the data are destroyed and not used for another purpose. *Form Number:* CMS–10252 (OMB#: 0938–1046); *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 84. (For policy questions regarding this collection, contact Sharon Kavanagh at (410) 786–5441. For all other issues call (410) 786–1326.)

3. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Data Use Agreement (DUA) for Data Acquired from the Centers for Medicare & Medicaid Services (CMS); *Use:* The Privacy Act of 1976, § 552a requires the Centers for Medicare & Medicaid Services (CMS) to track all disclosures of the agency's Personally Identifiable Information (PII) and the exceptions for these data releases. CMS is also required by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the Federal Information Security Management Act (FISMA) of 2002 to properly protect all PII data maintained by the agency. When entities request CMS PII data, they enter into a Data Use Agreement (DUA) with CMS. The DUA stipulates that the recipient of CMS PII data must properly protect the data according to FISMA and also provide for its appropriate destruction at the completion of the project/study or the expiration date of the DUA. The DUA form enables the data recipient and CMS to document the request and approval for release of CMS PII data. The form requires the submitter to provide the Requestor's organization; project/study name; CMS contract number (if applicable); data descriptions and the years of the data; retention date; attachments to the agreement; name, title, contact information to include address, city, state, zip code, phone, e-mail, signature and date signed by the requester and custodian; disclosure provision; name of Federal Agency sponsor; Federal Representative name, title, contact information, signature, date; CMS representative name, title, contact information, signature and date;

and concurrence/non-concurrence signatures and dates from 3 CMS System Manager or Business Owners. While the data elements collected are not subject to change, the individualized clauses that are incorporated into any specific DUA are subject to change based on a specific case or situation such as disclosures to states, oversight agencies or DUAs for disproportionate share hospital (DSH) data requests as well as updates to DUAs with additional data descriptions, changes to the requestor or adding custodians to current DUAs. *Form Number:* CMS–R–235 (OCN: 0938–0734) *Frequency:* Once; *Affected Public:* Private Sector—Business or other For-profits and Not-for-profit Institutions; *Number of Respondents:* 2,200; *Number of Responses:* 2,200; *Total Annual Hours:* 916. (For policy questions regarding this collection, contact Sharon Kavanagh at 410–786–5441. For all other issues call (410) 786–1326.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate Program—Labelers Reconciliation of State Invoice (CMS–304) and Prior Quarter Adjustment Statement (CMS–304a); *Use:* Section 1927(b)(2) of the Social Security Act establishes manufacturer requirements for paying quarterly rebates to States as part of the Medicaid Drug Rebate Program. Specifically, in order to receive a rebate on drugs dispensed to Medicaid recipients, States are required to submit quarterly utilization data to drug manufacturers that have national rebate agreements with the Federal Government. Form CMS–304 is used by manufacturers for both unit adjustments and disputes in response to the State's invoice for current quarter utilization. The form CMS–304a is required only in those instances where a manufacturer discovers unit adjustments and/or disputes from a previous quarter's State invoice. Both forms are used to reconcile drug rebate payments made by manufacturer with the State invoices of rebates due; *Form Numbers:* CMS–304 and CMS–304a (OMB#: 0938–0676); *Frequency:* Quarterly; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 1,011; *Total Annual Responses:* 4,044; *Total Annual Hours:* 183,120. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* State Medicaid Drug Rebate Forms: CMS–368 (Administrative Data) and CMS–R–144 (Quarterly Report Data); *Use:* Section 1927(b)(2) of the Social Security Act establishes State requirements for reporting drug utilization data to CMS and to drug manufacturers participating in the Medicaid Drug Rebate Program. Specifically, in order to receive a rebate on drugs dispensed to Medicaid recipients, States are required to submit quarterly utilization data reports to drug manufacturers that have national rebate agreements with the Federal Government. In addition, a copy of these reports must also be submitted to CMS. Form CMS–R–144 is used by the States to submit this utilization information to both manufacturers and CMS. Form CMS–368 is a report of contact for the State to name the individuals involved in the drug rebate program and is required only in those instances where a change to the original data submittal is necessary. The ability to require the reporting of any changes to these data is necessary to the efficient operation of the rebate program; *Form Numbers:* CMS–R–144 and CMS–368 (OMB#: 0938–0852); *Frequency:* Quarterly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 224; *Total Annual Hours:* 12,101. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490. For all other issues call 410–786–1326.)

6. *Type of Information Collection Request:* Extension of a currently approved collection;

7. *Title of Information Collection:* Notice of Provider Non-Coverage (CMS–10123) and Detailed Explanation of Non-Coverage (CMS–10124); *Use:* The Notice of Medicare Provider Non-Coverage (CMS–10123) is used to inform fee-for-service Medicare beneficiaries of the determination that their provider services will end, and of their right to an expedited review of that determination. The Detailed Explanation of Non-Coverage (CMS–10124) is used to provide beneficiaries who request an expedited determination with detailed information of why the services should end. The revised Notice of Provider Non-Coverage and Detailed Explanation of Provider Non-Coverage will no longer require use of the beneficiary's Medicare number as a patient identifier. Instead, when applicable, providers may use a number that helps to link the notice with a related claim. *Form Number:* CMS–10123 and 10124 (OMB#: 0938–0953); *Frequency:* Occasionally; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and Individuals or households; *Number of Respondents:* 5,314,164; *Total Annual Responses:* 5,314,194; *Total Annual Hours:* 885,699. (For policy questions regarding this collection contact Janet Miller at 404–562–1799. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on August 8, 2011.

OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov.*

Dated: July 1, 2011.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2011–17052 Filed 7–7–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10209]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality,

utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Advantage Chronic Care Improvement Program and Quality Improvement Project Reporting Tools; *Use:* Section 1852e(1), (2), (3)(a)(i) of the Social Security Act and 42 CFR 422.152 of the regulations describe CMS' regulatory authority to require each Medicare Advantage Organization (MAO) coordinated care plan that offers one or more MA plans to have an ongoing quality assessment and performance improvement program. This program must include assessing performance using standard measures required by the Center for Medicare and Medicaid Services (CMS), and reporting its performance to CMS.

MAOs will submit their Chronic Care Improvement Programs (CCIPs) and Quality Improvement Project (QIPs) using the revised CCIP and QIP Reporting Tools that are included in this collection. The tools have been redesigned: (1) To decrease the response burden through limiting the amount of narrative required and using an automated system; (2) to be more aligned with the standard QI reporting format; and (3) to improve the information provided by MAOs by using more structured reporting tools. CMS believes the new reporting tools will provide a simpler, easier way for MAOs to report the required data. The new tool will also generate consistency in reporting among plans so that collected data can be used more efficiently by CMS and the plans. *Form Number:* CMS–10209 (OMB#: 0938–1023); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 1,904; *Total Annual Responses:* 1,904; *Total Annual Hours:* 9,520. (For policy questions regarding this collection contact Letticia Ramsey at 410–786–5262. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at *http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage* or email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office at 410–786–1326.

In commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *September 6, 2011:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 1, 2011.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2011–17087 Filed 7–7–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Personal Responsibility Education Program (PREP) Multi-Component Evaluation.

OMB No.: New Collection.

Description: The Family and Youth Services Bureau (HHS/ACF/ACYF/FYSB) and the Office of Planning, Research, and Evaluation (HHS/ACF/OPRE) in the Administration for Children and Families (ACF) are proposing a data collection activity to be undertaken for the Personal Responsibility Education Program (PREP) Multi-Component Evaluation.

The impact study included in the PREP Multi-Component Evaluation is a random assignment evaluation which will expand available evidence on whether the replication of evidence-based effective programs, or the substantial incorporation of elements of these programs, funded as part of the Personal Responsibility Education Program, are effective at delaying sexual activity, increasing condom or contraceptive use for sexually active youth, or reducing pregnancy among youth. The evaluation will document and test a range of pregnancy prevention approaches in up to five program sites. The findings from the evaluation will be of interest to the general public, to policy-makers, and to organizations interested in teen pregnancy prevention.

This **Federal Register** Notice is to notify the public regarding field data collection for the ''Impact and In-Depth Implementation Study'' component of the Personal Responsibility 'Education Program (PREP) Multi-Component Evaluation.

The proposed field data collection activity involves the collection of information from interviews, focus groups, and short surveys with a range of experts and persons involved with programs about various aspects of existing prevention programs and topics the experts view as important to address through evaluation. Interviews and short surveys will focus on information leading to site selection. These data will be also used to help enhance decisions about the types of programs to be evaluated in the study.

Respondents

Researchers; Policy Experts; State Level Coordinators; Program Directors; Program Staff; Program Participants; School Administrators.

ANNUAL BURDEN ESTIMATES

Field data collection instrument clearance				
Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Discussion Guide for Use with Researchers, Policy Experts, and Macro-Level Coordinators	10	1	1	10
Discussion Guide for Use with Program Directors	20	2	2	80

ANNUAL BURDEN ESTIMATES—Continued

Field data collection instrument clearance				
Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Discussion Guide for Use with Program Staff	40	1	2	80
Focus Group Discussion Guide for Use with Program Participants	100	1	1.5	150
Discussion Guide for Use with School Administrators	70	1	1	70
Short Survey with Program Directors	70	1	0.25	17.5
Short Survey with Program Staff	140	1	0.25	35
Short Survey with School Administrators	70	1	0.25	17.5
Estimated Annual Burden Total for Field Clearance				460

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: July 1, 2011.

Steven M. Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. 2011–16977 Filed 7–7–11; 8:45 am]

BILLING CODE 4184–37–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Descriptive Study of Early Head Start (Early Head Start Family and Child Experiences Study; Baby FACES).

OMB No.: 0970–0354.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), anticipates continuing data collection for wave 4 of the parent interview, teacher child reports, care provider interviews and observations, direct child assessments, program director interviews, and family service tracking for the pen-natal cohort of the Descriptive Study of Early Head Start (Early Head Start Family and Child Experiences Study; Baby FACES). Data collection will continue for an additional 12 months beyond the current date of expiration (October 31, 2011).

This data collection is a part of Baby FACES, which is an important opportunity to provide a description of the characteristics, experiences, and outcomes of Early Head Start children and families, and Early Head Start Program services and delivery. All of the information obtained will be used to help Early Head Start improve services to infants and toddlers and their families. Baby FACES uses a longitudinal age cohort study design that selected all children in the spring of 2009 that were within a four month pen-natal window. These children will be followed in the study until they are age 3 unless they leave the Early Head Start before reaching that age.

Materials for the wave 4 program visit data collection effort, previously submitted to OMB, covered peri-natal and age 1 cohort data collections. Data collection for the age 1 cohort will be completed by October 31, 2011. ACF anticipates collecting data for an additional 12 months in order to complete data collection for the peri-natal cohort.

Respondents: Program Directors, teachers and home visitors of sampled children, parents of sampled children, sampled children.

Estimates of Annualized Burden Hours

As in the first three waves, the proposed data collection does not impose a financial burden on respondents. Respondents will not incur any expenses other than the time spent completing the interviews, reports and direct assessments.

The estimated annual burden for study respondents—parents, children, and program staff—is listed in the table below.

Response times are the same as reported in the initial OMB statement. The times were derived from previous studies using the same instruments with a similar population and confirmed with our population during earlier rounds of data collection. The number of respondents is based on the number of pen-natal cohort members as of spring 2010 (our most recent round of data collection).

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Parent Interview	1,554	1	.95	1,479
Program Director Interview	90	1	.67	60
Child Care Provider Interview	180	1	.25	45

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Home Visitor Interview	270	1	.25	68
Primary Caregiver/Home Visitor Child Rating	450	3.2	.333	480
Family Service Tracking	450	166	.125	9,360
Child Direct Assessment	774	1	1	774
Parent-Child Interaction	774	1	.25	194
Estimated Total Annual Burden Hours				12,460

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection.

E-mail address: OPREinfocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: July 1, 2011.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2011–16976 Filed 7–7–11; 8:45 am]

BILLING CODE 4184–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Evaluation of Adolescent Pregnancy Prevention Approaches—First Follow-up Data Collection.

OMB No.: ICRAS: 0970–0360.

Description: The Office of Adolescent Health (OAH), Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS), is overseeing and coordinating adolescent pregnancy prevention evaluation efforts as part of the Teen Pregnancy Prevention Initiative. OAH is working collaboratively with the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Centers for Disease Control and Prevention (CDC), and the Administration for Children and Families (ACF) on adolescent pregnancy prevention evaluation activities.

The Evaluation of Adolescent Pregnancy Prevention Approaches (PPA) is one of these efforts. PPA is a random assignment evaluation which will expand available evidence on effective ways to reduce teen pregnancy. The evaluation will document and test a range of pregnancy prevention approaches in up to eight program sites. The findings from the evaluation will be of interest to the general public, to policy-makers, and to organizations interested in teen pregnancy prevention.

This request for comment follows on a 60-Day **Federal Register** Public Comment Request Notice, published on Monday, July 12, 2010, pp. 39695–39696, with the document identifier of OS–0990–New.

This proposed information collection activity focuses on collecting follow-up data from a self-administered questionnaire which will be analyzed to determine program effects. Through a survey instrument, respondents will be asked to answer questions about demographics and risk and protective factors related to teen pregnancy.

Respondents: The data will be collected through private, self-administered questionnaires completed by study participants, i.e. adolescents assigned to a select school or community teen pregnancy prevention program or to a control group. Surveys will be distributed and collected by trained professional staff.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Chicago Public Schools/Health Teacher	430	1	.5	215
Oklahoma Institute of Child Advocacy/Power Through Choices	306	1	.6	184
Estimated Total Annual Burden Hours				399

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information

between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: July 1, 2011.

Steven Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. 2011–16974 Filed 7–7–11; 8:45 am]

BILLING CODE 4150–30–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0237]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 8, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0646. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs—(OMB Control Number 0910–0646)—Extension

In the **Federal Register** of July 28, 2009 (74 FR 37163), FDA published a final rule that required the holder of a new drug application (NDA) to notify the Agency if an authorized generic drug is marketed by clearly including this information in annual reports in an easily accessible place and by sending a copy of the relevant portion of the annual reports to a central contact point. We took this action as part of our implementation of the Food and Drug Administration Amendments Act, which requires that FDA publish a list of all authorized generic drugs included in an annual report after January 1, 1999, and that the Agency update the list quarterly. We initially published this list on June 27, 2008, on the Internet and notified relevant Federal Agencies that the list was published, and we will continue to update it.

During the past several years, FDA has been reviewing annual reports it has received under § 314.81(b)(2) (21 CFR 314.81(b)(2)) to discern whether an authorized generic drug is being marketed by the NDA holder. Based on information learned from this review and based on the number of annual reports the Agency currently receives under § 314.81(b)(2), we estimate that we will receive approximately 400 annual reports containing the information required under § 314.81(b)(2)(ii)(*b*), for authorized generic drugs that were marketed during the time period covered by an annual report submitted after January 1, 1999. Based on the number of sponsors that currently submit annual reports, we estimate that approximately 60 sponsors will submit these 400 annual reports with authorized generics. As indicated in table 1 of this document, we are estimating that the same number of annual reports will be submitted each year from the same number of sponsors containing the information required under § 314.81(b)(2)(ii)(*b*), and that the same number of copies of that portion of each annual report containing the authorized generic drug information will be submitted from the same number of sponsors. Concerning the hours per response, based on our estimate of 40 hours to prepare each annual report currently submitted under § 314.81(b)(2), we estimate that sponsors will need approximately 1 hour to prepare the information required under § 314.81(b)(2)(ii)(*b*) for each authorized generic drug that was marketed during the time period covered by an annual report submitted after January 1, 1999; approximately 15 minutes to prepare the information required under § 314.81(b)(2)(ii)(*b*) for each subsequent annual report; and approximately 3 minutes to submit to FDA a copy of that portion of each annual report containing the authorized generic drug information.

In the **Federal Register** of April 13, 2011 (76 FR 20677), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR 314.81(b)(2)(ii)(*b*)	Number of respondents	Number of reponses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
Authorized generic drug information on first marketed generics in an annual report	60	6.7	400	1	400
Authorized generic drug information submitted in each subsequent annual report	60	6.7	400	15/60	100
The submission of a copy of that portion of each annual report containing authorized generic drug information	60	6.7	400	3/60	20

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR 314.81(b)(2)(ii)(*b*)	Number of respondents	Number of reponses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
Total					520

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format ''[number of minutes per response]/60.''

Dated: July 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–17141 Filed 7–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0108]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Revised Draft Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by August 8, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''Revised Draft Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products; Availability.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Revised Draft Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products; Availability—(OMB Control Number 0910—New)

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''User Fee Waivers, Reductions, and Refunds for Drug and Biological Products.'' This revised draft guidance provides recommendations for applicants planning to request waivers or reductions in user fees assessed under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379g and 379h). This revised draft guidance describes the types of waivers and reductions permitted under the user fee provisions of the FD&C Act, and the procedures for submitting requests for waivers or reductions and requests for reconsideration and appeal. The revised draft guidance also provides clarification on related issues such as user fee exemptions for orphan drugs. After comments are received and considered, FDA intends to promptly issue a final guidance.

This revised 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 user fee waivers and reductions for drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal Agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The draft guidance describes how to submit requests for waivers, reductions, and refunds of certain user fees. It also includes recommendations for submitting information for requests for reconsideration of denials of waiver or reduction requests, and for requests for appeals. We estimate that the total annual number of waiver requests submitted for all of these categories will be 90, submitted by 75 different sponsors. We estimate that the average burden hours for preparation of a submission will total 16 hours. Because FDA may request additional information from the applicant during the review period, we have also included in this estimate time to prepare any additional information.

The reconsideration and appeal requests are not addressed in the FD&C Act but are discussed in the draft guidance. We estimate that we will receive three requests for reconsideration annually, and that the total average burden hours for a reconsideration request will be 24 hours. We estimate that we will receive one request annually for an appeal of a user fee waiver determination, and that the time needed to prepare an appeal would be approximately 12 hours. Reconsideration requests are sent to the Associate Director for Policy at the Center for Drug Evaluation and Research (CDER), and requests for appeals are sent to the User Fee Appeals Officer at FDA, with a copy to the Associate Director for Policy at CDER. We have also included in this estimate both the time needed to prepare the request for appeal and the time needed to create and send a copy of the request for an appeal to the Associate Director for Policy at CDER.

The burden for filling out and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) has not been included in the burden analysis because that information collection is already approved by OMB under OMB control number 0910–0297. The collections of information associated with a new drug application or biologics license application have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively.

We have included in the burden estimate the preparation and submission of application fee waivers for small businesses because small businesses requesting a waiver must submit documentation to FDA on the number of their employees and must include the information that the application is the first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval. Because the Small Business Administration (SBA) makes the size determinations for FDA, small businesses must also submit information to the SBA. The submission of information to SBA is already approved by OMB under OMB control number 3245–0101.

In the **Federal Register** of March 14, 2011 (76 FR 13629), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Section 736 of the FD&C Act	75	1.2	90	16	1,440
Reconsideration Requests	3	1	3	24	72
Appeal Requests	1	1	1	12	12
Total					1,524

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–17142 Filed 7–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0595]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exports: Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 8, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *FAX:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0482. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794; *Jonna.Capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:.

Exports: Notification and Recordkeeping Requirements—21 CFR Part 1 (OMB Control Number 0910–0482—Extension

The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or marketed in the United.States as allowed under section 801(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act (21 U.S.C. 381)). In general, the notification identifies the product being exported (e.g. name, description, and in some cases, country of destination) and specifies where the notification should be sent. These notifications are sent only for an initial export; subsequent exports of the same product to the same destination (or, in the case of certain countries identified in section 802(b) of the FD&C Act (21 U.S.C. 382) would not result in a notification to FDA.

The recordkeepers to this information collection are exporters who export human drugs, biologics, devices, animal drugs, foods and cosmetics that may not be sold in the United States and maintain records demonstrating their

compliance with the requirements in section 801(e)(1) of the FD&C Act.

In the **Federal Register** of December 6, 2010 (75 FR 75677), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
1.101 (d)	400	3	1,200	15	18,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR section	Number of record-keepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours
1.101(b), (c), (e)	320	3	960	22	21,120

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–17140 Filed 7–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0492]

Agency Information Collection Activities; Proposed Collection; Comment Request; Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for the labeling of natural rubber latex condoms.

DATES: Submit either electronic or written comments on the collection of information by September 6, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300—(OMB Control Number 0910–0633)—Extension

Under the Medical Device Amendments of 1976 (Pub. L. 94–295), class II devices were defined as those devices for which there was insufficient information to show that general controls themselves would provide a reasonable assurance of safety and effectiveness, but for which there was sufficient information to establish performance standards to provide such assurance.

Condoms without spermicidal lubricant containing nonoxynol-9 are classified in class II. They were originally classified before the enactment of provisions of the Safe Medical Devices Act of 1990 (Pub. L. 101–629) that broadened the definition of class II devices and now permit FDA to establish special controls beyond performance standards, including guidance documents, to help provide

reasonable assurance of the safety and effectiveness of such devices. In December 2000, Congress enacted Public Law 106–554, which among other provisions, directed FDA to ''reexamine existing condom labels'' and ''determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness in preventing sexually transmitted diseases * * *.'' In response, FDA recommended labeling intended to provide important information for condom users, including the extent of protection provided by condoms against various types of sexually transmitted diseases.

Respondents to this collection of information are manufacturers and repackagers of male condoms made of natural rubber latex without spermicidal lubricant.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
884.5300	3	34	102	12	1,224

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA expects approximately three new manufacturers or repackagers to enter the market yearly, and collectively have a third party disclosure burden of 1,224 hours. The number of respondents and prospective new manufacturers cited in table 1 of this document are based on FDA's database of premarket submissions. The remaining figures were derived from a study performed for FDA by Eastern Research Group, Inc., an economic consulting firm, to estimate the impact of the 1999 over-the-counter (OTC) human drug labeling requirements final rule (64 FR 13254, March 17, 1999). Because the packaging requirements for condoms are similar to those of many OTC drugs, we believe the burden to design the labeling for OTC drugs is an appropriate proxy for the estimated burden to design condom labeling.

The special controls guidance document also refers to currently approved collections of information found in FDA regulations. The collections of information under 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information under 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in part 801 (21 CFR part 801) have been approved under OMB control number 0910–0485.

The collection of information under § 801.437 does not constitute a ''collection of information'' under the PRA. Rather, it is a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

Dated: July 5, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–17156 Filed 7–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0076]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 8, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0303. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Records; Electronic Signatures—(OMB Control Number 0910–0303)—Revision

FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided the Agency has stated its ability to accept the records electronically in an Agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (21 CFR part 11) (§§ 11.10, 11.30, 11.50, and 11.300) require the following standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

In the **Federal Register** of February 16, 2011 (76 FR 9024), FDA published a 60-day notice requesting public comment on the proposed collection of

information. FDA received one comment which was related to the Paperwork Reduction Act burden associated with this collection of information.

The comment indicated that table 2 in the 60-day notice was not clear if it represented burden for all respondents, or just one respondent. In addition, the commenter noted that if table 2 represented the estimated burden for all respondents, that they did not agree with the accuracy of FDA's estimate, as the table appears to assume that each respondent creates one SOP per each 21 CFR section listed. The commenter felt that this assumption is not correct for large companies, who could possibly have several thousand systems, each requiring their own SOPs. If this were the case, the recordkeeping burden in Table 2 would be severely understated.

FDA's response is to note that the recordkeeping burden in table 2 is an estimate of both large and small firms, and the burden represented in the table is an average of the burden for all forms. In addition, the recordkeeping requirements ask each respondent to this collection maintain a set of SOPs which could help the company and FDA in the future determine the methodology the company employed in its systems to ensure that the electronic signatures for its employees on documents submitted to the FDA were valid, if needed. Over the years, FDA developed this recordkeeping burden by listening to feedback from its staff and external stakeholders, and feels that the burden adequately represents the average burden a firm might expend to complete the recordkeeping requirements for this collection.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. The Agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records. The respondents will be businesses and other for-profit organizations, State or local governments, Federal Agencies, and nonprofit institutions.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
11,100	4,500	1	4,500	1	4,500
Total					4,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
11.10	2,500	1	2,500	20	50,000
11.30	2,500	1	2,500	20	50,000
11.50	4,500	1	4,500	20	90,000
11.300	4,500	1	4,500	20	90,000
Total					280,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 5, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–17155 Filed 7–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

New Proposed Collection; Comment Request; Study Logistic Formative Research Methodology Studies for the National Children's Study

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Child Health and Human Development (NIHCD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval. This proposed information collection was previously published in the **Federal Register** on April 27, 2011, pages 23605–23606, and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

Proposed Collection

Title: Study Logistics Formative Research Methodology Studies for the National Children's Study (NCS).

Type of Information Collection Request: Generic Clearance.

Need and Use of Information Collection: The Children's Health Act of 2000 (Pub. L. 106–310) states:

(a) PURPOSE.—It is the purpose of this section to authorize the National Institute of Child Health and Human Development* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

(b) IN GENERAL.—The Director of the National Institute of Child Health and Human Development* shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

(1) Plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

(2) Investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.

(c) REQUIREMENT.—The study under subsection (b) shall—

(1) Incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;

(2) Gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and

(3) Consider health disparities among children, which may include the consideration of prenatal exposures.

To fulfill the requirements of the Children's Health Act, the results of formative research will be used to maximize the efficiency (measured by scientific robustness, participant and infrastructure burden, and cost) of new and existing study measures, participant communication techniques, and technologies being utilized, and thereby inform data collection methodologies for the National Children's Study (NCS) Vanguard and Main Studies. With this submission, the NCS seeks to obtain OMB's generic clearance to conduct formative research relating to instrument design and modality with a view to reduce item and unit non-response to Study instruments while preserving scientific quality.

The results from these formative research projects will inform the feasibility (scientific robustness), acceptability (burden to participants and study logistics) and cost of NCS Vanguard and Main Study instrument design and modality in a manner that minimizes public information collection burden compared to burden anticipated if these projects were incorporated directly into either the NCS Vanguard or Main Study.

Frequency of Response: Annual [As needed on an on-going and concurrent basis].

Affected Public: Members of the public, researchers, practitioners, and other health professionals.

Type of Respondents: Women of child-bearing age, fathers, health care facilities and professionals, public health professional organizations and practitioners, and schools and child care organizations. These include both persons enrolled in the NCS Vanguard Study and their peers who are not participating in the NCS Vanguard Study.

Annual reporting burden: See Table 1. The annualized cost to respondents is estimated at: $300,000 (based on $10 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN SUMMARY, STUDY OPERATIONS

Data collection activity	Type of respondent	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Small, focused survey and instrument design and administration.	NCS participants	4,000	2	1	8,000
	Members of NCS target population (not NCS participants).	4,000	2	1	8,000
	Health and Social Service Providers.	2,000	1	1	2,000
	Community Stakeholders	2,000	1	1	2,000
Focus groups	NCS participants	2,000	1	1	2,000
	Members of NCS target population (not NCS participants).	2,000	1	1	2,000
	Health and Social Service Providers.	2,000	1	1	2,000
	Community Stakeholders	2,000	1	1	2,000
Cognitive interviews	NCS participants	500	1	2	1,000
	Members of NCS target population (not NCS participants).	500	1	2	1,000
Total		21,000			30,000

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 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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Sarah L. Glavin, Deputy Director, Office of Science Policy, Analysis and Communication, National Institute of Child Health and Human Development, 31 Center Drive Room 2A18, Bethesda, Maryland, 20892, or call non-toll free number (301) 496–1877 or E-mail your request, including your address to *glavins@mail.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: June 21, 2011.

Sarah L. Glavin,

Deputy Director, Office of Science Policy, Analysis and Communications, National Institute of Child Health and Human Development.

[FR Doc. 2011–17201 Filed 7–7–11; 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.

ADDRESSES: 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.

Breakthrough Immunotherapy for Brain Cancer: Epidermal Growth Factor Receptor Variant III Chimeric Antigen Receptors

Description of Technology: Scientists at the National Institutes of Health (NIH) have developed chimeric antigen receptors (CARs) with high affinity for the epidermal growth factor receptor variant III (EGFRvIII) to use as a promising immunotherapy for aggressive brain cancer (glioblastoma) as well as several other malignancies. CARs are hybrid proteins consisting of the portion of an antibody that recognizes a cancer antigen, in this case human monoclonal antibody 139 which recognizes EGFRvIII, fused to protein signaling domains that serve to activate the CAR-expressing cell. Human cells that express CARs, most notably T cells, can recognize specific tumor antigens in an MHC-unrestricted manner with high reactivity and mediate an immune response that promotes robust tumor cell elimination.

Advantages

- EGFRvIII CAR immunotherapy is a breakthrough treatment for glioblastomas, a cancer with no other effective treatment option.
- EGFRvIII CARs can cross the blood-brain barrier, are expected to target only tumor cells, and thus, generate fewer side effects than other brain cancer treatment approaches.
- With the advent of Provenge®, personalized immunotherapy is becoming more widely accepted as a viable cancer treatment option.

Applications

- Immunotherapeutics to treat and/or prevent the recurrence of a variety of cancers that overexpress human EGFRvIII, primarily glioblastoma multiforme (GBM). About half of GBM tumor cells express the EGFRvIII antigen. Other cancers that overexpress EGFRvIII include breast, ovarian, prostate, bladder, colorectal, non-small cell lung carcinomas, and head and neck squamous cell carcinomas.
- A personalized cancer treatment strategy for patients whose tumor cells express EGFRvIII whereby the patient's own T cells are isolated, engineered to express the EGFRvIII specific CAR, and re-infused into the patient to attack the tumor.

EGFRvIII is a rare antigen in that is highly expressed by tumor cells, but not expressed by other cells in the body. This cancer antigen is expressed on nearly 50% of GBM tumor cells and also in other tumor types, such as other nervous system cancers and head and neck cancers. There exist very few, if any, effective treatments for GBM, so the expected clinical benefit of an anti-EGFRvIII CAR to patients is expected to be a therapeutic breakthrough for treatment of this cancer. These CARs are expected to combine high affinity recognition of EGFRvIII provided by the antibody portion with the target cell killing activity of cytotoxic T cells. Infusion of these EGFRvIII-specific CARs into patients could prove to be a powerful new immunotherapeutic tool for treating brain cancers, a type of cancer with a long-felt need for breakthrough therapeutics.

Development Status: This technology could soon be ready for clinical development. A clinical protocol to utilize an EGFRvIII CAR to treat GBM is currently under review at NIH.

Inventors: Richard A. Morgan and Steven A. Rosenberg (NCI).

Patent Status: U.S. Provisional Application No. 61/473,409 filed April 8, 2011 (HHS Reference No. E–148–2011/0–US–01).

Related Technologies

- E–269–2010/0—U.S. Provisional Application No. 61/384,931 filed September 21, 2010.
- E–236–2010/0—U.S. Provisional Application No. 61/405,931 filed October 22, 2010.
- E–205–2009/0—PCT Application No. PCT/US2010/048701 filed September 14, 2010, which published as WO2011/041093 on April 7, 2011.

Relevant Publications

1. Weber R, *et al.* U.S. Patent No. 7,628,986 issued December 8, 2009 entitled ''Antibodies Directed to the Deletion Mutants of Epidermal Growth Factor Receptor and Uses Thereof''.
2. Carter B.S., *et al.* U.S. Patent Application No. 12/444,090 filed April 2, 2009 entitled ''Chimeric T–Cell Receptors and T–Cells Targeting EGFRvIII on Tumors''.
3. Bullian SS, *et al.* Genetically engineered T cells to target EGFRvIII expressing glioblastoma. *J Neurooncol.* 2009 Sept;94(3):373–382. [PMID: 19387557].
4. Ohno M, *et al.* Retrovirally engineered T-cell based immunotherapy targeting type III variant epidermal growth factor receptor, a glioma-associated antigen. *Cancer Sci.* 2010 Dec;101(12):2518–2524. [PMID: 20880333].

Licensing Status: Available for licensing.

Licensing Contact: Samuel E. Bish, PhD; 301–435–5282; *bishse@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute, Surgery Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize cell-based immunotherapies targeting EGFRvIII expressing cancers. Please contact John Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

An Improved Anti-Mesothelin Immunotoxin for Treatment of Mesothelioma, Lung Cancer, Ovarian Cancer and Pancreatic Cancer

Description of Technology: Mesothelin is a cell surface glycoprotein that is highly expressed in many cancers (*e.g.,* malignant mesothelioma, lung cancer, ovarian cancer, and pancreatic cancer). Because of its differential expression, mesothelin is an excellent

target for the selective killing of cancer cells. For instance, anti-mesothelin monoclonal antibodies can carry cellular toxins specifically to mesothelin-expressing cancer cells, resulting in their selective killing while healthy, essential cells remain unharmed.

A high affinity anti-mesothelin antibody (SS1) was previously combined with a functional fragment of *Pseudomonas* Exotoxin A (PE), producing the immunotoxin SS1P. SS1P selectively killed mesothelin-expressing cancer cells, suggesting it could be an excellent therapeutic agent. Unfortunately, PE-based immunotoxins can lose therapeutic efficacy following multiple administrations, due to the formation of neutralizing antibodies against the PE portion of the molecule. As a result, less immunogenic variants of PE have been created in order to develop immunotoxins that do not induce the formation of neutralizing antibodies.

Improved PE variants have been created which lack lysosomal protease sites, a dominant T-cell epitope (PE–LR), and several major B-cell epitopes (PE–LR/8M). Although these new PE variants demonstrate efficient cell killing activity when used in combination with certain antibodies, their activity when using SS1 as the targeting agent (SS1–LR and SS1–LR/8M) was less impressive. Fortunately, the inventors surprisingly discovered that the addition of a small linker peptide within these immunotoxins was able to restore their cell killing activity to the level of SS1P.

These new SS1-targeted immunotoxins (*e.g.,* SS1–LR/GGS and SS1–LR/GGS/8M) have the cell-killing activity of SS1P, but are less likely to generate neutralizing antibodies. As a result, these immunotoxins are considered to be very promising prospects for treating patients suffering from mesothelin-expressing cancers.

Applications

- Treatment of mesothelin expressing cancers, including mesothelioma, pancreatic cancer, ovarian cancer and lung adenocarcinoma.
- Treatment in combination with standard chemotherapy.
- Diagnostic agent for the detection of mesothelin-expressing cancers.

Advantages

- Immunotoxins are highly selective for cancer cells, reducing side-effects due to the non-specific killing of essential, healthy cells.
- Less immunogenic PE variants increase the efficacy of the immunotoxin by reducing the formation and action of neutralizing antibodies.
- PE variants include the removal of both B-cell and T-cell epitopes.
- Use of a small linker peptide offers an unexpected advantage of strong cell-killing activity with reduced immunogenicity.

Development Status: Preclinical stage of development for anti-mesothelin immunotoxins; immunotoxins directed to other targets have some clinical data to demonstrate proof-of-concept

Inventors: Ira Pastan (NCI) *et al.*

Patent Status

- U.S. provisional patent application 61/483,531 (HHS technology E–117–2011/0–US–01).
- U.S. provisional patent application 61/495,085 (HHS technology E–174–2011/0–US–01).

For More Information

- U.S. Patent 7,081,518 (HHS technology E–139–1999/0–US–07).
- U.S. Patent Publication US 20090142341 A1 (HHS technology E–262–2005/0–US–06).
- U.S. Patent Publication US 20100215656 A1 (HHS technology E–292–2007/0–US–06).
- PCT Publication WO 2011/032022 (HHS technology E–269–2009/0–PCT–02).

Licensing Status: Available for licensing.

Licensing Contact: David A. Lambertson, PhD; 301–435–4632; *lambertsond@mail.nih.gov.*

Efficient Production of Functional Recombinant Human Neonatal Receptor (FcRn) Proteins

Description of Technology: Human monoclonal antibodies are becoming common therapeutics for numerous diseases, including rheumatoid arthritis, multiple sclerosis, and several different types of cancers. To improve their half-life, antibodies are engineered to have a high affinity to the Fc receptor (FcRn). This requires a reliable method to produce high yields of functional FcRn which comprises a 1:1 molar ratio of the alpha to the beta chain. Unfortunately, current methods can be difficult to implement and are not very efficient in producing functional FcRns with the 1:1 molar ratio of the alpha to the beta chain. Thus, there is a strong need for quick and economical methods of producing functional FcRn to aid in antibody development and the improvement of existing antibody therapeutics.

This technology describes a new and efficient method for producing functional human FcRn at a 1:1 molar ratio of the alpha to the beta chain. The uniqueness of this invention is that the expression of both the beta and the alpha chains is under the control of a single promoter and the correct 1:1 molar folding of the two chains is facilitated by the intermediate flexible linker. The method is easy to scale up for producing large quantities of highly pure FcRn. Further, the inventors have recently developed a stable cell line for large scale production.

Benefits: Improving the half-life of existing monoclonal antibodies as well as monoclonal antibodies still in development.

Advantages

- Efficient method of producing high yields of functional human FcRn at a 1:1 molar ratio of the alpha to the beta chain.
- Stable cell line also available.

Market: The monoclonal antibodies market generated over $40 billion in sales for therapeutic uses last year and is expected to grow significantly over the next several years.

Publications: Feng Y, Gong R, Dimitrov D.S. Design, expression and characterization of a soluble single-chain functional human neonatal Fc receptor. Protein Expr Purif. 2011 Mar 29, E-pub ahead of print. [PMID: 21453773]

Inventors: Dimiter S. Dimitrov and Yang Feng (NCI).

Patent Status: HHS Reference No. E–296–2010/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

Licensing Contact: Whitney A. Hastings; 301–451–7337; *hastingw@mail.nih.gov.*

Immunocompetent Mouse Model for Tracking Cancer Progression

Description of Technology: The technology is a transgenic mouse model tolerized to firefly Luciferase (ffLuc)- and enhanced green fluorescent protein (eGFP)-labeled tissue whilst maintaining normal immune function. Luc and eGFP are the most frequently used bioimaging markers to track cancer progression in pre-clinical mouse models. As these markers are immunogenic, their reporter activity becomes diminished over time and so their use has largely been limited to immunodeficient mice. However, immune function is crucial for tumor development and progression, making the use of immunocompetent mice more desirable.

The immunocompetent mouse model described in this invention was

generated using the rat growth hormone gene promoter (rGH) to target ffLuc-eGFP fusion gene expression to the pituitary gland, restricting any resulting interfering reporter signal within the head. This allows the tracking of cancer progression throughout the body, where the reporter activity of introduced ffLuc/eGFP-labeled tumors is maintained, despite normal immune function. These immunocompetent rGH-ffLuc-eGFP transgenic mice can be used as hosts in cancer models, allowing long-term in vivo monitoring of the progression of ffLuc/eGFP-labeled tumor cells in the body, which may lead to more clinically relevant insights into cancer progression, metastases and response to therapies.

Applications

- In vivo model for studying tumor progression and testing anti-cancer therapeutics using ffLuc or eGFP labeling for bioimaging.
- Since rGH-ffLuc-eGFP is also a growth hormone-responsive reporter, these rGH–Luc-GFP mice may also be used to screen growth-hormone stimulating drugs for treating Achondroplasia (dwarf syndrome) or as a test for illegal performance-enhancing drugs.

Advantages

- This technology represents a more clinically relevant in vivo model of cancer progression for testing anti-cancer therapeutics.
- This immunocompetent mouse model is more desirable as a pre-clinical model over the currently used immunodeficient mouse models as immune function is crucial for tumor development and progression.

Development Status

- Early-stage.
- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventors: Chi-Ping Day and Glenn Merlino (NCI).

Relevant Publications

1. Day C.P., *et al.* Preclinical therapeutic response of residual metastatic disease is distinct from its primary tumor of origin. *Int J Cancer.* 2011 Feb 10, doi: 10.1002/ijc.25978. [Epub ahead of print].

2. Day C.P., *et al.* Lentivirus-mediated bifunctional cell labeling for in vivo melanoma study. *Pigment Cell Melanoma Res.* 2009 Jun;22(3):283–295. [PMID: 19175523].

3. Luque R.M., *et al.* Reporter expression, induced by a growth hormone promoter-driven Cre recombinase (rGHp-Cre) transgene, questions the developmental relationship between somatotropes and lactotropes in the adult mouse pituitary gland. *Endocrinology.* 2007 May;148(5):1946–1953. [PMID: 17289844].

4. Latta-Mahieu M., *et al.* Gene transfer of a chimeric trans-activator is immunogenic and results in short-lived transgene expression. *Hum Gene Ther.* 2002 Sep 1;13(13):1611–1620. [PMID: 12228016].

5. Stripecke R., *et al.* Immune response to green fluorescent protein: implications for gene therapy. *Gene Ther.* 1999 Jul;6(7):1305–1312. [PMID: 10455440].

6. Liao C.P., *et al.* Mouse models of prostate adenocarcinoma with the capacity to monitor spontaneous carcinogenesis by bioluminescence or fluorescence. *Cancer Res.* 2007 Aug 1;67(15):7525–7533. [PMID: 17671224].

Patent Status: HHS Reference No. E–173–2010/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

Licensing Contact: Sabarni K. Chatterjee, PhD; 301–435–5587; *chatterjeesa@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute Center for Cancer Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize immunocompetent rGH-ffLuc-eGFP transgenic mice. Please contact John Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: July 1, 2011.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2011–17228 Filed 7–7–11; 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: Public Health Service, National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 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.

ADDRESSES: 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.

Mouse Model and Derived Cells That Hypersecrete Leukemia Inhibitory Factor (LIF)

Description of Technology: Embryonic stem cells (ESCs) are pluripotent cells that can be cultured indefinitely, and maintain their capability to differentiate into all cell lineages. To maintain these cells as well as various types of related induced stem cells and progenitor cells in culture, Mouse Embryonic Fibroblasts (MEFs) are routinely used as feeder cells, largely to serve as a source of Leukemia Inhibitory Factor (LIF). ESCs can also be cultured without feeders if the medium is supplemented with recombinant LIF and other factors. However, these methods of culturing ESCs suffer from certain drawbacks, such as limited proliferation capacity and variability of primary MEFs. Therefore, finding improved conditions that maintain ESC pluripotency is an area of great interest.

Scientists at NIEHS have now developed a knock-in (KI) mouse model in which LIF is overproduced from its endogenous locus because of increased stability of its mRNA. MEFs and presumably other cells derived from the homozygous mice hypersecrete LIF protein; lesser degrees of overexpression would be expected from heterozygous mice. These mice can be used to study LIF function, including how LIF contributes to various physiological and pathological states. Cells derived from these mice can be used to culture ESCs, as well as other progenitor cells. Cells or genetic material derived from these mice can also be used as sources of LIF for isolation and purification.

Applications

- Maintenance of ESCs and progenitor cells.
- *In vivo,* cellular and cell-free sources of LIF.
- Sources of LIF for isolation and purification.
- Studies of LIF function in mice, such as contribution of LIF to tumor growth.

Inventors: Dr. Perry Blackshear (NIEHS), *et al.*

Patent Status: HHS Reference No. E–175–2011/0 —Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing under a Biological Materials License Agreement.

Licensing Contact: Betty B. Tong, PhD; 301–594–6565; tongb@mail.nih.gov.

Collaborative Research Opportunity: The NIEHS Laboratory of Signal Transduction is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize these mice or other strains derived from them, or cells or other reagents derived from them. Please contact Dr. Elizabeth Denholm (*denholme@niehs.nih.gov*) in the NIEHS Office of Technology Transfer, or the Inventor Dr. Perry Blackshear (*black009@niehs.nih.gov*) for more information.

Inhibitors of Human Apurinic/Apyrimidinic Endonuclease 1 (APE1), an Anticancer Drug Target

Description of Technology: APE1 is the primary mammalian enzyme responsible for the removal of abasic (AP sites) in DNA and functions as part of the base excision DNA repair pathway (BER). BER is instrumental in the repair of DNA damage caused by DNA alkylating agents (*e.g.* many cancer chemotherapeutics). APE1 has been shown to be overexpressed in cancer cells. It has been postulated that APE1 would be an attractive target in anti-cancer treatment paradigms; preclinical and clinical data confirm that APE1 is a valid anticancer drug target.

To date, only one APE1 small molecule inhibitor has progressed to clinical trials (methoxyamine hydrochloride), and this compound inhibits a wide range of repair processes, which could result in undesired side-effects. The NIH inventors now report the discovery of a novel APE1 small molecule inhibitor, which exhibits potent *in vitro* activity, potentiates the cytotoxicity of DNA damaging agents (alkylators methylmethane sulfonate and Temozolomide), results in the accumulation of AP sites, and has favorable pharmacokinetic properties. The inventors plan to carry out further studies in mouse tumor xenograft models.

Applications: Cancer therapeutics as single agent as well as in combination therapy.

Development Status: In vivo pharmacokinetics data on lead compounds available.

Inventors: David J. Maloney, *et al.* (NHGRI).

Publication: Manuscript submitted.

Patent Status: U.S. Provisional Patent Application No. 61/480,145 filed April 28, 2011 (HHS Reference No. E–094–2011/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Betty B. Tong, PhD; 301–594–6565; *tongb@mail.nih.gov.*

Collaborative Research Opportunity: The NIH Center for Translational Therapeutics, NHGRI is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the above technology. Please contact Lili Portilla, Acting Director of Technology Transfer and Partnerships, NCTT at *Lilip@nih.gov* for more information.

Dated: July 1, 2011.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2011–17227 Filed 7–7–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center on Minority and Health Disparities; 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 materials, 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 Center on Minority Health and Health Disparities Special, Emphasis Panel, U24 Grant Review.

Date: July 11–12, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Robert Nettey, M.D., Chief, Scientific Review Officer, National Institute on Minority Health and Health Disparities, 6707 Democracy Boulevard, Suite 800, Bethesda, MD 20892. (301) 496–3996. *netteyr@mail.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: National Center on Minority Health and Health Disparities Special Emphasis Panel, R13 Review.

Date: July 13, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6707 Democracy Boulevard, Suite 800, Bethesda, MD 20892. (Virtual Meeting.)

Contact Person: Robert Nettey, M.D., Chief, Scientific Review Officer, National Institute on Minority Health and Health Disparities, 6707 Democracy Boulevard, Suite 800, Bethesda, MD 20892. (301) 496–3996. *netteyr@mail.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.

Dated: July 1, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–17225 Filed 7–7–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel, NCRR Animal Resource.

Date: July 28, 2011.

Time: 1 to 2 p.m.

Agenda: To review and evaluate grant applications,

Place: National Institutes of Health/NCRR/OR, Democracy 1, 6701 Democracy Blvd., 1078, Bethesda, MD 20892.

Contact Person: Lee Warren Slice, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, 6701

Democracy Blvd., Room 1068, Bethesda, MD 20892, 301–435–0965, *slicelw@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333; 93.702, ARRA Related Construction Awards, National Institutes of Health, HHS)

Dated: July 1, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–17214 Filed 7–7–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases Notice of 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 Arthritis and Musculoskeletal and Skin Diseases, Special Emphasis Panel, Ancillary Studies to Large Ongoing Clinical Projects Grant Review.

Date: July 20, 2011.

Time: 10 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Suite 800, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: Charles H Washabaugh, PhD, Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, National Institutes of Health, 6701 Democracy Blvd, Suite 800, Bethesda, MD 20817. 301–594–4952. *washabac@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: July 1, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–17206 Filed 7–7–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–907, Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day notice of information collection under review: form I–907, request for premium processing service.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on April 12, 2011, at 76 FR 20361, allowing for a 60-day public comment period. USCIS did not receive any comments.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until August 8, 2011. This process is conducted in accordance with 5 CFR 1320.10.

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 Department of Homeland Security (DHS), and to the Office of Management and Budget (OMB), USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Products Division, Clearance Office, 20 Massachusetts Avenue, Washington, DC 20529–2020. Comments may also be submitted to DHS via facsimile to 202–272–0997 or via e-mail at uscisfrcomment@dhs.gov, and to the OMB USCIS Desk Officer via facsimile at 202–395–5806 or via e-mail at *oira_submission@omb.eop.gov.*

When submitting comments by e-mail please make sure to add OMB Control Number 1615–0048 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* Request for Premium Processing Service.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–907. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Businesses.* Through this form, USCIS provides employers with the opportunity to request expedite processing of certain employment-based requests.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

- Filing by Mail 96,000 responses at .50 hours (30 minutes) per response.
- Electronically 4,000 responses at .333 hours (20 minutes) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 49,332 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: *http://www.regulations.gov/*. We may also be contacted at: USCIS, Regulatory Products Division, 20 Massachusetts Avenue, NW., Washington, DC 20529–2020, telephone number 202–272–8377.

Dated: July 1, 2011.

Evadne Hagigal,

Acting Chief, Regulatory Products Division, Office of the Executive Secretariat, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2011–17124 Filed 7–7–11; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–905, Extension of an Existing Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Form I–905, Application for Authorization to Issue Certification for Health Care Workers and Related Requirements.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on April 12, 2011, at 76 FR 20362, allowing for a 60-day public comment period. USCIS received one comment after publishing this notice.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until August 8, 2011. This process is conducted in accordance with 5 CFR 1320.10.

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 Department of Homeland Security (DHS), and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Products Division, Clearance Officer, 20 Massachusetts Avenue, Washington, DC 20529–2020. Comments may also be submitted to DHS via facsimile to 202–272–0997 or via e-mail at *uscisfrcomment@dhs.gov,* and to the OMB USCIS Desk Officer via facsimile at 202–395–5806 or via e-mail at *oira_submission@omb.eop.gov.*

When submitting comments by e-mail please make sure to add OMB Control Number 1615–0086 in the subject box.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* Application for Authorization to Issue Certification for Health Care Workers and Related Requirements.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–905. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as brief abstract: Primary:* Individuals or households. This form will be used by USCIS to permit an organization to apply for authorization to issue certificates to health care workers.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

Request to issue Certificates: 10 responses at 4 hours per response.

Credential Organization: 14, 000 responses at 2 hours per response.

Applications: 14,000 responses at 1 hour and 40 minutes (1.66) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 51,280 annual burden hours.

If you have additional comments, suggestions, or need a copy of the information collection instrument, please visit the USCIS Web site at: *http://www.regulations.gov/.*

We may also be contacted at: USCIS, Regulatory Products Division, 20 Massachusetts Avenue, NW., Washington, DC 20529–2020, telephone number 202–272–8377.

Dated: July 1, 2011.

Evadne Hagigal,

Acting Chief, Regulatory Products Division, Office of the Executive Secretariat, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2011–17125 Filed 7–7–11; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5477–N–27]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7266, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing-and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the

three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Theresa Ritta, Division of Property Management, Program Support Center, HHS, Room 5B–17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (i.e., acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *Army:* Ms. Veronica Rines, Department of the Army, Office of the Assistant Chief of Staff for Installation Management, DAIM–ZS, Room 8536, 2511 Jefferson Davis Hwy, Arlington, VA 22202: (571)–256–8145; *COE:* Mr. Scott Whiteford, Army Corps of Engineers, Real Estate, CEMP–CR, 441 G Street, NW., Washington, DC 20314; (202) 761–5542; *Energy:* Mr. Mark Price, Department of Energy, Office of Engineering & Construction Management, MA–50, 1000 Independence Ave., SW., Washington, DC 20585: (202) 586–5422; *GSA:* Mr. John E.B. Smith, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street, NW., Room 7040 Washington, DC 20405; (202) 501–0084; (These are not toll-free numbers).

Dated: June 30, 2011.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 07/08/2011

Suitable/Available Properties

Building

Minnesota

Bldg. 921
W. Main St.
Paynesville MN
Landholding Agency: GSA
Property Number: 54201120017
Status: Excess
GSA Number: 1–D–MN–0591
Comments: Bldg: 5,486 sf, Land: 3.9 acres, current use: Admin./Training Facility

Unsuitable Properties

Building

Georgia

7 Bldgs.
5625 Anderson Hwy
Hartwell GA 30643
Landholding Agency: COE
Property Number: 31201120011
Status: Unutilized
Directions: 16029, 16555, 16613, 16844, 17701, 18405, 19188
Reasons: Extensive deterioration

Unsuitable Properties

Building

Illinois

Bldg. 649
Philip H. Sheridan Reserve Ctr.
Ft. Sheridan IL
Landholding Agency: Army
Property Number: 21201120107
Status: Unutilized
Reasons: Extensive deterioration

Bldg. 141
COL P. Schulstad USARC
Arlington Heights IL
Landholding Agency: Army
Property Number: 21201120108
Status: Unutilized
Reasons: Extensive deterioration

St. Louis District
Rend Lake Project Office
Benton IL 62812
Landholding Agency: COE
Property Number: 31201120006
Status: Unutilized
Reasons: Extensive deterioration

Unsuitable Properties

Building

Kansas

Marion Reservoir
Cottonword Point
Marion KS
Landholding Agency: COE
Property Number: 31201120001
Status: Underutilized
Reasons: Extensive deterioration

Mississippi

Old Uithoven Homestead
Tenn-Tom Project
Columbus MS 39701
Landholding Agency: COE
Property Number: 31201120004
Status: Unutilized
Reasons: Extensive deterioration

Unsuitable Properties

Building

Mississippi

One Eaton Homestead
Tenn-Tom Project Office
Columbus MS 39701
Landholding Agency: COE
Property Number: 31201120005
Status: Unutilized
Reasons: Extensive deterioration

Missouri

St. Louis District
Foot Arsenal Rd.
St. Louis MO
Landholding Agency: COE
Property Number: 31201120003
Status: Unutilized
Reasons: Extensive deterioration

Unsuitable Properties

Building

Missouri

2 Bldgs.
Clearwater Lake Project
Piedmont MO
Landholding Agency: COE
Property Number: 31201120008
Status: Unutilized
Directions: House w/Garage
Reasons: Secured Area

New Mexico

Santa Rosa State Park

2528 Joe & Louise Page Rd.
Santa Rosa NM 88435
Landholding Agency: COE
Property Number: 31201120002
Status: Unutilized
Directions: SNROSA–6011 AND SNROSA–8312
Reasons: Extensive deterioration

Unsuitable Properties

Building

New York

Trailer 505
Brookhaven Nat'l Lab
Upton NY 11973
Landholding Agency: Energy
Property Number: 41201120004
Status: Excess
Reasons: Secured Area

Texas

Brookdale Park Restroom
1625 Brookdale Park Rd.
Allen TX
Landholding Agency: COE
Property Number: 31201120009
Status: Underutilized
Reasons: Extensive deterioration

Unsuitable Properties

Building

Texas

Bldg.28838
Friendship Park Campgroud Bathroom
Granger TX
Landholding Agency: COE
Property Number: 31201120010
Status: Unutilized
Reasons: Extensive deterioration

Lake Texoma
Overlook and Burns Run West
Denison TX
Landholding Agency: COE
Property Number: 31201120013
Status: Underutilized
Reasons: Extensive deterioration

Unsuitable Properties

Building

Washington

Bldg. T–17
McNary Lock and Dam Project
Pasco WA 99301
Landholding Agency: COE
Property Number: 31201120007
Status: Unutilized
Reasons: Extensive deterioration

Wisconsin

Bldgs. 302 and 303
USARC
Milwaukee WI
Landholding Agency: Army
Property Number: 21201120109
Status: Unutilized
Reasons: Secured Area

[FR Doc. 2011–16916 Filed 7–7–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Establishment of the Commission on Indian Trust Administration and Reform

AGENCY: Office of the Secretary, Interior.

ACTION: Notice and request for nominations.

SUMMARY: The Department of the Interior is announcing the establishment of the Commission on Indian Trust Administration and Reform (Commission). The purpose of the Commission is to provide advice and recommendations to the Secretary of the Interior (Secretary) regarding trust management. This includes a thorough evaluation of the existing management and administration of the trust administration system to support a reasoned and factually based set of options for potential management improvements. This further includes a review of the manner in which the Department audits the management of the trust administration system, including the possible need for audits of management of trust assets.

The Department of the Interior is seeking nominations for individuals to be considered as Commission members. Nominations should describe and document the proposed member's qualifications for membership to the Commission, and include a resume listing their name, title, address, telephone, e-mail, and fax number.

DATES: Written nominations must be received by August 8, 2011.

ADDRESSES: Send nominations to: Meghan Conklin, Associate Deputy Secretary, Office of the Secretary, 1849 C Street, NW., Mailstop 7328, Washington, DC 20240; (202) 273–0394.

FOR FURTHER INFORMATION CONTACT: Meghan Conklin, Associate Deputy Secretary, Office of the Secretary, 1849 C Street, NW., Mailstop 7328, Washington, DC 20240; (202) 273–0394.

SUPPLEMENTARY INFORMATION: In accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. Appendix. 2, and with the concurrence of the General Services Administration, the Department of the Interior is announcing the establishment of the Commission on Indian Trust Administration and Reform. The Commission is in the public interest in connection with the responsibilities of the Department of the Interior under Section 2 of the Reorganization Plan No. 3 of 1950 (64 Stat. 1262), as amended, the American Indian Trust Fund Management Reform Act of 1994, 25 U.S.C. 4001–4061, and the Claims Resettlement Act of 2010, Public Law 111–291.

The Commission will conduct its operations in accordance with the provisions of the FACA. It will report to the Secretary of the Interior through the Designated Federal Officer (DFO). The Office of the Secretary will provide administrative and logistical support to the Commission.

The duties of the Commission shall include: (1) Conducting a comprehensive evaluation of the Department's management and administration of the trust administration system, including a review of the report of a management consultant hired in accordance with Secretarial Order 3292; (2) reviewing the Department's provision of services to trust beneficiaries; (3) reviewing input from the public, interested parties, and trust beneficiaries, which should involve conducting a number of regional listening sessions; (4) considering the nature and scope of necessary audits of the Department's trust administration system; (5) recommending options to the Secretary to improve the Department's management and administration of the trust administration system based on information obtained from these activities, including whether any legislative or regulatory changes are necessary to permanently implement such improvements; and (6) recommending options to the Secretary on the need for and scope of audits on the effectiveness of all management reforms implemented as a result of Secretarial Order 3292 and the Department shall consider these recommendations in performing an audit of the effectiveness of such reforms; and (7) considering the provisions of the American Indian Trust Fund Management Reform Act of 1994 providing for the termination of the Office of the Special Trustee for American Indians, and making recommendations to the Secretary regarding any such termination.

Following the solicitation of nominations and in consultation with trust beneficiaries, the Secretary shall appoint the Commission Chair and four members who, collectively, shall have experience and/or expertise in trust management, financial management, asset management, natural resource management, Federal agency operations and budgets, as well as experience as account holders and in Indian Country.

Members will be appointed as special Government employees and are required to file on an annual basis a Confidential Financial Disclosure Report.

No individual who is currently registered as a Federal lobbyist is eligible to serve as a member of the Committee.

The Committee will meet approximately 2–4 times annually, and at such times as designated by the DFO.

Members of the Commission will serve without compensation. However, while away from their homes or regular places of business, Commission and subcommittee members engaged in Commission, or subcommittee business, approved by the DFO, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in Government service under Section 5703 of Title 5 of the United States Code.

Certification Statement: I hereby certify that the establishment of the Commission on Indian Trust Administration and Reform is necessary, is in the public interest and is established under the authority of the Secretary of the Interior, Department of the Interior under Section 2 of the Reorganization Plan No. 3 of 1950 (64 Stat. 1262), as amended, the American Indian Trust Fund Management Reform Act of 1994, 25 U.S.C. 4001–4061, and the Claims Resolution Act of 2010, Public Law 111–291.

Dated: July 1, 2011.

Ken Salazar,

Secretary of the Interior.

[FR Doc. 2011–17139 Filed 7–7–11; 8:45 am]

BILLING CODE 4310–10–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–MB–2011–N140; 10154–1231–0000–D3]

Information Collection Sent to the Office of Management and Budget (OMB) for Approval; Monitoring Recovered Species After Delisting—American Peregrine Falcon

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (U.S. Fish and Wildlife Service) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This information collection is scheduled to expire on July 31, 2011. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before August 8, 2011.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_DOCKET@OMB.eop.gov* (e-mail). Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS 2042–PDM, 4401 North Fairfax Drive, Arlington, VA 22203 (mail), or *INFOCOL@fws.gov* (e-mail). Please include ''1018–0101'' in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Hope Grey at *INFOCOL@fws.gov* (e-mail) or 703–358–2482 (telephone). You may review the ICR online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1018–0101.

Title: Monitoring Recovered Species After Delisting—American Peregrine Falcon.

Service Form Number(s): 3–2307, 3–2308, and 3–2309.

Type of Request: Extension of currently approved collection.

Description of Respondents: Professional biologists employed by State agencies and other organizations, and volunteers that have been involved in past peregrine falcon conservation efforts.

Respondent's Obligation: Voluntary.

Frequency of Collection: On occasion. Monitoring is conducted every 3 years. For eggs and feathers, 15 to 20 of each are collected over a period of no more than 5 years.

Estimated Nonhour Cost Burden: We estimate the total nonhour burden cost to be $156.00 for expenses incurred when contaminants samples must be shipped to designated labs for analysis and storage.

Activity	Number of respondents	Number of responses	Completion time per response (hours)	Total annual burden hours
FWS Form 3–2307	71	639	2.5	1,598
FWS Form 3–2308	8	8	2.5	20
FWS Form 3–2309	8	8	2.5	20
Totals	87	655	.....	1,638

Abstract: This information collection implements requirements of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) (ESA). There are no corresponding Service regulations for the ESA post-delisting monitoring requirement. This IC also implements the Migratory Bird Treaty Act (16 U.S.C. 704) and Service regulations in chapter I, subchapter B of title 50 of the Code of Federal Regulations (CFR).

The American peregrine falcon was removed from the List of Endangered and Threatened Wildlife on August 25, 1999 (64 FR 46542). Section 4(g) of the ESA requires that all species that are recovered and removed from the List of Endangered and Threatened Wildlife (delisted) be monitored in cooperation with the States for a period of not less than 5 years. The purpose of this requirement is to detect any failure of a recovered species to sustain itself without the protections of the ESA. We work with relevant State agencies and other species experts to develop appropriate plans and procedures for systematically monitoring recovered wildlife and plants.

The American peregrine falcon has a large geographic distribution that includes a substantial amount of non-Federal land. Although the ESA requires that monitoring of recovered species be conducted for not less than 5 years, the life history of American peregrine falcons is such that it is appropriate to monitor this species for a longer period of time in order to meaningfully evaluate whether or not the recovered species continues to maintain its

recovered status. The Monitoring Plan for the American Peregrine Falcon is available on our Web site at *http://library.fws.gov/pubs1/peregrine03.pdf.* Formal collection of monitoring data commenced in 2003. Rangewide population monitoring of American peregrine falcons under the Monitoring Plan will take place every 3 years through 2015.

We will use the information supplied on FWS Forms 3–2307, 3–2308, and 3–2309 to review the status of the American peregrine falcon in the United States and determine if it remains recovered and, therefore, does not require the protections of the ESA:

(1) FWS Form 3–2307 (Peregrine Falcon Monitoring Form) addresses the reporting requirements to record observations on the nesting pair, and the numbers of eggs and young during each nest visit. Each territory will be visited at least two times.

(2) FWS Form 3–2308 (Peregrine Falcon Egg Contaminants Data Sheet) addresses the reporting requirements to record data on eggs collected opportunistically during a nest visit.

(3) FWS Form 3–2309 (Peregrine Falcon Feather Contaminants Data Sheet) addresses the reporting requirements to record data on feathers collected opportunistically during a nest visit. Once collected, the eggs and feathers are archived in a deep freeze for analysis at a later time.

Comments: On March 28, 2011, we published in the **Federal Register** (76 FR 17147) a notice of our intent to request that OMB renew approval for this information collection. In that notice, we solicited comments for 60 days, ending on May 27, 2011. We received one comment. The commenter stated that the peregrine falcon should not have been removed from the List of Endangered and Threatened Wildlife, but did not address the information collection requirements or the burden estimates. We have not made any changes to our information collection requirements.

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, e-mail 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 OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: July 1, 2011.

Tina A. Campbell,

Chief, Division of Policy and Directives Management, U.S. Fish and Wildlife Service.

[FR Doc. 2011–17126 Filed 7–7–11; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CACA–051552, LLCAD0700 L51010000 FX0000 LVRWB10B3980]

Notice of Availability of a Draft Land Use Plan Amendment, Environmental Impact Statement and Environmental Impact Report for the Pattern Energy Group Ocotillo Express Wind Energy Project, Imperial County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA), as amended, and the Federal Land Policy and Management Act of 1976, as amended (FLPMA), the Bureau of Land Management (BLM) has prepared a Draft California Desert Conservation Area (CDCA) Plan Amendment (PA)/Draft Environmental Impact Statement (EIS) and Draft Environmental Impact Report (EIR) for the Ocotillo Express Wind Energy Project (OWEF) and by this notice is announcing the opening of the comment period on the Draft CDCA PA and EIS/EIR.

DATES: To ensure that your comments will be considered, the BLM must receive written comments on the Draft PA/EIS/EIR within 90 days following the date the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**. The BLM will announce future meetings or hearings and any other public involvement activities at least 15 days in advance through public notices, media releases, and/or mailings.

ADDRESSES: You may submit comments related to OWEF by any of the following methods:

- *Web site: http://www.blm.gov/ca/st/en/fo/elcentro.html.*
- *E-mail: caocotillo@blm.gov.*
- *Fax:* (760) 337–4490.
- *Mail:* Cedric Perry, Project Manager, California Desert District (CDD), BLM, 22835 Calle San Juan De Los Lagos, Moreno Valley, California 92553.

Copies of the Draft PA/EIS/EIR are available on the BLM Web site at: *http://www.ca.blm.gov/elcentro* and at the CDD at the above address and in the BLM El Centro Field Office, 1661 S. 4th Street, El Centro, California 92243.

FOR FURTHER INFORMATION CONTACT: For further information and/or to have your name added to our mailing list, contact Cedric Perry, BLM Project Manager, telephone (951) 697–5388; address 22835 Calle San Juan De Los Lagos, Moreno Valley, CA 92553; e-mail *Cedric_Perry@ca.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: Pattern Energy, Inc. through Ocotillo Express, LLC (OE LLC) has submitted a right-of-way (ROW) application to construct, operate, maintain, and decommission an approximate 12,436-acre, 474 megawatt (MW) wind energy project including 158 wind turbine generators, a substation, administration, operations and maintenance facilities, transmission lines, access roads, and temporary construction lay down areas.

The proposed wind energy project would be located on BLM-administered lands and a small portion of land under the jurisdiction of Imperial County, approximately 5 miles west of Ocotillo, Imperial County, California. The proposed OWEF would be constructed in 2 phases. Phase I is anticipated to total approximately 315 MW, with the installation of up to 137 turbines ranging from 1.6 to 3 MW in generating capacity. Phase II would include the construction of 21 turbines (also ranging 1.6 to 3 MW in capacity) generating up to 159 MW.

The BLM has invited the U.S. Army Corps of Engineers (Corps) to be a cooperating Federal agency in the preparation of the Draft PA/EIR/EIS because the Corps has jurisdiction by law under its delegated authority in

section 404 of the Clean Water Act of 1972, as amended (33 U.S.C. Section 1344), as well as special expertise in aquatic ecosystems that could be affected by the Ocotillo Project. The BLM and Corps agree that it will be beneficial to create a more streamlined, coordinated approach in developing the OWEF Draft PA/EIS/EIR. The two Federal agencies will be developing a Memorandum of Understanding for this purpose.

The BLM's purpose and need for the Draft PA/EIS/EIR is to respond to OE LLC's application for a ROW grant to construct, operate, maintain, and decommission a wind energy facility on public lands in compliance with FLPMA, BLM ROW regulations, and other applicable Federal laws. The BLM will decide whether to grant, grant with modification, or deny the ROW application for the proposed OWEF. Concurrently with its action on the ROW request, the BLM is also proposing to amend the CDCA Plan by designating the project area as either available or unavailable for wind energy projects. The CDCA Plan, while recognizing the potential compatibility of wind energy generation facilities with other uses on public lands, requires that all sites proposed for power generation or transmission not already identified in the CDCA Plan be considered through the plan amendment process. If the BLM decides to amend the CDCA Plan, a ROW for this project could be granted. If not, the ROW could not be granted.

In addition to the proposed action and a no action alternative, the BLM is analyzing a 137-turbine alternative and a 105-turbine alternative. The Draft PA/EIS/EIR also analyzes two ''no project'' alternatives that reject the project but amend the CDCA Plan to make the project area either (1) available to future wind energy generation projects; or (2) unavailable to future wind energy generation projects.

The Draft PA/EIS/EIR evaluates the potential impacts of the proposed OWEF on air quality, biological resources, cultural resources, water resources, geological resources and hazards, land use, noise, paleontological resources, public health, socioeconomics, soils, traffic and transportation, visual resources, wilderness characteristics, and other resources.

A Notice of Intent to Prepare an EIS/EIR for the OWEF project was published in the **Federal Register** on December 13, 2010 (75 FR 77654). The BLM held 2 public scoping meetings in El Centro and Ocotillo, California, on January 5th and 6th, 2011, respectively. The formal scoping period ended on February 4, 2011.

Please note that public comments and information submitted including names, street addresses, and e-mail addresses of persons who submit comments will be available for public review at the above address during regular business hours (8 a.m. to 4 p.m.), Monday through Friday, except holidays.

Before including your phone number, e-mail address, or other personal identifying information in your comments, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1506.6, 1506.10, 43 CFR 1610.2, and 1610.5.

Thomas Pogacnik,

Deputy State Director, California.

[FR Doc. 2011–17159 Filed 7–7–11; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLID9900000.L1210000.NU0000; G0–00]

Final Supplementary Rules on Public Lands in Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of final supplementary rules.

SUMMARY: The Bureau of Land Management (BLM) Idaho State Office is establishing supplementary rules relating to the illegal use and possession of alcohol, drugs, and drug paraphernalia on public lands. The BLM State Office is also establishing final supplementary rules prohibiting the possession of an open alcoholic beverage container by operators or passengers in or on either a vehicle or off-highway vehicle, on public lands administered by the BLM in Idaho. These supplementary rules are necessary to protect natural resources and the health and safety of public land users. These supplementary rules will allow BLM Law Enforcement personnel to continue enforcing existing public land regulations pertaining to alcohol and drug use in a manner consistent with current State of Idaho statutes.

DATES: These rules are effective August 8, 2011.

ADDRESSES: You may direct inquiries to Keith McGrath, State Staff Law Enforcement Ranger, Bureau of Land Management, Idaho State Office, 1387 S. Vinnell Way, Boise, Idaho 83709; or by e-mail to *Keith_McGrath@blm.gov.*

FOR FURTHER INFORMATION CONTACT: Keith McGrath, Bureau of Land Management, (208) 373–4046, *Keith_McGrath@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may contact this individual by calling the Federal Information Relay Service (FIRS) at (800) 877–8339, 24 hours a day, 7 days a week. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

I. Background
II. Discussion of Public Comments
III. Discussion of Final Supplementary Rules
IV. Procedural Matters

I. Background

Although two BLM Districts in the State of Idaho have issued rules mirroring the State of Idaho statutes pertaining to underage possession and consumption of alcohol, the BLM has no statewide supplementary rules regarding the illegal possession or use of alcohol on public lands. In the absence of specific regulations, law enforcement officers have regulated this illegal behavior under broader regulations, creating a lack of consistency with surrounding governing entities. These final supplementary rules will bring consistency to all BLM-administered land throughout the State and promote consistency between the BLM and other agencies, including the State of Idaho, County Sheriff's Offices, Idaho State Police, and various Federal agencies where working relationships and partnerships exist in public land management.

In keeping with the BLM's goal to reduce threats to public health, safety, and property, these final supplementary rules are necessary to protect natural resources, allow for safe public recreation, reduce the potential for damage to the environment, and enhance the safety of visitors and neighboring residents. Alcohol-related offenses are a growing problem on the public lands. Unlawful consumption of alcohol and drugs has the potential to pose a significant health and safety hazard to all users. Operation of motor vehicles while under the influence of alcohol or drugs has been demonstrated to result in the destruction of natural resources and property, and/or serious physical injury or death. Vandalism to public land resources resulting from illegal alcohol and drug use and the

clear risks to public safety demonstrate the need for greater regulation of these activities.

For the purposes of these final supplementary rules, an alcoholic beverage is any liquid or solid containing more than 3 percent of alcohol by weight. The BLM has chosen 3 percent alcohol by weight to account for 3.2 percent beer sold in Idaho. The State of Idaho defines an alcoholic beverage as a liquid or solid containing more than 4 percent of alcohol by weight, and addresses prohibition of open containers of beer in motor vehicles, including 3.2 percent beer, in a slightly different manner than BLM rules. The BLM has determined that setting the threshold at 3 percent alcohol by weight would be the clearest way to account for all Idaho State prohibitions.

Possession of drug paraphernalia has frequently been linked to other illegal uses of controlled substances including cultivation, manufacture, and possession for distribution. The BLM, in keeping with the mandates of the President's Office of National Drug Control Policy National Drug Control Strategy, will continue its efforts to reduce illegal use of controlled substances on public lands. These final supplementary rules provide for consistent application and enforcement of alcohol and drug regulations on public lands, further enhancing public safety by all public land users.

These final supplementary rules supersede that portion of the existing supplementary rule enacted in the BLM Idaho Falls District (67 FR 30958) and the restriction orders (ID–060–20 and ID–420–05) currently in place for the BLM Coeur d'Alene District pertaining to the underage possession and consumption of alcoholic beverages and the possession of an open container of alcohol in a motor vehicle.

II. Discussion of Public Comments

The BLM Idaho State Office proposed supplementary rules in the **Federal Register** on September 22, 2010 (75 FR 57813). Public comments were accepted by mail and/or e-mail for a 60-day period ending on November 22, 2010. The BLM received two written comments concerning the proposed rules. One commenter sought clarification on whether violators of the rules would be required to appear before a magistrate. Under these rules, violators would have the option of mailing payment of the fine associated with the citation or appearing before a magistrate.

The second commenter voiced concern about the fiscal impact of the proposed supplementary rules, as well as about the creation of new laws. These final supplementary rules will have no budgetary impact and do not create new laws, but rather serve to allow BLM Law Enforcement to continue to enforce existing laws in a manner consistent with Idaho Statutes and those of surrounding States. As such, neither comment resulted in changes to the proposed rules.

III. Discussion of Final Supplementary Rules

The final supplementary rules apply to BLM-managed lands within the State of Idaho. These final supplementary rules are necessary to protect natural resources and the health and safety of public land users. These supplementary rules will allow BLM Law Enforcement personnel to enforce existing public land regulations pertaining to alcohol and drug use in a manner consistent with current State of Idaho statutes.

No changes to the proposed supplementary rules were necessary after public comment and the final supplementary rules remain as proposed, with the exception of some minor editing that is not substantive.

IV. Procedural Matters

Executive Order 12866, Regulatory Planning and Review

The final supplementary rules are not a significant regulatory action and are not subject to review by the Office of Management and Budget under Executive Order 12866. The final supplementary rules will not have an effect of $100 million or more on the economy. They will 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 final supplementary rules will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. The final supplementary rules do not materially alter the budgetary effects of entitlements, grants, user fees, or loan programs or the right or obligations of their recipients; nor do they raise novel legal or policy issues. The rules merely contain rules of conduct for public use of a limited selection of public lands and provide greater consistency with the Idaho State Code to protect public health and safety.

National Environmental Policy Act

The BLM has found that these final supplementary rules comprise a category or kind of action that has no significant individual or cumulative effect on the quality of the human environment. See 40 CFR 1508.4; 43 CFR 46.210. Specifically, the establishment of these final supplementary rules is an action that is of an administrative, financial, legal, technical, or procedural nature within the meaning of 43 CFR 46.210(i), and none of the extraordinary circumstances listed at 43 CFR 46.215 are applicable. Therefore, the BLM is not required to prepare an environmental assessment or an environmental impact statement for these final supplementary rules.

Regulatory Flexibility Act

Congress enacted the Regulatory Flexibility Act of 1980 (RFA), 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. These final supplementary rules merely establish rules of conduct for public use of a limited area of public lands and should have no effect on business entities of any size. Therefore, the BLM has determined under the RFA that these final supplementary rules would not have a significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

These final supplementary rules do not constitute a ''major rule'' as defined at 5 U.S.C. 804(2). They would not result in an effect on the economy of $100 million or more, an increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. These rules merely establish rules of conduct for public use of a limited area of public lands and do not affect commercial or business activities of any kind.

Unfunded Mandates Reform Act

These final supplementary rules do not impose an unfunded mandate on State, local, or Tribal governments or the private sector of more than $100 million per year; nor do these final supplementary rules have a significant or unique effect on State, local, or Tribal governments or the private sector. These final rules have no effect on State, local, or Tribal governments and do not impose any requirements on any of

these entities. 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)

These final supplementary rules do not have significant takings implications, nor are they capable of interfering with constitutionally protected property rights. Therefore, the BLM has determined that these rules will not cause a ''taking'' of private property or require preparation of a takings assessment.

Executive Order 13132, Federalism

The final supplementary rules will not have a substantial direct effect on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. The final supplementary rules do not conflict with any Idaho State law or regulation. Therefore, in accordance with Executive Order 13132, the BLM has determined that these final supplementary rules do not have sufficient federalism implications to warrant preparation of a Federalism Assessment.

Executive Order 12988, Civil Justice Reform

The BLM has determined that these final supplementary rules would not unduly burden the judicial system and that they meet the requirements of Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

The BLM has found that these supplementary rules do not include policies that have Tribal implications. The supplementary rules prohibit the illegal use of alcoholic beverages and illegal drugs on public lands and do not involve Indian Tribal rights.

Information Quality Act

The Information Quality Act (Section 515 of Pub. L. 106–554) requires Federal agencies to maintain adequate quality, objectivity, utility, and integrity of the information that they disseminate. In developing these supplementary rules, the BLM did not conduct or use a study, experiment, or survey or disseminate any information to the public.

Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

These final supplementary rules do not constitute a significant energy action. The final supplementary rules will not have an adverse effect on energy supplies, production, or consumption, and have no connection with energy policy.

Paperwork Reduction Act

These final supplementary rules do not contain information collection requirements that the Office of Management and Budget must approve under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

Author

The principal author of this supplementary rule is Keith McGrath, State Staff Law Enforcement Ranger, Bureau of Land Management.

For the reasons stated in the Preamble, and under the authority of 43 CFR 8365.1–6, the Idaho State Director, Bureau of Land Management, issues supplementary rules for public lands in Idaho, to read as follows:

Supplementary Rules for the State of Idaho

Definitions

Alcoholic beverage means any liquid or solid, patented or not, containing alcohol, spirits, or wine, and susceptible of being consumed by a human being, for beverage purposes, and containing more than 3 percent of alcohol by weight.

Alcohol means the product of distillation of any fermented liquor, rectified either once or more often, whatever may be the origin thereof, or synthetic ethyl alcohol.

Beer means any alcoholic beverage obtained by the alcoholic fermentation of an infusion or decoction of barley, malt and/or other ingredients in drinkable water.

Wine means any alcoholic beverage obtained by the fermentation of the natural sugar content of fruits (grapes, apples, *etc.*) or other agricultural products containing sugar (honey, milk, *etc.*).

Vehicle means any motorized transportation conveyance designed and licensed for use on roadways, such as an automobile, bus, or truck, and any motorized conveyance originally equipped with safety belts.

Off-Highway Vehicle (OHV) means any motorized vehicle capable of, or designed for, travel on or immediately over land, water, or other natural terrain.

On public land administered by the BLM within the State of Idaho:

A. You must not violate any State laws relating to the purchase, possession, supply, use or consumption of alcohol.

B. You must not drink or possess an open alcoholic beverage, including beer or wine, while operating or as a passenger in or on either a vehicle or off highway vehicle.

C. You must not possess any drug paraphernalia in violation of any State law.

Penalties: On public lands under section 303(a) of the Federal Land Policy and Management Act of 1976 (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 enhanced fines provided for by 18 U.S.C. 3571.

Peter J. Ditton,

BLM Idaho State Director, Acting.

[FR Doc. 2011–17149 Filed 7–7–11; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decrees

Notice is hereby given that on July 1, 2011, two proposed Consent Decrees were lodged with the United States District Court for the Central District of California. The Consent Decrees were lodged in the case *United States et al.* v. *Seachrome Corporation,* Civil Action No. 11–0382 (C.D. Cal.) (consolidated with, inter alia, Civil Action No. 02–4565 (C.D. Cal.)).

The United States of America (''United States''), on behalf of the Administrator of the United States Environmental Protection Agency (''EPA''), and the California Department of Toxic Substances Control (''Department'') filed a complaint pursuant to Section 107 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (''CERCLA''), 42 U.S.C. 9607, seeking reimbursement of response costs incurred or to be incurred for response actions taken in connection with the release or threatened release of hazardous substances at the South El Monte Operable Unit of the San Gabriel Valley Area 1 Superfund Site in South El Monte, Los Angeles County, California (the ''South El Monte O.U.''). The United States' and Department's suit was consolidated with existing lawsuits also related to the South El Monte O.U.

Under the first proposed Consent Decree, Aerojet-General Corp., a potentially responsible party with respect to the South El Monte O.U., will pay a total of about $6.8 million to the United States, the Department, and certain plaintiffs in the consolidated lawsuits. Under the second Consent Decree, Mammoet Western, Inc., Time Realty Investments, and Tonks Properties, potentially responsible parties with respect to the South El Monte O.U., will collectively pay a total

of $545,000 to EPA and certain plaintiffs in the consolidated lawsuits. In exchange for the payments, the plaintiffs covenant not to sue each settling defendant under Section 106 or 107 of CERCLA.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Consent Decrees. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to: *United States et al.* v. *Seachrome Corp.* (C.D. Cal.), D.J. Ref. 90–11–2–09121/5.

The proposed Consent Decrees may be examined at EPA's Regional Office, 75 Hawthorne Street, San Francisco, California 94105. During the public comment period, the Consent Decrees may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the proposed Consent Decrees may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax No. (202) 514–0097, phone confirmation No. (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check payable to the ''U.S. Treasury'' or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address, in the following amount (25 cents per page reproduction cost): $6.50 for the Aerojet Consent Decree (without attachments) or $8.75 for the Mammoet Consent Decree (without attachments).

Henry S. Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–17178 Filed 7–7–11; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Office of Juvenile Justice and Delinquency Prevention

[OJP (OJJDP) Docket No. 1563]

Final Plan for Fiscal Year 2011

AGENCY: Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, Department of Justice.

ACTION: Notice of Final Plan for Fiscal Year 2011.

SUMMARY: The Office of Juvenile Justice and Delinquency Prevention is publishing this notice of its Final Plan for fiscal year (FY) 2011.

FOR FURTHER INFORMATION CONTACT: The Office of Juvenile Justice and Delinquency Prevention at 202–307–5911. [This is not a toll-free number.]

SUPPLEMENTARY INFORMATION: The Office of Juvenile Justice and Delinquency Prevention (OJJDP) is a component of the Office of Justice Programs (OJP) in the U.S. Department of Justice. Provisions within Section 204(b)(5)(A) of the Juvenile Justice and Delinquency Prevention Act of 1974, as amended, 42 U.S.C. Sec. 5601 *et seq.* (JJDP Act), direct the OJJDP Administrator to publish for public comment a Proposed Plan describing the program activities that OJJDP proposes to carry out during FY 2011 under Parts D and E of Title II of the JJDP Act, codified at 42 U.S.C. Sec. 5651–5665a, 5667, 5667a. Because the Office's discretionary activities extend beyond Parts D and E, the Acting Administrator of OJJDP published a proposed plan outlining a more comprehensive listing of the Office's programs. OJJDP invited the public to comment on the Proposed Plan for FY 2011, which was published in the **Federal Register** on January 12, 2011 (76 FR 2135). The deadline for submitting comments on the Proposed Plan was February 28, 2011.

The Acting Administrator reviewed and analyzed the public comments that OJJDP received, and a summary of OJJDP activities since the comment period ended appears later in this document. The Acting Administrator took these comments into consideration in developing this Final Plan, which describes the program activities that OJJDP intends to fund during FY 2011.

Since early in FY 2011, OJJDP has posted on its Web site (*http://www.ojjdp. gov*) solicitations for competitive programs to be funded under the Final Plan for FY 2011. These funding opportunities are announced via OJJDP's JUVJUST listserv and other methods of electronic notification. To obtain information about OJJDP and other OJP funding opportunities, visit Grants.gov's ''Find Grant Opportunities'' Web page at *http://www.grants.gov/applicants/find_grant_opportunities.jsp.* No proposals, concept papers, or other forms of application should be submitted in response to this Final Plan.

Department Priorities: OJJDP has structured this plan to reflect the high priority that the Administration and the Department have placed on addressing youth violence and victimization and improving protections for youth involved with the juvenile justice system. The programs presented here represent OJJDP's current thinking on how to advance the Department's priorities during this fiscal year. This Final Plan also incorporates feedback from OJJDP's ongoing outreach to the field seeking ideas on program areas and the most promising approaches for those types of areas.

OJJDP's Purpose: Congress established OJJDP through the JJDP Act of 1974 to help states and communities prevent and control delinquency and strengthen their juvenile justice systems and to coordinate and administer national policy in this area.

Although states, American Indian/Alaska Native (AI/AN) communities,[1] and other localities retain primary responsibility for administering juvenile justice and preventing juvenile delinquency, OJJDP supports and supplements the efforts of public and private organizations at all levels through program funding via formula, block, and discretionary grants; administration of congressional earmark programs; research; training and technical assistance; funding of demonstration projects; and dissemination of information. OJJDP also helps administer Federal policy related to juvenile justice and delinquency prevention through its leadership role in the Coordinating Council on Juvenile Justice and Delinquency Prevention.

OJJDP's Vision: OJJDP strives to be the recognized authority and national leader dedicated to the future, safety, and well-being of children and youth in, or at risk of entering, the juvenile justice system and to serving children, families, and community organizations that protect children from harm and exploitation.

OJJDP's Mission: OJJDP provides national leadership, coordination, and resources to prevent and respond to juvenile delinquency and victimization by supporting states, Tribal jurisdictions, and communities in their efforts to develop and implement effective coordinated prevention and intervention programs and improve the juvenile justice system so that it protects public safety, holds offenders accountable, and provides treatment and rehabilitation services tailored to the needs of juveniles and their families.

Guiding Principles for OJJDP's National Leadership: OJJDP provides

[1] In this plan, the terms ''Tribes'' and ''Tribal jurisdictions'' refer to both American Indian and Alaska Native communities.

targeted funding, sponsors research and demonstration programs, offers training and technical assistance, disseminates information, and uses technology to enhance programs and collaboration in exercising its national leadership role. In all of these efforts, the following four principles guide OJJDP:

(1) Empower communities and engage youth and families.

(2) Promote evidence-based practices.

(3) Require accountability.

(4) Enhance collaboration.

1. Empower communities and engage youth and families. Families and communities play an essential role in any effort to prevent delinquency and protect children from victimization. Communities must reach beyond the formal systems of justice, social services, and law enforcement to tap into the wisdom and energies of many others—including business leaders, the media, neighborhood associations, block leaders, elected officials, Tribal leaders, clergy, faith-based organizations, and especially families and young people themselves—who have a stake in helping local youth become productive, law-abiding citizens. In particular, OJJDP must engage families and youth in developing solutions to delinquency and victimization. Their strengths, experiences, and aspirations provide an important perspective in developing those solutions.

To be effective, collaboration among community stakeholders must be grounded in up-to-date information. With Federal assistance that OJJDP provides, community members can partner to gather data, assess local conditions, and make decisions to ensure resources are targeted for maximum impact.

2. Promote evidence-based practices. To make the best use of public resources, OJJDP must identify ''what works'' in delinquency prevention and juvenile justice. OJJDP is the only Federal agency with a specific mission to develop and disseminate knowledge about what works in this field. Drawing on this knowledge, OJJDP helps communities replicate proven programs and improve their existing programs. OJJDP helps communities match program models to their specific needs and supports interventions that respond to the developmental, cultural, and gender needs of the youth and families they will serve.

3. Require accountability. OJJDP requires the national, state, Tribal, and local entities whose programs OJJDP supports to explain how they use program resources, determine and report on how effective the programs are in alleviating the problems they are intended to address, and propose plans for remediation of performance that does not meet standards. OJJDP has established mandatory performance measures for all its programs and reports on those measures to the Office of Management and Budget. OJJDP requires its grantees and applicants to report on these performance measures, set up systems to gather the data necessary to monitor those performance measures, and use this information to continuously assess progress and fine-tune the programs.

4. Enhance collaboration. Juvenile justice agencies and programs are just one part of a larger set of systems that encompasses the many agencies and programs that work with at-risk youth and their families. For delinquency prevention and child protection efforts to be effective, they must be coordinated at the local, Tribal, state, and Federal levels with law enforcement, social services, child welfare, public health, mental health, school, and other systems that address family strengthening and youth development. One way to achieve this coordination is to establish broad-based coalitions to create consensus on service priorities and to build support for a coordinated approach. With this consensus as a foundation, participating agencies and departments can then build mechanisms to link service providers at the program level—including procedures for sharing information across systems.

OJJDP took its guidance in the development of this Final Plan from the priorities that the Attorney General has set forth for the Department. At the same time, OJJDP drew upon its Strategic Plan for 2009–2011. The four primary goals at the heart of OJJDP's Strategic Plan echo the Attorney General's priorities. Those goals are: Prevent and respond to delinquency, strengthen the juvenile justice system, prevent and reduce the victimization of children, and prevent and reduce youth violence to create safer neighborhoods.

OJJDP's Summary of Public Comments on the FY 2011 Proposed Plan

OJJDP published its Proposed Plan for FY 2011 in the **Federal Register** (76 FR 2135) on January 12, 2011. During the subsequent 45-day public comment period, OJJDP received 29 submissions. Since the close of public comment, OJJDP has carefully reviewed and considered each of the submissions in its development of the Final Plan for FY 2011.

Comments addressed many of the program areas and activities in which OJJDP is currently engaged. Improving conditions and services for youth with disabilities and mental health issues in the juvenile justice system was the single topic that elicited the most responses. More than a third of the comments dealt with some aspect of improving conditions in juvenile facilities for youth with disabilities and mental health issues. In keeping with U.S. Department of Justice priorities, many OJJDP programs, including the Defending Childhood Initiative, the Second Chance Act Juvenile Offender Reentry Project, the Tribal Youth Program, among other programs, allow grantees to provide mental health services to participating youth.

Other areas that drew comments were mentoring, disproportionate minority contact, prevention and early intervention programs, and conditions of confinement for juvenile offenders.

OJJDP looks to the field for guidance on emerging juvenile justice needs and issues of concern, and targets its allocation of funding and resources, based, in part, on the feedback the Office receives from policymakers and practitioners through such vehicles as the Proposed Plan. OJJDP wishes to note that in the interim period between publication of the Proposed Plan in January and this Final Plan, Congress identified the Office's funding streams for FY 2011, and OJJDP adjusted its funding priorities accordingly. As a result, OJJDP will not fund in 2011 some programs that appeared in the Proposed Plan, and OJJDP also has added new programs. Comments the Office received on the Proposed Plan, Administration priorities, and available funds informed these decisions.

OJJDP is encouraged by the quality of the comments that the Office received for the 2011 Proposed Plan and looks forward to continued communication and collaboration with the juvenile justice field.

OJJDP Final Plan for Fiscal Year 2011

Each year OJJDP receives formula and block grant funding as well as discretionary funds for certain program areas. Based on its proposed budget for FY 2011, OJJDP offers the following 2011 Final Plan for its discretionary funding. Programs are organized according to Department priorities and traditional OJJDP focus areas.

Department and OJJDP Priorities

OJJDP administers grant programs authorized by the JJDP Act of 1974, as amended. OJJDP also administers programs under other legislative authority and through partnerships with other Federal agencies. In keeping with OJJDP's mission, these programs are designed to help strengthen the juvenile

justice system, prevent juvenile delinquency and violence, and protect and safeguard the nation's youth. The Obama Administration and the Attorney General have identified children's exposure to violence, gang violence, and community violence as focus areas for the Department. *http://www.wrightslaw.com/info/jj.index.htm.*

The Attorney General's Initiative on Children Exposed to Violence Program: Phase II

On September 23, 2011, Attorney General Holder launched Defending Childhood, an initiative that harnesses resources from across the Department of Justice to prevent children's exposure to violence; mitigate the negative impact of that exposure; and develop knowledge and spread awareness about the issue. The Attorney General's Initiative on Children Exposed to Violence is the programmatic expression of Defending Childhood. Following an initial planning year, DOJ will award supplemental funds to the original eight sites to implement activities to prevent and reduce the impact of children's exposure to violence in their homes, schools, and communities. Subsequently, DOJ will select four communities to receive substantial support through an invitation-only competition. The remaining four sites will receive supplemental funding for specific program services under DOJ guidelines. OJJDP will conduct process and outcome evaluations of the initiative.

Community-Based Violence Prevention Program

OJJDP will fund new sites to replicate intervention programs, such as the Boston Gun Project, the Richmond Comprehensive Homicide Initiative, the Chicago CeaseFire model, or other programs, to reduce violence in targeted communities. Applicants must focus their proposed programs on the high-risk activities and behaviors of a small number of carefully selected members of the community who are likely to be involved in gun violence in the immediate future. The intervention with this target population should include improved coordination of existing resources and activities that support multiple, complementary anti-violence strategies. An additional evaluation grant (continuation) will be made to ensure data from the new sites are included in the national evaluation.

Continuations

In FY 2011, OJJDP will continue to support:

- Safe Start Promising Approaches Project.
- Children's Exposure to Violence Fellowship.
- National Survey of Children Exposed to Violence.
- Gang Resistance Education and Training (G.R.E.A.T.) Program.

Tribal Youth

Since 1998, Congress has appropriated funding to support programs addressing Tribal youth. OJJDP administers most of its Tribal initiatives through the Tribal Youth Program (TYP). These programs fund initiatives, training and technical assistance, and research and evaluation projects to improve juvenile justice systems and delinquency prevention efforts among Federally recognized American Indian and Alaska Native (AI/AN) Tribes.

U.S. Department of Justice Coordinated Tribal Assistance

In response to concerns that Tribes voiced during recent public listening sessions, DOJ developed the Coordinated Tribal Assistance Solicitation (CTAS) that combines all of its existing competitive Tribal solicitations into one document. The CTAS solicitation is posted on the Office of Justice Programs (OJP) Web site (*http://www.ojp.gov*). The following are the OJJDP programs within the CTAS:

- *Tribal Youth Program* supports and enhances Tribal efforts to prevent and control delinquency and improve their juvenile justice systems. Grantees develop and implement delinquency prevention programs, interventions for court-involved youth, improvements to their juvenile justice systems, alcohol and substance abuse prevention programs, and emotional/behavioral program services.
- OJJDP will support *Tribal Youth Demonstration Programs* that address gaps in programs and services for Tribal youth. Services include risk and needs assessments, educational and vocational programs, mental health services, substance abuse programs, family strengthening, recreational activities, and extended reentry aftercare to help offenders successfully reintegrate into the Tribal community.

Tribal Youth Field-Initiated Research and Evaluation Programs

OJJDP will fund field-initiated studies to further what is understood regarding the experiences, strengths, and needs of Tribal youth, their families, and communities and what works to reduce their risks for delinquency and victimization. Accordingly, OJJDP will seek applications addressing a broad range of research topics, such as the identification of risk factors for delinquent behavior and substance abuse, pathways to delinquency and desistance, victimization experiences among Tribal youth and an assessment of gang problems in Tribal communities.

Tribal Youth National Mentoring Program

OJJDP will support the development, maturation, and expansion of mentoring services for Tribal youth on Tribal reservations that are underserved due to location, shortage of mentors, emotional or behavioral challenges of the targeted population, or other situations. Grantees will assess Tribal needs, develop plans, and implement and monitor mentoring activities in multiple states that have Tribal reservations.

Continuation

In FY 2011, OJJDP will continue to support:

- Child Protection Programs in Tribal Communities.

Juvenile Justice System Reform

OJJDP recognizes the need for states to have effective and efficient juvenile justice systems and for the Office to assist them in identifying and implementing promising and evidence-based practices. Reforming juvenile justice and improving systems across the country is a priority for OJJDP. In 2011, OJJDP will focus on youth transitioning back to their communities from a detention or corrections facility.

Second Chance Act Adult and Juvenile Offender Reentry Demonstration Projects

OJJDP, in collaboration with the Bureau of Justice Assistance, will support additional demonstration projects under the Second Chance Act Youth Offender Reentry Initiative, a comprehensive response to the increasing number of people who are released from prison, jail, and juvenile facilities each year and are returning to their communities. The goal of this initiative is to reduce the rate of recidivism for offenders released from a juvenile residential facility and increase public safety. Demonstration projects provide necessary services to youth while in confinement and following their release into the community. The initiative will focus on addressing the unique needs of girls reentering their communities.

Continuations

In FY 2011, OJJDP will continue to support;

- Juvenile Indigent Defense National Clearinghouse.
- National Training and Technical Assistance Center for Youth in Custody.
- Juvenile Detention Alternatives Initiative.
- The National Girls Institute.

Research, Evaluation, and Data Collection

OJJDP supports and promotes research, vigorous and informative evaluations of demonstration programs, and collection and analysis of statistical data. The goal of these activities is to generate credible and useful information to improve decisionmaking in the juvenile justice system. OJJDP sponsors research that has the greatest potential to improve the nation's understanding of juvenile delinquency and victimization and of ways to develop effective prevention and intervention programs to respond to it.

Child Protection Research Program

OJJDP will fund field-initiated research and evaluation projects on crimes against children and juveniles, primarily on issues of exploitation and abuse. These projects will produce information that will assist Federal, state, and local law enforcement and prosecutors involved with crimes against children cases, policymakers, and professionals who care for and educate children and youth. OJJDP will consider applications proposing research in other areas that will fill a critical gap in the field's knowledge and practice.

Evaluation of Second Chance Act Juvenile Mentoring Initiative

OJJDP will conduct a comprehensive process and rigorous impact evaluation of the Second Chance Act Juvenile Mentoring Initiative to determine the effectiveness of combining mentoring with other reentry services for participating juvenile offenders during their confinement, through their transition back to the community, and following release. OJJDP will select a national evaluator to assess the implementation of these programs and their impact on service delivery and key outcomes for participating youth, including recidivism.

Mentoring Research Best Practices Program

OJJDP will fund a program of research that seeks to enhance the understanding of mentoring as a prevention strategy for youth at risk of involvement or already involved in the juvenile justice system. While mentoring appears to be a promising intervention for youth, more evaluation work is needed to further highlight the components of a mentoring program that are most effective and how effective mentoring is as a delinquency prevention/intervention technique.

Youth Gang Research Initiative

OJJDP will fund research on gangs that provides current information on the nature and scope of the gang problem in the United States, examines programs and strategies that communities have implemented to prevent and intervene in gang activity, and identifies emerging trends in gang prevention and intervention programs. Further research and examination is needed to develop a better understanding of the factors that lead to gang involvement, the nature and scope of different types of gangs, and the most effective strategies, programs, and practices to prevent and intervene with gang-involved youth. *Also,* OJJDP will fund an assessment of the nature and scope of youth gangs in juvenile detention and correctional facilities.

Field-Initiated Research and Evaluation Program

OJJDP will support multiple grant awards for research and evaluations of programs and initiatives that focus on the juvenile justice system's response to delinquency and system improvement. The goal of the research questions posed will be to inform policy and lead to recommendations for juvenile justice system improvement.

National Juvenile Probation Census Project

OJJDP will support the next round of its National Juvenile Probation Census, which describes youth under justice supervision and the services they receive. The census provides critical data on the characteristics of youth on probation, the nature of their offenses, and how they are served. The significance of such information is evident when one considers that the number of youth on probation is roughly five times that of the population of youth in custody.

Evaluations of Girls' Delinquency Programs

OJJDP will support evaluations that will measure the effectiveness of delinquency prevention, intervention, and/or treatment programs to prevent and reduce girls' risk behavior and offending. Over the past two decades, the number of girls entering the juvenile justice system has dramatically increased. This trend raised a number of questions for OJJDP, including whether this reflected an increase in girls' delinquency or changes in society's responses to girls' behavior. OJJDP's Girls Study Group recently completed a review of evaluations of girls' delinquency programs and found that most programs have not been evaluated, thereby limiting knowledge about the most appropriate and effective programs for girls.

Continuations

In FY 2011, OJJDP will continue to support:

- National Juvenile Justice Evaluation Center.
- National Juvenile Justice Data Analysis Program.
- National Juvenile Justice Data Collection Program.

Substance Abuse and Treatment

OJJDP, often in partnership with other Federal agencies and private organizations, develops programs, research, or other initiatives to address juvenile use and abuse of illegal, prescription, and nonprescription drugs and alcohol. OJJDP's substance abuse efforts include control, prevention, and treatment programs.

Best Practices for Juvenile Drug Courts and Adolescent Treatment

OJJDP will fund an initiative in partnership with the Department of Health and Human Services' Center for Substance Abuse Treatment to identify best practices for merging juvenile drug courts and adolescent treatment. This initiative will also develop and implement training for juvenile drug courts on models of adolescent treatment that support the drug court.

Family Drug Court Programs

OJJDP will implement and enhance family drug courts that serve substance-abusing adults who are involved in the family dependency court system as a result of child abuse and neglect issues. Grantees must provide services to the children of the parents in the program as well as to the parents. The Center for Children and Family Futures will provide training and technical assistance to family drug courts.

Enforcing Underage Drinking Laws Program

The Enforcing Underage Drinking Laws (EUDL) Program supports states' efforts to reduce drinking by juveniles through its four components: block grants to the 50 states, the 5 territories, and the District of Columbia;

discretionary grants; technical assistance; and research and evaluation. Under the block grant component, each state, the District of Columbia, and the territories receive approximately $360,000 annually to support law enforcement activities, media campaigns, and coalition building. The EUDL discretionary grant component supports several diverse initiatives to help communities develop promising approaches to address underage drinking. EUDL training and technical assistance supports communities and states in their efforts to enforce underage drinking laws. EUDL funds and Federal partnerships also support evaluations of community initiatives within the EUDL discretionary grant component.

Enforcing Underage Drinking Laws Assessment, Strategic Planning, and Implementation Initiative

OJJDP will support this discretionary component of the Enforcing Underage Drinking Laws program, in which states will implement an assessment and strategic planning process to develop targeted, effective activities to reduce underage access to and consumption of alcohol. Grantees will assess local conditions and design a long-term strategic plan; implement selected and approved actions of that plan; collect, analyze, and report data; and evaluate how the state responded to the recommendations, crafted its strategic plan, and implemented portions of the plan with the remaining funds.

Continuations

In FY 2011, OJJDP will continue to support:

- Juvenile Drug Court Programs.

Mentoring

OJJDP supports mentoring programs for youth at risk of failing in school, dropping out of school, or becoming involved in delinquent behavior, including gang activity and substance abuse. The goals of the programs are to reduce juvenile delinquency and gang participation, improve academic performance, and reduce the school dropout rate. Mentoring funds support mentoring programs that provide general guidance and support; promote personal and social responsibility; increase participation in education; support juvenile offenders returning to their communities after confinement in a residential facility; discourage use of illegal drugs and firearms; discourage involvement in gangs, violence, and other delinquent activity; and encourage participation in community service activities. OJJDP will also sponsor several research projects that will evaluate mentoring programs or approaches and the effectiveness of specific mentoring practices.

Mentoring Commercial Child Sexual Exploitation Victim Service Agencies

OJJDP proposes to support the development and enhancement of the mentoring capacity of community organizations that provide direct services to children who are sexually exploited for commercial purposes. Community service programs that build or enhance mentoring programs for these high-risk youth and provide other appropriate support services can empower girls and boys to exit the commercial sex industry and move past their involvement with the justice system and their experiences with victimization. Such programs should be led by a local community collaborative that is designed to address local needs and use local resources.

Mentoring for Youth With Disabilities

OJJDP proposes to fund mentoring programs and strategies that support at-risk youth with disabilities to prevent them from engaging in risky behaviors such as substance abuse and criminal activity. OJJDP anticipates coordinating this initiative with the U.S. Departments of Education and Health and Human Services.

Second Chance Act Juvenile Mentoring Initiative

OJJDP will provide grants for mentoring and other transitional services to reintegrate juvenile offenders into their communities. The grants will be used to mentor juvenile offenders during confinement, through transition back to the community, and following release; to provide transitional services to assist them in their reintegration into the community; and to support training in offender and victims issues. The initiative's goals are to reduce recidivism among juvenile ex-offenders, enhance community safety, and enhance the capacity of local partnerships to address the needs of juvenile ex-offenders returning to their communities.

National and Multi-State Mentoring Programs

OJJDP will support national organizations and organizations with mentoring programs in at least five states to enhance or expand mentoring services to high-risk populations that are underserved due to location; shortage of mentors; special physical or mental challenges of the targeted population; youth with a parent in the military, including a deployed parent; or other analogous situations that the community in need of mentoring services identifies.

Missing Children

These programs enhance the national response of state, local, and Federal law enforcement agencies, prosecutors, and nongovernmental organizations to missing and exploited children. They serve as the primary vehicles for building a national infrastructure to support efforts to prevent the abduction and exploitation of our nation's children.

National Center for Missing & Exploited Children

OJJDP will fund the National Center for Missing & Exploited Children to serve as the national resource center and information clearinghouse for missing and exploited children; operate a national 24-hour toll-free telephone line by which individuals may report information regarding the location of any missing child; operate a cyber tipline to provide online users and electronic service providers a means to report Internet-related child sexual exploitation; and, provide training and technical assistance to individuals and law enforcement agencies in the prevention, investigation, prosecution, and treatment of cases involving missing and exploited children.

AMBER Alert

OJJDP will fund the AMBER Alert network, which is a voluntary partnership of state and local media, law enforcement, and transportation agencies that work together to notify the public about an abducted child and to request their assistance in the recovery of the child. The AMBER Alert program increases and improves law enforcement response to missing, endangered, and abducted children; increases the recovery rate of abducted children; strengthens child alert systems in the nation's northern and southern borders to better protect American children abducted to or through foreign countries; creates greater community capacity to understand broader issues related to exploitation and abuse of children; and enhances public participation in the recovery of missing, endangered, and abducted children.

Child Victimization

Since its inception, OJJDP has consistently strived to safeguard children from victimization by supporting research, training, and community programs that emphasize prevention and early intervention. A

commitment to children's safety is written into the Office's legislative mandate, which includes the JJDP Act of 1974, the Missing Children's Assistance Act of 1984, and the Victims of Child Abuse Act of 1990. OJJDP continues to improve the responses of the justice system and related systems, increase public awareness, and promote model programs for addressing child victimization in states and communities across the country.

Children's Advocacy Centers

OJJDP will continue funding for programs that improve the coordinated investigation and prosecution of child abuse cases. These programs include a national subgrant program for local children's advocacy centers, a membership and accreditation program, regional children's advocacy centers, and specialized technical assistance and training programs for child abuse professionals and prosecutors. Local children's advocacy centers bring together multidisciplinary teams of professionals to coordinate the investigation, treatment, and prosecution of child abuse cases.

Court Appointed Special Advocates Programs

OJJDP will continue funding for Court Appointed Special Advocates (CASA) programs that provide children in the foster care system or at risk of entering the dependency system with high-quality, timely, effective, and sensitive representation before the court. CASA programs train and support volunteers who advocate for the best interests of the child in dependency proceedings. OJJDP funds a national CASA training and technical assistance provider and a national membership and accreditation organization to support state and local CASA organizations' efforts to recruit volunteer advocates, including minority volunteers, and to provide training and technical assistance to these organizations and to stakeholders in the child welfare system.

Child Exploitation

The increasing number of children and teens using the Internet, the proliferation of child pornography, and the increasing number of sexual predators who use the Internet and other electronic media to prey on children present both a significant threat to the health and safety of young people and a formidable challenge for law enforcement. OJJDP took the lead early on in addressing this problem. More than a decade ago, the Office established the Internet Crimes Against Children Task Force program.

Internet Crimes Against Children Program

OJJDP will continue funding to support the operations of the 61 Internet Crimes Against Children (ICAC) task forces. The ICAC Task Force program helps state and local law enforcement agencies develop an effective response to sexual predators who prey upon juveniles via the Internet and other electronic devices and child pornography cases. This program encompasses forensic and investigative components, training and technical assistance, victim services, and community education.

ICAC Commercial Child Sexual Exploitation

OJJDP will support select law enforcement agencies in their development of strategies to protect children from commercial sexual exploitation. Grantees will improve training and coordination activities, develop policies and procedures to identify child victims of commercial sexual exploitation, investigate and prosecute cases against adults who sexually exploit children for commercial purposes, and provide essential services to victims, including cases where technology is used to facilitate the exploitation of the victim.

ICAC Deconfliction System

OJJDP will fund an ICAC Deconfliction System (IDS) to allow OJJDP-credentialed users, including Federal, state, local, and Tribal agencies and ICAC task forces investigating and prosecuting child exploitation to contribute and access data for use in resolving case conflicts. A governmental agency or a credentialed law enforcement agency will host the system. Also, IDS will permit the real-time analysis of data to facilitate identification of targets and to estimate the size of the law enforcement effort to address these crimes.

In addition, OJJDP will support related ICAC activities and programs, including:

- Designing and implementing the 2011 ICAC-Project Safe Childhood National Training Conference.
- Research on Internet and other technology-facilitated crimes against children.
- Training for ICAC officers, prosecutors, judges, and other stakeholders.
- Technical assistance to support implementation of the ICAC program.

Continuation

In FY 2011, OJJDP will continue to support:

- Missing and Exploited Children Training and Technical Assistance Program.

Juvenile Justice System Improvement

OJJDP works to improve the effectiveness and efficiency of the juvenile justice system. A major component of these efforts is the provision of training and technical assistance (TTA) resources that address the needs of juvenile justice practitioners and support state and local efforts to build capacity and expand the use of evidence-based practices.

Training and technical assistance is the planning, development, delivery, and evaluation of activities to achieve specific learning objectives, resolve problems, and foster the application of innovative approaches to juvenile delinquency and victimization. OJJDP has developed a network of providers to deliver targeted training and technical assistance to policymakers and practitioners.

National Gang Center

OJJDP will fund, in partnership with the Bureau of Justice Assistance, a National Gang Center to provide training and technical assistance to law enforcement agencies and communities on gang prevention and intervention programs and strategies. The National Gang Center will also administer the annual National Youth Gang Survey and disseminate current research and practice on gang prevention, intervention, and suppression strategies and programs.

Model Programs Guide

OJJDP will fund a program to maintain and expand the databases that make up OJJDP's Model Programs Guide. The award recipient will actively identify, review, and assess new programs; add new programs that meet the evaluation criteria, their descriptions, and performance indicators; and develop, maintain, and expand subject-specific databases including, but not limited to, the disproportionate minority contact and deinstitutionalization of status offenders best practices databases. Moreover, OJJDP is looking to improve technical capacity, expand and refine the database, and, generally, assure ease, speed, and precision in searching the database.

National Training and Technical Assistance Center for Truancy Prevention and Intervention

OJJDP will fund a National Training and Technical Assistance Center for Truancy Prevention and Intervention.

The center will disseminate information regarding what works to prevent and intervene with school truancy and dropout problems and promote the use of evidence-based practices through training, technical assistance, and resources.

State Juvenile Justice Formula and Block Grants Training and Technical Assistance Program

OJJDP will award a cooperative agreement to an organization that will provide training and technical assistance to national, state, and local-level grantees and non-grantees that will assist them in planning, establishing, operating, coordinating, and evaluating delinquency prevention and juvenile justice systems improvement projects. Training and technical assistance topic areas will fall under the Title II Formula Grants and Juvenile Accountability Block Grants (JABG) program areas. The successful applicant shall develop, enhance, and refine OJJDP program-specific training, on, but not limited to, state and local level disproportionate minority contact reduction strategies, state-level compliance monitoring, graduated sanctions, and juvenile justice systems improvement efforts. Additionally, the selected organization will coordinate the State Relations and Assistance Division's national training conferences.

Continuations

In FY 2011, OJJDP will continue to support:

- Child Abuse Training for Judicial and Court Personnel.
- Engaging Law Enforcement To Reduce Juvenile Crime, Victimization, and Delinquency.
- State Advisory Group Training and Technical Assistance Project.

Fellowships

OJJDP's fellowship program is designed to enhance the Office's efforts to develop and improve innovative programs that serve children, youth, and families. A secondary goal is to provide practitioners an opportunity to work closely with career and political Federal staff, contractors, grantees, and other public and private organizations in Washington, DC, and across the country. The fellow will provide direct operational assistance to OJJDP staff through assessment and capacity building, design and development of innovative initiatives and training programs, resource development, research and evaluation, policy development, and outreach and awareness. The fellow will also develop articles for publication and other products on specific topics.

Concentration of Federal Efforts Fellowship

OJJDP will fund a fellow in the Concentration of Federal Efforts program for 2 years to strengthen the Office's cross-agency partnership efforts. Currently, OJJDP staff and leadership participate in dozens of interagency efforts. The fellow will build on related ongoing work of other Federal agencies, develop new cross-agency partnerships and initiatives, identify and assess opportunities for cross-agency partnerships, and track the impact of existing partnership efforts.

Dated: July 1, 2011.

Jeff Slowikowski,

Acting Administrator, Office of Juvenile Justice and Delinquency Prevention.

[FR Doc. 2011–17186 Filed 7–7–11; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–75,181]

Sony Music Holdings, Inc., D/B/A Sony DADC Americas, a Subsidiary of Sony Corporation of America Including On-Site Leased Workers From Employment Plus, Aerotek, and Robert Half, Pitman, NJ; Notice of Affirmative Determination Regarding Application for Reconsideration

By application dated June 15, 2011, a petitioner requested administrative reconsideration of the negative determination regarding workers' eligibility to apply for Trade Adjustment Assistance (TAA) applicable to workers and former workers of Sony Music Holdings, Inc. (''SMHI''), d/b/a Sony DADC Americas, a subsidiary of Sony Corporation of America, including on-site leased workers from Employment Plus, Aerotek, and Robert Half, Pitman, New Jersey (subject firm). The negative determination was issued on May 19, 2011. The Department's Notice of Determination was published in the **Federal Register** on June 3, 2011 (76 FR 32229). The workers were engaged in activities related to the production of optical discs containing content.

The negative determination was based on the findings that there was no increase in imports of optical discs (or like or directly competitive articles) by the subject firm or its customers and no shift to or acquisition from a foreign country by the workers' firm of production of articles like or directly competitive with the optical discs produced by the subject firm.

In the request for reconsideration, the petitioner stated that ''There was a shift by the workers' firm to a foreign country in the production of articles like those produced by the Song DADC–Pitman site. The attached documents illustrate the project plan by 'SMHI' to expand customers and increase capacity and services in the Sony Nuevo Laredo plant located in Mexico.'' The documents include a ''Sony DADC Communique, Volume 3, Issue 1'' (dated January/February 2010), a ''Sony Nuevo Laredo Project Plan'' (undated), copies of shipping documents, and copies of electronic mail messages.

The Department has carefully reviewed the petitioner's request for reconsideration and the existing record, and has determined that the Department will conduct further investigation to determine if the petitioning workers meet the eligibility requirements of the Trade Act of 1974, as amended.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the U.S. Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 28th day of June, 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–17088 Filed 7–7–11; 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 and Alternative Trade 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 (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the period of *June 13, 2011 through June 24, 2011.*

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. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. The country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected 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(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (*i.e.,* conditions within the industry are adverse).

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.

None.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) of the Trade Act have been met.

None.

Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade 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) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–80,014; Geneon Entertainment (USA), Santa Monica, CA: March 1, 2010.

TA–W–80,037; Boralex Ashland LP, Ashland, ME: March 10, 2010.

TA–W–80,048; Hancock Company, d/b/a/ As Gitman Company/IAG, Ashland, PA: December 19, 2010.

TA–W–80,058; Alliance One International, Inc., Morrisville, NC: March 18, 2010.

TA–W–80,076; Nexergy, Inc., Columbus, OH: March 28, 2010 TA–W–80,083; The Genie Company, Shenandoah, VA: March 31, 2011.

TA–W–80,094; Motorola Mobility, Inc., Libertyville, IL: March 26, 2010.

TA–W–80,110; Callaway Golf Ball Operations, Inc., Chicopee, MA: July 1, 2011.

TA–W–80,115; Domtar Industries, Inc., Ashdown, AR: April 18, 2010.

TA–W–80,120; Premier Manufacturing Corp., Cleveland, OH: April 11, 2010.

TA–W–80,198; Tyco Healthcare Group, LP, San Jose, CA: May 20, 2010.

TA–W–80,218; Unimin Corporation, Hamilton, WA: June 3, 2010.

TA–W–80,065; Genesis Furniture Industries, Inc., Pontotoc, MS: March 22, 2010.

TA–W–80,139; Electrolux Home Products, Inc., Webster City, IA: June 26, 2011.

TA–W–80,216; Solar power Industries, Belle Vernon, PA: June 2, 2010.

TA–W–80,216A; Solar Power Industries, Mt. Pleasant PA: June 2, 2010.

TA–W–80,225; Finisar Corporation, Horsham, PA: April 3, 2011.

TA–W–80,225A; Leased Workers from McGrath Technical Staffing, Inc., Horsham, PA: June 8, 2010.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–80,060; Valspar Corporation, High Point, NC: June 21, 2010.
TA–W–80,060A; Valspar Corporation, High Point, NC: March 16, 2010.
TA–W–80,227; BOS Automotive Products, Inc., Morristown, TN: January 13, 2011.
TA–W–80,233; Ellison Educational Equipment, Inc., Lake Forest, CA: June 13, 2010.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–80,205; Nidec Motor Corporation, Frankfort, IN: October 28, 2010.
TA–W–80,205A: Leased Workers from Manpower, Frankfort, IN: May 26, 2010.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

None.

Negative Determinations for Alternative Trade Adjustment Assistance

In the following cases, it has been determined that the requirements of 246(a)(3)(A)(ii) have not been met for the reasons specified.

The Department has determined that criterion (1) of Section 246 has not been met. The firm does not have a significant number of workers 50 years of age or older.

None.

The Department has determined that criterion (2) of Section 246 has not been met. Workers at the firm possess skills that are easily transferable.

None.

The Department has determined that criterion (3) of Section 246 has not been met. Competition conditions within the workers' industry are not adverse.

None.

Negative Determinations for Worker Adjustment Assistance and Alternative Trade 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.

Because the workers of the firm are not eligible to apply for TAA, the workers cannot be certified eligible for ATAA.

The investigation revealed that criteria (a)(2)(A)(I.A.) and (a)(2)(B)(II.A.) (employment decline) have not been met.

TA–W–80,054; W.M. Glenn Construction, Durham, NC.

The investigation revealed that criteria (a)(2)(A)(I.B.) (Sales or production, or both, did not decline) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

None.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

TA–W–80,041; Quad/Graphics, Depew, NY.
TA–W–80,068; New Enterprise Stone and Lime Company, Inc. (NESL), Erie, PA.
TA–W–80,074; AES Westover, LLC, Johnson City, NY.
TA–W–80,103; HiRel Systems, LLC, Duluth, MN.
TA–W–80,163; Dentsply International, Inc., GAC, Bohemia, NY.

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–80,026; Computer Task Group, Inc., Mechanicsburg, PA.
TA–W–80,031; Thomson Reuters, Creve Coeur, MO.
TA–W–80,118; PSC Industrial Outsourcing, LP, Kelso, WA.
TA–W–80,126; Ryder Integrated Logistics, Highland Park, MI.
TA–W–80,213; Healthlink, St. Louis, MO.
TA–W–80,219; Beacon Medical Services, LLC, Aurora, CO.

The investigation revealed that criteria of Section 222(b)(2) has not been met. The workers' firm (or subdivision) is not a supplier to or a downstream producer for a firm whose workers were certified eligible to apply for TAA.

None.

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–80,042; Capstar Drilling, Wooster, OH.
TA–W–80,131; Invensys Operations Management, Irvine, CA.
TA–W–80,170; Getty Images, Los Angles, CA.
TA–W–80,206; West Clermont School, Cincinnati, OH.
TA–W–80,214; California Newspaper Limited Partnership, Callejo, CA.
TA–W–80,221; International Netherlands Group, ING, Windsor, CT.

The following determinations terminating investigations were issued because the petitioning group of workers are covered by Active certifications. Consequently, further investigation in these cases would serve no purpose since the petition group of workers cannot be covered by more than one certification at a time.

TA–W–75,255; Cooper Standard Automotive, Bowling Green, OH.
TA–W–80,106; Delphi Corporation, El Paso, TX.
TA–W–80,124; Bestway, Inc., Saint Marys, PA.

I hereby certify that the aforementioned determinations were issued during the period of *June 13, 2011 through June 24, 2011.* Copies of these determinations may be requested under the Freedom of Information Act. Requests may be submitted by fax, courier services, or mail to FOIA Disclosure Officer, Office of Trade Adjustment Assistance (ETA), U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 or *tofoiarequest@dol.gov.* These determinations also are available on the Department's Web site at *http://www.doleta.gov/tradeact* under the searchable listing of determinations.

Dated: June 29, 2011.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–17090 Filed 7–7–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

TA–W–72,953

Matthews International Corporation, Bronze Division, Kingwood, WV; Notice of Negative Determination on Reconsideration

On January 28, 2011, the Department of Labor issued an Affirmative Determination Regarding Application for Reconsideration for workers and former workers of Matthews International Corporation, Bronze

Division, Kingwood, West Virginia (subject firm). The Department's Notice of determination was published in the **Federal Register** on February 10, 2011 (76 FR 7584). Workers were engaged in the production of cast bronze memorial products.

The initial investigation resulted in a negative determination based on the findings that, during the relevant period, the subject firm did not import articles like or directly competitive with those produced at the subject firm, or shift to/acquire from a foreign country the production of these articles. The Department's survey of the subject firm's major declining customers regarding their purchases of cast bronze memorial products (and like or directly competitive articles) in 2007, 2008, 2009, and during January through February 2010 revealed no imports.

In the request for reconsideration, the petitioner alleged that, during the relevant time period, the subject firm had transferred equipment from the subject facility to Mexico and that the subject worker group was impacted by customer imports.

During the reconsideration investigation, the Department requested the subject firm to submit a new Confidential Data Request form, collected new information to address the allegations, and obtained clarification of previously-submitted information. The Department also obtained additional U.S. aggregate import data of articles like or directly competitive with those produced by the subject worker group.

Based on a careful review of information obtained during the initial and reconsideration investigations, the Department determines that imports of articles like or directly competitive with the cast bronze memorial products manufactured at the subject firm did not contribute importantly to worker group separations and to subject firm sales/production declines. Therefore, the criteria set forth in Section 222(a) have not been met.

Conclusion

After careful reconsideration, I affirm the original notice of negative determination of eligibility to apply for worker adjustment assistance for workers and former workers of Matthews International Corporation, Bronze Division, Kingwood, West Virginia.

Signed in Washington, DC, this 27th day of June, 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–17091 Filed 7–7–11; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–75,162]

Pisgah Yarn and Dyeing Company Including On-Site Leased Workers From Manpower, Inc., Old Fort, NC; Notice of Revised Determination on Reconsideration

On May 16, 2011, the Department issued a Notice of Affirmative Determination Regarding Application for Reconsideration for the workers and former workers of Pisgah Yarn & Dyeing Company, Old Fort, North Carolina (subject firm) to apply for Trade Adjustment Assistance. The Department's Notice was published in the **Federal Register** on May 25, 2011 (76 FR 30392). Workers are engaged in employment related to the production of cotton yarn. The worker group includes on-site leased workers from Manpower, Inc.

During the reconsideration investigation, the Department received new information that revealed that there has been an acquisition from a foreign country by the workers' firm of production of like or directly competitive articles.

Criterion I has been met because a significant number or proportion of workers at the subject firm have become totally or partially separated or are threatened with such separation.

Criterion II has been met because there has been an acquisition from a foreign country by the workers' firm of production of articles that are like or directly competitive with those produced by the subject firm.

Criterion III has been met because the acquisition of cotton yarn contributed importantly to the workers' separation or threat of separation at the subject firm.

Conclusion

After careful review of the additional facts obtained on reconsideration, I determine that workers and former workers of the subject firm, who are engaged in employment related to the production of cotton yarn, meet the worker group certification criteria under Section 222(a) of the Act, 19 U.S.C. 2272(a). In accordance with Section 223 of the Act, 19 U.S.C. 2273, I make the following certification:

''All workers of Pisgah Yarn & Dyeing Company, including on-site leased workers from Manpower, Inc., Old Fort, North Carolina, who became totally or partially separated from employment on or after January 28, 2010, through two years from the date of this revised certification, 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 28th day of June, 2011.

Del Min Amy Chen,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2011–17092 Filed 7–7–11; 8:45 am]

BILLING CODE 4510–FN–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–244; Docket No. 72–67]

R.E. Ginna Nuclear Power Plant, LLC, R.E. Ginna Nuclear Power Plant, R.E. Ginna Independent Spent Fuel Storage Installation; Notice of Consideration of Approval of Application Regarding Proposed Corporate Merger, and Opportunity for a Hearing

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of request for license transfer, opportunity to comment, opportunity to request a hearing.

DATES: Comments must be filed by August 8, 2011. A request for a hearing must be filed by July 28, 2011.

ADDRESSES: Please include Docket ID NRC–2009–0192 in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site *http://www.regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in

their comments that they do not want publicly disclosed.

You may submit comments by any one of the following methods.

• *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2009–0192. Address questions about NRC dockets to Carol Gallagher 301–492–3668; e-mail *Carol.Gallagher@nrc.gov.*

• *Mail comments to:* Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, *Mail Stop:* TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

• *Fax comments to:* RADB at 301–492–3446.

You can access publicly available documents related to this notice using the following methods:

• *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr.resource@nrc.gov.* The application dated May 12, 2011, contains proprietary information and, accordingly, those portions are being withheld from public disclosure. A redacted version of the application is available electronically under ADAMS Accession No. ML11138A159.

FOR FURTHER INFORMATION CONTACT: Douglas Pickett, Senior Project Manager, Plant Licensing Branch I–1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555. *Telephone:* 301–415–1364; *e-mail: Douglas.Pickett@nrc.gov.*

The U.S. Nuclear Regulatory Commission (NRC, the Commission) is considering the issuance of an Order under Title 10 of the *Code of Federal Regulations* (10 CFR) 50.80 approving the indirect transfer of Renewed Facility Operating License No. DPR–18, for the R.E. Ginna Nuclear Power Plant (Ginna), currently held by R.E. Ginna Nuclear Power Plant, LLC as owner and licensed operator. R.E. Ginna Nuclear Power Plant, LLC is owned by Constellation Energy Nuclear Group, LLC (CENG). The indirect transfer of control would result from the proposed merger between Exelon Corporation (Exelon) and one of CENG's parent companies, Constellation Energy Group, Inc (CEG).

According to the application dated May 12, 2011, filed by Exelon Generation Company, LLC (Exelon Generation) acting on behalf of itself, Exelon, and Exelon Ventures Company, LLC (Exelon Ventures) and CENG acting on behalf of its subsidiary licensee, R.E. Ginna Nuclear Power Plant, LLC, the applicants seek approval pursuant to 10 CFR 50.80 of the indirect transfer of control of the Ginna Renewed Facility Operating License No. DPR–18 and the Ginna Independent Spent Fuel Storage Installation Facility (ISFSI).

CEG is one of two parent companies of CENG. CEG, through its subsidiaries, has a 50.01 percent ownership interest in CENG. EDF Inc. has the remaining 49.99 percent ownership interest in CENG.

According to the application:

• EDF Inc.'s 49.99 percent ownership interest in CENG is not affected by the corporate merger of Exelon and CEG. EDF Inc. is a U.S. corporation organized under the laws of the State of Delaware and a wholly-owned subsidiary of E.D.F. International SAS, a limited company organized under the laws of France, which is, in turn, a wholly-owned subsidiary of Electricité de France SA, a French limited company;

• The existing chain of ownership for Exelon Generation's current licensed facilities is unaffected by the proposed transaction and associated license transfer for Ginna and the ISFSI;

• The proposed transaction does not result in any transfer of control with respect to the licenses for the current Exelon Generation plants;

• Upon completion of the transaction, CEG will become a direct, wholly-owned subsidiary of Exelon Generation; and

• Throughout the transaction, the direct ownership by CEG of 100 percent of Constellation Nuclear, LLC and, indirectly, the ownership by CEG of 50.01 percent in CENG and CENG's ownership of Constellation Nuclear Power Plants, LLC, Ginna, and the ISFSI, will remain unchanged.

No physical changes to the Ginna facility or the ISFSI, or operational changes are being proposed in the application.

Pursuant to 10 CFR 50.80, no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission shall give its consent in writing. The Commission will approve an application for the indirect transfer of a license, if the Commission determines that the proposed corporate merger will not affect the qualifications of the licensee to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

The filing of requests for hearing and petitions for leave to intervene, and written comments with regard to the license transfer application, are discussed below.

Within 20 days from the date of publication of this notice, any person(s) whose interest may be affected by the Commission's action on the application may request a hearing and intervention via electronic submission through the NRC E-filing system. Requests for a hearing and petitions for leave to intervene should be filed in accordance with the Commission's rules of practice set forth in Subpart C ''Rules of General Applicability: Hearing Requests, Petitions to Intervene, Availability of Documents, Selection of Specific Hearing Procedures, Presiding Officer Powers, and General Hearing Management for NRC Adjudicatory Hearings,'' of 10 CFR Part 2. In particular, such requests and petitions must comply with the requirements set forth in 10 CFR 2.309. Untimely requests and petitions may be denied, as provided in 10 CFR 2.309(c)(1), unless good cause for failure to file on time is established. In addition, an untimely request or petition should address the factors that the Commission will also consider, in reviewing untimely requests or petitions, set forth in 10 CFR 2.309(c)(1)(i)–(viii). NRC regulations are accessible electronically from the NRC Library on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.*

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139, August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic

storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) A digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html.* System requirements for accessing the E-Submittal server are detailed in NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through EIE, users will be required to install a Web browser plug-in from the NRC Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The E-Filing system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by e-mail at *MSHD.Resource@nrc.gov,* or by a toll-free call at 866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, *Attention:* Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at: *http://ehd1.nrc.gov/EHD/,* unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 20 days from the date of publication of this notice. Non-timely filings will not be entertained absent a determination by the presiding officer that the petition or request should be granted or the contentions should be admitted, based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)–(viii).

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

Within 30 days from the date of publication of this notice, persons may submit written comments regarding the license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and should cite the publication date and page number of this **Federal Register** notice.

For further details with respect to this license transfer application, see the application dated May 12, 2011, available for public inspection at the

Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available documents created or received at the NRC are accessible electronically through ADAMS in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, or 301–415–4737 or by e-mail to *pdr.resource@nrc.gov.*

Dated at Rockville, Maryland this 28th day of June 2011.

For the Nuclear Regulatory Commission.

Douglas V. Pickett,

Senior Project Manager, Plant Licensing Branch I–1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2011–17164 Filed 7–7–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Meeting of the ACRS Subcommittee on Plant Operations and Fire Protection; Revision to an ACRS Subcommittee Meeting Federal Register Notice

The **Federal Register** Notice for the ACRS Subcommittee Meeting on Plant Operations and Fire Protection scheduled to be held on July 28, 2011, is being revised to notify the following:

The Subcommittee will meet with Region II to discuss the construction inspection program, the reactor oversight program, and other items of mutual interest.

If attending this meeting, please contact Ms. Denise Edwards (Telephone 404–997–4432) to be escorted to the meeting room.

The notice of this meeting was previously published in the **Federal Register** on Wednesday, June 29, 2011 [75 FR 38212]. All other items remain the same as previously published.

Further information regarding this meeting can be obtained by contacting Mrs. Ilka Berrios, Designated Federal Official (*Telephone:* 301–415–3179 or E-mail: *Ilka.Berrios@nrc.gov*) between 7:30 a.m. and 5:15 p.m. (ET).

Dated: July 1, 2011.

Yoira Diaz-Sanabria,

Senior Staff Engineer, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2011–17154 Filed 7–7–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2011–0147]

Receipt of Request for Action

Notice is hereby given that by petition dated March 12, 2011, Thomas Saporito (petitioner) has requested that the Nuclear Regulatory Commission (NRC) take action to order shutdown of all ''nuclear power reactors in the USA [United States of America] which are known to be located on or near an earthquake fault-line.''

As the basis for this request, the petitioner states that following an 8.9 magnitude earthquake on March 11, 2011, in Fukushima, Japan, one or more nuclear power reactors there sustained significant damage which resulted in the release of radioactive particles into the environment, and that the Japanese authorities ordered a ''General Emergency Evacuation,'' but many Japanese citizens were not able to timely leave the affected area and were subject to radioactive contamination at this time. The petitioner further stated that many of NRC's licensees operate nuclear power reactors on or near earthquake fault lines and could, therefore, be subject to significant earthquake damage and loss-of-coolant accidents similar to that experienced by those in Japan for which an on-going state of emergency continued to unfold.

The request is being treated pursuant to Title 10 of the *Code of Federal Regulations* Section 2.206 of the Commission's regulations. The request has been referred to the Director of the Office of Nuclear Reactor Regulation (NRR). As provided by Section 2.206, appropriate action will be taken on this petition within a reasonable time. The NRR Petition Review Board (PRB) held two recorded teleconferences on April 14 and May 25, 2011, with the petitioner, during which the petitioner supplemented and clarified the petition. The results of those discussions were considered in the PRB's determination regarding the petitioner's request for immediate action and in establishing the schedule for the review of the petition. As a result, the PRB acknowledged the petitioner's concern about the impact of a Fukushima-type earthquake and tsunami on U.S. nuclear plants, noting that this concern is consistent with the NRC's mission of protecting public health and safety. Currently, the NRC's monitoring of the events that unfolded at Fukushima has resulted in the Commission establishing a senior-level task force to conduct a methodical and systematic review to evaluate currently available technical and operational information from the Fukushima events. This will allow the NRC to determine whether it should take certain near-term operational or regulatory actions potentially affecting all 104 operating reactors in the United States. In as much as this task force charge encompasses the petitioner's request, which has been interpreted by the PRB to be a determination if additional regulatory action is needed to protect public health and safety in the event of earthquake damage and loss-of-coolant accidents similar to those experienced by the nuclear power reactors in Japan resulting in dire consequences, the NRC is accepting the petition in part, and as described in this paragraph.

A copy of the petition, and the transcripts of the April 14 and May 25, 2011, teleconferences are available for inspection at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available documents created or received at the NRC are accessible electronically through the Agencywide Documents Access and Management System (ADAMS) in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209 or 301–415–4737, or by e-mail to *PDR.Resource@nrc.gov.*

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 28th day of June, 2011.

Eric J. Leeds,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 2011–17163 Filed 7–7–11; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 29713; 812–13834]

Sterling Capital Funds and Sterling Capital Management LLC; Notice of Application

July 1, 2011.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from section 15(a) of the Act and rule 18f–2 under the Act, as well as from certain disclosure requirements.

SUMMARY OF APPLICATION: Applicants request an order that would permit them to enter into and materially amend subadvisory agreements without shareholder approval and would grant relief from certain disclosure requirements.

APPLICANTS: Sterling Capital Funds (the ''Trust'') and Sterling Capital Management LLC (''Sterling'' and collectively, ''Applicants'').

DATES: *Filing Dates:* The application was filed on October 15, 2010, and amended on February 18, 2011. Applicants have agreed to file an amendment during the notice period, the substance of which is reflected in this notice.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on July 25, 2011, and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090. Applicants: The Trust, 434 Fayetteville Street Mall, Fifth Floor, Raleigh, NC 27601; Sterling, Two Morrocroft Centre, 4064 Colony Road, Suite 300, Charlotte, NC 28211.

FOR FURTHER INFORMATION CONTACT: Lewis B. Reich, Senior Counsel, at (202) 551–6919, or Jennifer L. Sawin, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Trust, a Massachusetts business trust, is registered under the Act as an open-end management investment company and currently offers 23 series (each a ''Series''), each of which has its own distinct investment objectives, policies and restrictions.[1] Sterling is, and each other Adviser will be, registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). Sterling or another Adviser serves or will serve as the investment adviser to each Subadvised Series pursuant to an investment advisory agreement (each an ''Advisory Agreement''). The Advisory Agreement for each existing Series was approved by the Trust's board of trustees (the ''Board''),[2] including a majority of the trustees who are not ''interested persons,'' as defined in section 2(a)(19) of the Act, of the Trust or the Adviser (''Independent Trustees'') and by the shareholders of that Series in the manner required by sections 15(a) and 15(c) of the Act and rule 18f–2 under the Act.

2. Under the terms of the Advisory Agreement, the Adviser, subject to the oversight of the Board, provides continuous investment management of the assets of each Subadvised Series. The Adviser periodically reviews investment policies and strategies of each Subadvised Series and based on the need of a particular Subadvised Series may recommend changes to the investment policies and strategies of the Subadvised Series for consideration by its Board. For its services to each Subadvised Series, the Adviser receives an investment advisory fee from that Subadvised Series based on the average daily net assets of that Subadvised Series. The terms of the Advisory Agreement also permit the Adviser, subject to the approval of the Board, including a majority of the Independent Trustees, and the shareholders of the applicable Subadvised Series (if required by applicable law), to delegate portfolio management responsibilities of all or a portion of the Subadvised Series to one or more subadvisers (''Sub-Advisers''). Sterling has entered into subadvisory agreements (''Sub-Advisory Agreements'') with various Sub-Advisers to provide investment advisory services to various Subadvised Series.[3] Each Sub-Adviser is, and each future Sub-Adviser will be, an investment adviser as defined in section 2(a)(20) of the Act as well as registered with the Commission as an ''investment adviser'' under the Advisers Act. The Adviser evaluates, allocates assets to and oversees the Sub-Advisers, and makes recommendations about their hiring, termination and replacement to the Board, at all times subject to the authority of the Board. The Adviser will compensate each Sub-Adviser out of the fee paid to the Adviser under the Advisory Agreement.

3. Applicants request an order to permit the Adviser, subject to Board approval, to select certain Sub-Advisers to manage all or a portion of the assets of a Series pursuant to a Sub-Advisory Agreement and materially amend Sub-Advisory Agreements without obtaining shareholder approval. The requested relief will not extend to any Sub-Adviser that is an affiliated person, as

[1] Applicants also request relief with respect to future Series and any other existing or future registered open-end management investment company or series thereof that: (a) Is advised by Sterling or any entity controlling, controlled by, or under common control with Sterling or its successors (any such entity, along with Sterling, an ''Adviser''); (b) uses the multi-manager structure described in the application; and (c) complies with the terms and conditions set forth in the application (together with any Series that currently uses a multi-manager structure, each a ''Subadvised Series'' and collectively the ''Subadvised Series''). For purposes of the requested order, ''successor'' is limited to an entity or entities that result from a reorganization into another jurisdiction or a change in the type of business organization. All entities that currently intend to rely on the requested order are named as applicants. All Series that are or currently intend to be Subadvised Series are identified in the application. If the name of any Subadvised Series contains the name of a Sub-Adviser (as defined below), the name of the Adviser, or a trademark or trade name that is owned by the Adviser, will precede the name of the Sub-Adviser.

[2] The term ''Board'' also includes the board of trustees of any future Subadvised Series.

[3] Sterling has entered into Sub-Advisory Agreements with the following Sub-Advisers on behalf of the named Subadvised Series. Artio Global Management LLC serves as a Sub-Adviser of Sterling Capital International Fund; and Federated Investment Management Company serves as a Sub-Adviser of Sterling Capital National Tax-Free Money Market Fund and Sterling Capital Prime Money Market Fund. Sterling has also entered into a Sub-Advisory Agreement with Scott & Stringfellow LLC, which is under common control with Sterling, to serve as Sub-Adviser of Sterling Capital Equity Income Fund and Sterling Capital Special Opportunities Fund. The requested relief will not extend to Scott & Stringfellow LLC or any other Affiliated Sub-Adviser, as defined below.

defined in section 2(a)(3) of the Act, of a Subadvised Series or the Adviser, other than by reason of serving as a Sub-Adviser to a Subadvised Series (''Affiliated Sub-Adviser'').

4. Applicants also request an order exempting the Subadvised Series from certain disclosure provisions described below that may require the Subadvised Series to disclose fees paid to each Sub-Adviser. Applicants seek an order to permit each Subadvised Series to disclose (as a dollar amount and a percentage of each Subadvised Series' net assets) only: (a) The aggregate fees paid to the Adviser and any Affiliated Sub-Advisers; and (b) the aggregate fees paid to Sub-Advisers other than Affiliated Sub-Advisers (collectively, the ''Aggregate Fee Disclosure''). A Subadvised Series that employs an Affiliated Sub-Adviser will provide separate disclosure of any fees paid to the Affiliated Sub-Adviser.

Applicants' Legal Analysis

1. Section 15(a) of the Act provides, in relevant part, that it is unlawful for any person to act as an investment adviser to a registered investment company except pursuant to a written contract that has been approved by the vote of a majority of the company's outstanding voting securities. Rule 18f–2 under the Act provides that each series or class of stock in a series investment company affected by a matter must approve that matter if the Act requires shareholder approval.

2. Form N–1A is the registration statement used by open-end investment companies. Item 19(a)(3) of Form N–1A requires disclosure of the method and amount of the investment adviser's compensation.

3. Rule 20a–1 under the Act requires proxies solicited with respect to an investment company to comply with Schedule 14A under the Securities Exchange Act of 1934 (''1934 Act''). Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A, taken together, require a proxy statement for a shareholder meeting at which the advisory contract will be voted upon to include the ''rate of compensation of the investment adviser,'' the ''aggregate amount of the investment adviser's fees,'' a description of the ''terms of the contract to be acted upon,'' and, if a change in the advisory fee is proposed, the existing and proposed fees and the difference between the two fees.

4. Regulation S–X sets forth the requirements for financial statements required to be included as part of a registered investment company's registration statement and shareholder reports filed with the Commission. Sections 6–07(2)(a), (b) and (c) of Regulation S–X require a registered investment company to include in its financial statement information about the investment advisory fees.

5. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or from any rule thereunder, if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants state that the requested relief meets this standard for the reasons discussed below.

6. Applicants assert that the shareholders expect the Adviser, subject to the review and approval of the Board, to select the Sub-Advisers who are best suited to achieve the Subadvised Series' investment objective. Applicants assert that, from the perspective of the shareholder, the role of the Sub-Adviser is substantially equivalent to the role of the individual portfolio managers employed by an investment adviser to a traditional investment company. Applicants state that requiring shareholder approval of each Sub-Advisory Agreement would impose unnecessary delays and expenses on the Subadvised Series, and enable the Subadvised Series to act more quickly when the Board and the Adviser believe that a change would benefit a Subadvised Series and its shareholders. Applicants note that the Advisory Agreement and any Sub-Advisory Agreement with an Affiliated Sub-Adviser will continue to be subject to the shareholder approval requirements of section 15(a) of the Act and rule 18f–2 under the Act.

7. Applicants assert that the requested disclosure relief would benefit shareholders of the Subadvised Series because it would improve the Adviser's ability to negotiate the fees paid to Sub-Advisers. Applicants state that the Adviser may be able to negotiate rates that are below a Sub-Adviser's ''posted'' amounts, if the Adviser is not required to disclose the Sub-Advisers' fees to the public. Applicants submit that the requested relief will also encourage Sub-Advisers to negotiate lower subadvisory fees with the Adviser if the lower fees are not required to be made public.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Before a Subadvised Series may rely on the order requested herein, the operation of the Subadvised Series in the manner described in this application will be approved by a majority of the Subadvised Series' outstanding voting securities as defined in the Act, or, in the case of a Subadvised Series whose public shareholders purchase shares on the basis of a prospectus containing the disclosure contemplated by condition 2 below, by the initial shareholder before such Subadvised Series' shares are offered to the public.

2. The prospectus for each Subadvised Series will disclose the existence, substance, and effect of any order granted pursuant to the application. In addition, each Subadvised Series will hold itself out to the public as employing a multi-manager structure as described in the application. The prospectus will prominently disclose that the Adviser has the ultimate responsibility, subject to oversight by the Board, to oversee the Sub-Advisers and recommend their hiring, termination, and replacement.

3. Within ninety (90) days of the hiring of a new Sub-Adviser, shareholders of the relevant Subadvised Series will be furnished all information about the new Sub-Adviser that would be included in a proxy statement, except as modified to permit Aggregate Fee Disclosure. This information will include Aggregate Fee Disclosure and any change in disclosure caused by the addition of the new Sub-Adviser. To meet this obligation, each Subadvised Series will provide its shareholders, within ninety (90) days of the hiring of a new Sub-Adviser, an information statement meeting the requirements of Regulation 14C, Schedule 14C and Item 22 of Schedule 14A under the 1934 Act, except as modified by the order to permit Aggregate Fee Disclosure.

4. The Adviser will not enter into a Sub-Advisory Agreement with any Affiliated Sub-Adviser without that agreement, including the compensation to be paid thereunder, being approved by the shareholders of the applicable Subadvised Series.

5. At all times, at least a majority of the Board will be Independent Trustees, and the nomination of new or additional Independent Trustees will be placed within the discretion of the then-existing Independent Trustees.

6. Independent legal counsel, as defined in rule 0–1(a)(6) under the Act, will be engaged to represent the Independent Trustees. The selection of such counsel will be within the discretion of the then-existing Independent Trustees.

7. Whenever a Sub-Adviser change is proposed for a Subadvised Series with an Affiliated Sub-Adviser, the Board,

including a majority of the Independent Trustees, will make a separate finding, reflected in the Board minutes, that the change is in the best interests of the Subadvised Series and its shareholders, and does not involve a conflict of interest from which the Adviser or the Affiliated Sub-Adviser derives an inappropriate advantage.

8. Whenever a Sub-Adviser is hired or terminated, the Adviser will provide the Board with information showing the expected impact on the profitability of the Adviser.

9. The Adviser will provide the Board, no less frequently than quarterly, with information about the profitability of the Adviser on a per Subadvised Series basis. The information will reflect the impact on profitability of the hiring or termination of any Sub-Adviser during the applicable quarter.

10. The Adviser will provide general management services to each Subadvised Series, including overall supervisory responsibility for the general management and investment of the Subadvised Series' assets and, subject to review and approval of the Board, will: (a) Set the Subadvised Series' overall investment strategies; (b) evaluate, select and recommend Sub-Advisers to manage all or a portion of the Subadvised Series' assets; (c) allocate and, when appropriate, reallocate the Subadvised Series' assets among Sub-Advisers; (d) monitor and evaluate the Sub-Advisers' performance; and (e) implement procedures reasonably designed to ensure that Sub-Advisers comply with the Subadvised Series' investment objective, policies and restrictions.

11. No trustee or officer of the Trust or a Subadvised Series or director or officer of the Adviser, will own directly or indirectly (other than through a pooled investment vehicle that is not controlled by such person), any interest in a Sub-Adviser except for (a) Ownership of interests in the Adviser or any entity that controls, is controlled by or is under common control with the Adviser; or (b) ownership of less than 1% of the outstanding securities of any class of equity or debt of any publicly traded company that is either a Sub-Adviser or an entity that controls, is controlled by or is under common control with a Sub-Adviser.

12. Each Subadvised Series will disclose in its registration statement the Aggregate Fee Disclosure.

13. In the event the Commission adopts a rule under the Act providing substantially similar relief to that in the order requested in the application, the requested order will expire on the effective date of that rule.

For the Commission, by the Division of Investment Management, under delegated authority.

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–17188 Filed 7–7–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64798; File No. SR–NSCC–2011–05]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Fees Associated With the Obligation Warehouse Service

July 1, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] notice is hereby given that on June 20, 2011, 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 proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act[2] and Rule 19b–4(f)(2) thereunder[3] 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 Terms of Substance of the Proposed Rule Change

The proposed rule change will revise NSCC's trade recording and recording service fees related to the new Obligation Warehouse service.

II. Self-Regulatory Organization's Statement of 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 such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78s(b)(3)(A)(ii).

[3] 17 CFR 240.19b–4(f)(2).

A. Self-Regulatory Organization's Statement of Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to revise NSCC's fee schedule (as set forth in Addendum A of NSCC's Rules and Procedures) to add fees for NSCC's Obligation Warehouse service, a new functionality that was designed to enhance and replace NSCC's legacy Reconfirmation and Pricing Service (RECAPS).[4] The Obligation Warehouse launched on March 4, 2011, and the fees included in this proposed rule change will be effective on July 1, 2011.

The proposal includes fees for: (1) Warehousing of each compared item; (2) matching of each submission; (3) each pending comparison advisory (aged days two through four); (4) each pending comparison advisory (aged five days are more); (5) closure and delivery of an item to CNS; (6) withholding of closure and delivery of an item to CNS; (7) applying mandatory corporate action events to compared obligations; (8) delivery notification request advisories informing a party to an Obligation Warehouse obligation that the submitting party has acknowledged that obligation has settled (aged two days or older); (9) pending cancel request advisories requesting that a previously compared Obligation Warehouse obligation be cancelled (aged two days or older); and (10) each obligation closed per RECAPS cycle. The fee for each pending comparison advisory (aged five days or more) will be implemented in a tiered, phased-in manner over the course of six months as Members become familiar with the functionality of the Obligation Warehouse. Details regarding all fee changes mentioned above are available in the revised Addendum A set forth in Exhibit 5 to NSCC's rule filing, which can be found on NSCC's Web site (*http://www.dtcc.com/legal/rule_filings/nscc/2011.php*).

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

NSCC has not solicited or received written comments relating to the proposed rule change. NSCC will notify

[4] Securities Exchange Act Release No. 63588 (Dec. 21, 2010), 75 FR 82112 (Dec. 29, 2010).

the Commission of any written comments it receives.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act [5] and Rule 19b–4(f)(2) [6] because the proposed rule change establishes or changes a due, fee, or other charge applicable only to a member. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an e-mail to *rule-comments@sec.gov.* Please include File No. SR–NSCC–2011–05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NSCC–2011–05. This file number should be included on the subject line if e-mail 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 a.m. and 3 p.m. Copies of such filings also will be available for inspection and copying at NSCC's principal office and NSCC's Web site (*http://www.dtcc.com/legal/rule_filings/nscc/2011.php*). All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NSCC–2011–05 and should be submitted on or before July 29, 2011.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[7]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–17187 Filed 7–7–11; 8:45 am]

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[5] *Supra* note 2.

[6] *Supra* note 3.

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64797; File No. SR–NYSEAmex–2011–46]

Self-Regulatory Organizations; NYSE Amex LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Exchange Rule 1000(a)(iv) To Provide for a Different Liquidity Replenishment Point Value Range During the First Day of Trading of an Initial Public Offering on the Exchange

July 1, 2011.

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 June 28, 2011, NYSE Amex LLC (''NYSEAmex'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Amex Equities Rule 1000(a)(iv) to provide for a different liquidity replenishment point (''LRP'') value range during the first day of trading of an initial public offering (''IPO'') on the Exchange. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.com.*

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 NYSE Amex Equities Rule 1000(a)(iv) to provide for a different LRP value range during the first day of trading of an IPO on the Exchange. Specifically, the Exchange proposes to add proposed Rule 1000(a)(iv)(E) to provide that on the first day of trading of an IPO, the LRP value shall be the greater of $2.00 or the LRP value range that would be applicable based on the offering price of the IPO.

I. Background

Pursuant to NYSE Amex Equities Rule 1000(a)(iv), LRPs are pre-determined price points that function to moderate volatility in a particular security, improve price continuity, and foster market quality by temporarily converting the electronic market to an auction market and permitting new trading interest to add liquidity.[3]

Pursuant to NYSE Amex Equities Rule 60, Autoquote is suspended when an LRP is reached, i.e., when the unfilled balance of an incoming automatically executing order is able to trade at a price above (below) the LRP, or if the incoming interest would create a locked or crossed market. Autoquote resumes after a manual trade or when the lock or cross is cleared.[4]

LRPs are calculated by adding and subtracting a value to the security's last

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See also* NYSE Amex Equities Rules 60(e)(i).

[4] *See* NYSE Amex Equities Rule 60(d)(i)(C).

sale price. The LRP values are based on an examination of trading data and vary based on the security's Exchange average daily volume (''ADV''), price, and volatility. The values used to calculate the LRPs' range do not change intraday and are disseminated daily by the Exchange on its Web site.

II. Modification to LRP Value Ranges

The Exchange proposes to amend NYSE Amex Equities Rule 1000(a)(iv) to provide for a different LRP value range during the first day of trading of an IPO on the Exchange. Specifically, the Exchange proposes to provide that for the first day of trading of an IPO on the Exchange, the LRP value will be the greater of $2.00 or the LRP value that would be applicable based on the offering price.

The Exchange currently uses the offering price of an IPO, as set by the investment bank syndicate the night before the first day of trading, to determine the LRP value range in that security. However, trading prices on the first day of an IPO can often be volatile, both compared to the offering price as well as intra-day. As a result, using the offering price to determine the LRP value range may be inconsistent with the actual trading prices, resulting in more frequent triggering of LRPs than is typical on the Exchange, thus unnecessarily limiting automatic execution of orders on the first day of trading.

A recent example of how an IPO can trade at prices beyond the original offering prices recently occurred on the New York Stock Exchange LLC (''NYSE''), which has the same rules as the Exchange governing LRPs.[5] For the May 19, 2011, IPO of LinkedIn Corp. (LNKD) on the NYSE, the offering price was set the night before at $45 per share and based on that price and pursuant to Rule 1000(a)(iv)(C), the NYSE set the LRP value for the security at $0.70 for the first day of trading. Notwithstanding the offering price, the opening price for LNKD at the NYSE was $83.00 and the stock reached a trading high of $122.70 during the first day of trading, closing at $94.25. LNKD therefore traded at prices throughout the day that would have otherwise warranted a higher LRP value and as a result, there was a greater occurrence of LRPs being reached than would have otherwise occurred on a regular trading day. The first day of trading in LNKD is illustrative of the type of volatility and price fluctuations that can occur on the first day of trading of an IPO.

The Exchange proposes to widen the LRP values for the first day of trading of an IPO in order to reflect that the first day of trading of an IPO generally differs from regular trading days in that there is often greater volume and volatility, with wider price fluctuations. The NYSE is similarly filing to amend NYSE Rule 1000.[6] While the Exchange does not have the same volume of IPOs as occur on the NYSE, the Exchange believes that the changes to LRP values that are being proposed for NYSE should also be adopted at the Exchange. As proposed, the LRP value range would be the greater of $2.00 or the LRP value range that would be applicable based on the IPO's offering price. For example, if the IPO's offering price were priced above $150, the LRP value range could be $4.00 rather than $2.00.

The Exchange believes that widening the LRP value ranges for the first day of trading of an IPO would allow for more continuous automatic executions of securities before hitting an LRP. While the purpose of the LRP is to dampen volatility and to provide market participants with time to react, the Exchange believes that the proposed amendment is necessary to lessen artificial limitations on trading. If an LRP is triggered too frequently, such as when the price of a security increases during the trading day well beyond the LRP value that has been assigned to that security for the day, trading in the security may be overly restrained. As such, the Exchange believes that allowing for an expanded value range on the first day of trading of an IPO will better facilitate the natural trading of a particular security.

2. Statutory Basis

The basis under the Act for these proposed rule changes are the requirement under Section 6(b)(5)[7] that an Exchange have rules that are designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[8] in that it seeks to assure economically efficient execution of securities transactions, make it practicable for brokers to execute investors' orders in the best market and provide an opportunity for investors' orders to be executed without the participation of a dealer. The Exchange's proposal to provide flexibility in setting the LRP range on the first day of trading for an IPO is intended to provide for faster executions of securities by limiting the amount of time automatic executions are suspended when an LRP is triggered.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6)[12] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[13] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become

[5] *See* NYSE Rule 1000(a)(iv).

[6] *See* SR–NYSE–2011–31.

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78k–1(a)(1).

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to provide the Commission with 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. The Exchange has fulfilled this requirement.

[12] 17 CFR 240.19b–4(f)(6).

[13] 17 CFR 240.19b–4(f)(6)(iii).

operative upon filing. The Commission hereby grants that request. The New York Stock Exchange LLC has proposed a similar change to its Rule 1000, and the Commission is waiving the 30-day operative delay for that proposal.[14] Waiving the operative delay for this proposal will thus keep Exchange Rule 1000 consistent with NYSE Rule 1000 in this respect. In addition, waiving the 30-day operative delay will enable this change to be implemented immediately so that the wider LRP values will be available for the next IPO that takes place on the Exchange. Therefore, the Commission believes it is consistent with the protection of investors and the public interest to waive the 30-day operative delay and designates the proposal as operative upon filing.[15]

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 e-mail to *rule-comments@sec.gov*. Please include File Number SR–NYSEAmex–2011–46 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–NYSEAmex–2011–46. This file number should be included on the subject line if e-mail 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 a.m. and 3 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–NYSEAmex–2011–46, and should be submitted on or before July 29, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–17123 Filed 7–7–11; 8:45 am]

BILLING CODE 8011–01–P

[14] *See* SR–NYSE–2011–31.

[15] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64777; File No. SR–FINRA–2011–030]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Update Certain Cross-References and Make Non-Substantive Technical Changes to Certain FINRA Rules

June 30, 2011.

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 June 27, 2011, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to update cross-references within certain FINRA rules to reflect changes adopted in the consolidated FINRA rulebook.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org*, at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA is in the process of developing a new consolidated rulebook (''Consolidated FINRA Rulebook'').[4] That process involves FINRA submitting to the Commission for approval a series of proposed rule changes over time to adopt rules in the Consolidated FINRA Rulebook. The phased adoption and implementation of those rules necessitates periodic amendments to update rule cross-references and other

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] The current FINRA rulebook consists of (1) FINRA Rules; (2) NASD Rules; and (3) rules incorporated from NYSE (''Incorporated NYSE Rules'') (together, the NASD Rules and Incorporated NYSE Rules are referred to as the ''Transitional Rulebook''). While the NASD Rules generally apply to all FINRA members, the Incorporated NYSE Rules apply only to those members of FINRA that are also members of the NYSE (''Dual Members''). The FINRA Rules apply to all FINRA members, unless such rules have a more limited application by their terms. For more information about the rulebook consolidation process, *see Information Notice*, March 12, 2008 (Rulebook Consolidation Process).

non-substantive technical changes in the Consolidated FINRA Rulebook.

The proposed rule change would update rule cross-references to reflect rule changes adopted in the Consolidated FINRA Rulebook. In this regard, the proposed rule change would update references in FINRA Rules 0150 (Application of Rules to Exempted Securities Except Municipal Securities), 9217 (Violations Appropriate for Disposition Under Plan Pursuant to SEA Rule 19d–1(c)(2)) and 9610 (Application) that are needed as the result of Commission approval of two FINRA proposed rule changes.[5]

FINRA has filed the proposed rule change for immediate effectiveness. The implementation date for the proposed rule changes to FINRA Rules 0150, 9217 and 9610 will be August 1, 2011.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[6] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes the proposed rule change will provide greater clarity to members and the public regarding FINRA's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[7] and Rule 19b–4(f)(6) thereunder.[8]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2011–030 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–FINRA–2011–030. This file number should be included on the subject line if e-mail 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 website 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 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2011–030 and should be submitted on or before July 29, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–17127 Filed 7–7–11; 8:45 am]

BILLING CODE 8011–01–P

[5] *See* Securities Exchange Act Release No. 58643 (September 25, 2008), 73 FR 57174 (October 1, 2008) (Order Approving File No. SR–FINRA–2008–029); and Securities Exchange Act Release No. 63999 (March 1, 2011), 76 FR 12380 (March 7, 2011) (Order Approving File No. SR–FINRA–2010–061).

[6] 15 U.S.C. 78*o*–3(b)(6).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64793; File No. SR–NYSE–2011–31]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Exchange Rule 1000(a)(iv) To Provide for a Different Liquidity Replenishment Point Value Range During the First Day of Trading of an Initial Public Offering on the Exchange

July 1, 2011.

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 June 28, 2011, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 1000(a)(iv) to provide for a different liquidity replenishment point (''LRP'') value range during the first day of trading of an initial public offering (''IPO'') on the Exchange. The text of the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.com.*

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 Exchange Rule 1000(a)(iv) to provide for a different LRP value range during the first day of trading of an IPO on the Exchange. Specifically, the Exchange proposes to add proposed Rule 1000(a)(iv)(E) to provide that on the first day of trading of an IPO, the LRP value shall be the greater of $2.00 or the LRP value range that would be applicable based on the offering price of the IPO.

I. Background

Pursuant to NYSE Rule 1000(a)(iv), LRPs are pre-determined price points that function to moderate volatility in a particular security, improve price continuity, and foster market quality by temporarily converting the electronic market to an auction market and permitting new trading interest to add liquidity.[3]

Pursuant to Exchange Rule 60, Autoquote is suspended when an LRP is reached, i.e., when the unfilled balance of an incoming automatically executing order is able to trade at a price above (below) the LRP, or if the incoming interest would create a locked or crossed market. Autoquote resumes after a manual trade or when the lock or cross is cleared.[4]

LRPs are calculated by adding and subtracting a value to the security's last sale price. The LRP values are based on an examination of trading data and vary based on the security's NYSE average daily volume (''ADV''), price, and volatility. The values used to calculate the LRPs' range do not change intraday and are disseminated daily by the Exchange on its Web site.

II. Modification to LRP Value Ranges

The Exchange proposes to amend NYSE Rule 1000(a)(iv) to provide for a different LRP value range during the first day of trading of an IPO on the Exchange. Specifically, the Exchange proposes to provide that for the first day of trading of an IPO on the Exchange, the LRP value will be the greater of $2.00 or the LRP value that would be applicable based on the offering price.

The Exchange currently uses the offering price of an IPO, as set by the investment bank syndicate the night before the first day of trading, to determine the LRP value range in that security. However, trading prices on the first day of an IPO can often be volatile, both compared to the offering price as well as intra-day. As a result, using the offering price to determine the LRP value range may be inconsistent with the actual trading prices, resulting in more frequent triggering of LRPs than is typical on the Exchange, thus unnecessarily limiting automatic execution of orders on the first day of trading.

For example, for the May 19, 2011, IPO of LinkedIn Corp. (LNKD), the offering price was set the night before at $45 per share and based on that price and pursuant to Rule 1000(a)(iv)(C), the Exchange set the LRP value for the security at $0.70 for the first day of trading. Notwithstanding the offering price, the opening price for LNKD at the Exchange was $83.00 and the stock reached a trading high of $122.70 during the first day of trading, closing at $94.25. LNKD therefore traded at prices throughout the day that would have otherwise warranted a higher LRP value and as a result, there was a greater occurrence of LRPs being reached than would have otherwise occurred on a regular trading day. The first day of trading in LNKD is illustrative of the type of volatility and price fluctuations that can occur on the first day of trading of an IPO.

The Exchange proposes to widen the LRP values for the first day of trading of an IPO in order to reflect that the first day of trading of an IPO generally differs from regular trading days in that there is often greater volume and volatility, with wider price fluctuations. As proposed, the LRP value range would be the greater of $2.00 or the LRP value range that would be applicable based on the IPO's offering price. For example, if the IPO's offering price were priced above $150, the LRP value range could be $4.00 rather than $2.00.

The Exchange believes that widening the LRP value ranges for the first day of trading of an IPO would allow for more continuous automatic executions of securities before hitting an LRP. While the purpose of the LRP is to dampen volatility and to provide market participants with time to react, the Exchange believes that the proposed amendment is necessary to lessen artificial limitations on trading. If an LRP is triggered too frequently, such as when the price of a security increases during the trading day well beyond the LRP value that has been assigned to that security for the day, trading in the security may be overly restrained. As such, the NYSE believes that allowing for an expanded value range on the first day of trading of an IPO will better facilitate the natural trading of a particular security.

2. Statutory Basis

The basis under the Act for these proposed rule changes are the requirement under Section 6(b)(5)[5] that an Exchange have rules that are designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The proposed rule change also is designed to support the principles of Section 11A(a)(1)[6] in that it seeks to assure economically efficient execution of securities transactions, make it practicable for brokers to execute investors' orders in the best market and provide an opportunity for investors' orders to be executed without the participation of a dealer. The Exchange's proposal to provide flexibility in setting the LRP range on the first day of trading for an IPO is intended to provide for faster executions of securities by limiting the amount of time automatic executions are suspended when an LRP is triggered.

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.

[3] *See also* NYSE Rules 60(e)(i).

[4] *See* NYSE Rule 60(d)(i)(C).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78k–1(a)(1).

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [7] and Rule 19b 4(f)(6) thereunder.[8] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[9]

A proposed rule change filed under Rule 19b–4(f)(6)[10] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[11] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest.

The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative upon filing. The Commission hereby grants that request. The proposed wider LRP values may facilitate trading by limiting the amount of time automatic executions are suspended when an LRP is triggered. Waiving the 30-day operative delay will enable this change to be implemented immediately so that the wider LRP values will be available for the next IPO that takes place on the Exchange. Therefore, the Commission believes it is consistent with the protection of investors and the public interest to waive the 30-day operative delay and designates the proposal as operative upon filing.[12]

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 e-mail to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2011–31 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–2011–31. This file number should be included on the subject line if e-mail 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 a.m. and 3 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–NYSE–2011–31, and should be submitted on or before July 29, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–17122 Filed 7–7–11; 8:45 am]

BILLING CODE 8011–01–P

[7] 15 U.S.C. 78s(b)(3)(A)(iii).

[8] 17 CFR 240.19b–4(f)(6).

[9] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to provide the Commission with 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. The Exchange has fulfilled this requirement.

[10] 17 CFR 240.19b–4(f)(6).

[11] 17 CFR 240.19b–4(f)(6)(iii).

[12] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64788; File No. SR–Phlx–2011–89]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing of Proposed Rule Change Relating to Alpha Index Options

July 1, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 [2] thereunder, notice is hereby given that on June 23, 2011, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II, 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, pursuant to Section 19(b)(1) of the Act [3] and Rule 19b–4 thereunder,[4] proposes to list and trade options on a number of new Alpha Indexes and to amend Exchange Rule 1001A, Position Limits, with respect to certain Alpha Index options.[5]

The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaqtrader.com/micro.aspx?id=PHLXRulefilings*, at the principal office of the Exchange, and at

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(1).

[4] 17 CFR 240.19b–4.

[5] Alpha Indexes are a family indexes developed by NASDAQ OMX Group, Inc. (''Nasdaq'').

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

On February 7, 2011, the Commission approved the Exchange's proposed rule change to list and trade options on a number of Alpha Indexes.[6] Alpha Indexes measure relative total returns of one underlying stock or exchange traded fund (''ETF'') share against another underlying stock or ETF share underlying options which are also traded on the Exchange (each such combination of two components is referred to as an ''Alpha Pair''). Thus, an Alpha Index measures the relative total return of one stock or ETF share against another stock or ETF share. The first component identified in an Alpha Pair (the ''Target Component'') is measured against the second component identified in the Alpha Pair (the ''Benchmark Component''). Total return measures performance (rate of return) of price appreciation plus dividends over a given evaluation period.

The Alpha Index options which the Commission has approved for listing and trading on the Exchange are limited to specific Alpha Indexes the Target Component of which is a single stock.[7] The purpose of this proposed rule change is to expand the number of Alpha Indexes on which options can be listed to include certain Alpha Indexes based on the following Alpha Pairs: DIA/SPY, EEM/SPY, EWJ/SPY, EWZ/SPY, FXI/SPY, GLD/SPY, IWM/SPY, QQQ/SPY, SLV/SPY, TLT/SPY, XLE/SPY and XLF/SPY. In these Alpha Indexes the Target Component as well as the Benchmark Component is an ETF share. The proposed Alpha Index options will enable investors to trade the relative performance of the market sectors represented by the Target Components as compared with the overall market performance represented by the Benchmark Component SPY.

As with each initial Alpha Index option, each proposed new Alpha Index option will meet the criteria set forth in Exchange Rule 1009A(f).[8] Further, following the listing of these Alpha Index options, options on each of the component securities of the Alpha Index must continue to meet the continued listing standards set forth by Exchange Rule 1010, Withdrawal of Approval of Underlying Securities or Options.

Position Limits

The Exchange also proposes to amend section (f) of Exchange Rule 1001A to establish a 15,000 contract position limit in options on Alpha Indexes in which the Target Component is an ETF share. This 15,000 contract position limit would apply not only to the specific Alpha Index options proposed herein, but also to any options the Exchange may list in the future on Alpha Indexes in which the Target Component is an ETF share.[9] For purposes of determining compliance with position limits, positions in Alpha Index options will be aggregated with positions in equity options on the underlying securities. All position limit hedge exemptions will apply.

Clearing

Like the Alpha Index options that are currently trading, the proposed new Alpha Index options are ''Strategy Based Options'' that will be cleared by the Options Clearing Corporation.

Surveillance

Surveillance for opening price manipulation will be in place for the launch of these new Alpha Index options and other existing surveillance patterns will be utilized to monitor trading in these options. The Exchange represents that these surveillance procedures are adequate to monitor the trading of the new Alpha Index options. For surveillance purposes, the Exchange will have complete access to information regarding trading activity in the pertinent underlying securities and options thereon.

Margin

The Exchange will set customer margin levels for the new Alpha Index options at the higher of the margin required for options on the Target Component or the margin required for options on the Benchmark Component.

Systems Capacity

Additionally, the Exchange affirms that it possesses the necessary systems capacity to support new series that would result from the introduction of these new Alpha Index options. The Exchange also has been informed that OPRA has the capacity to support such new series.

Customer Protection

Exchange rules designed to protect public customers trading in options would apply to the new Alpha Index options. Phlx Rule 1026 is designed to ensure that options, including Alpha Index options, are sold only to customers capable of evaluating and bearing the risks associated with trading in the instruments. Phlx Rule 1024, applicable to the conduct of accounts, Phlx Rule 1025 relating to the supervision of accounts, Phlx Rule 1028 relating to confirmations, and Phlx Rule 1029 relating to delivery of options

[6] *See* Securities Exchange Act Release No. 63860 (February 7, 2011), 76 FR 7888 (February 11, 2011) SR–Phlx–2010–176.

[7] The Commission approved listing and trading of options on Alpha Indexes based on the following Alpha Pairs: AAPL/SPY, AMZN/SPY, CSCO/SPY, F/SPY, GE/SPY, GOOG/SPY, HPQ/SPY, IBM/SPY, INTC/SPY, KO/SPY, MRK/SPY, MSFT/SPY, ORCL/SPY, PFE/SPY, RIMM/SPY, T/SPY, TGT/SPY, VZ/SPY and WMT/SPY. In connection with its proposed rule change to list and trade this initial set of Alpha Index options, the Exchange represented that it would not list Alpha Index options on any other Alpha Pairs without filing a proposed rule change seeking Commission approval.

[8] Rule 1009A(f) requires that options on Alpha Indexes meet the following criteria: (1) Alpha Index options will be A.M.-settled. The exercise settlement value will be based upon the opening prices of the individual stock or ETF from the primary listing market on the last trading day prior to expiration (usually a Friday). (2) At the time of listing an Alpha Index option, options on each underlying component of an Alpha Index will also be listed and traded on the Exchange and will meet the requirements of Rule 1009, Criteria for Underlying Securities. Additionally, each underlying component's trading volume (in all markets in which the underlying security is traded) must have averaged at least 2,250,000 shares per day in the preceding twelve months. (3) Following the listing of an Alpha Index option, options on each of the component securities of the Alpha Index will continue to meet the continued listing standards set forth by PHLX Rule 1010, Withdrawal of Approval of Underlying Securities or Options. Additionally, each underlying component's trading volume (in all markets in which the underlying security is traded) must have averaged at least 2,000,000 shares per day in the preceding twelve months. (4) No Alpha Index option will be listed unless and until options overlying each of the Alpha Index component securities have been listed and traded on a national securities exchange with an average daily options trading volume during the three previous months of at least 10,000 contracts. Following the listing of an Alpha Index option, options on each of the component securities of the Alpha Index must continue to meet this options average daily volume standard.

[9] The Exchange will not, however, list options on any such Alpha Pairs without filing a proposed rule change seeking Commission approval.

disclosure documents also apply to trading in Alpha Index options.

Exchange Rules Applicable

All other Exchange rules applicable to Alpha Options will also apply to the Alpha Options proposed herein.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [10] in general, and furthers the objectives of Section 6(b)(5) of the Act [11] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by making available additional options for investors. In particular, the listing of the proposed new Alpha Index options will present investors with new investment alternatives.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2011–89 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2011–89. This file number should be included on the subject line if e-mail 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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2011–89 and should be submitted on or before July 29, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–17119 Filed 7–7–11; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–64790; File No. SR–Phlx–2011–84]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Qualified Contingent Cross Transaction Fees

July 1, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1], and Rule 19b–4 [2] thereunder, notice is hereby given that, on June 24, 2011, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Fee Schedule to adopt fees applicable to a Floor Qualified Contingent Cross order (''Floor QCC Order'') for execution in the Phlx XL II System.[3]

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqtrader.com/micro.aspx?id=PHLXRulefilings,* at the principal office of the Exchange, at the Commission's Public Reference Room, and on the Commission's Web site at *http://www.sec.gov.*

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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A Floor QCC Order must: (i) Be for at least 1,000 contracts, (ii) meet the six requirements of Rule 1080(o)(3) which are modeled on the QCT Exemption, (iii) be executed at a price at or between the National Best Bid and Offer (''NBBO''); and (iv) be rejected if a Customer order is resting on the Exchange book at the same price. In order to satisfy the 1,000-contract requirement, a Floor QCC Order must be for 1,000 contracts and could not be, for example, two 500-contract orders or two 500-contract legs. *See* Rule 1064(e). *See also* Securities Exchange Act Release No. 64688 (June 16, 2011) (SR–Phlx–2011–56).

statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend Sections I and II, of the Exchange's Fee Schedule, entitled ''Rebates and Fees for Adding and Removing Liquidity in Select Symbols''[4] and ''Equity Options Fees''[5] to indicate that Qualified Contingent Cross Transaction Fees (''QCC Transaction Fees'') apply to both electronic Qualified Contingent Cross orders (''QCC Orders'')[6] and Floor QCC Orders, which are orders that are electronically entered by a Floor Broker[7] on the floor of the Exchange using the Floor Broker Management System (''FBMS'').[8] The Exchange currently assesses QCC Transaction Fees on QCC Orders (electronic).[9] The Exchange is proposing to assess the same QCC Transaction Fees on Floor QCC Orders.

There are currently several categories of market participants: Customers, Directed Participants,[10] Specialists,[11] Registered Options Traders,[12] SQTs,[13] RSQTs,[14] Broker-Dealers, Firms and Professional.[15] The Exchange currently assesses Directed Participants, Specialists, ROTs, SQTs, RSQTs, Broker-Dealers, Firms and Professionals a $0.20 per contract QCC Transaction Fee for QCC Orders (electronic) in both Select Symbols[16] (Section I of the Exchange's Fee Schedule) and Multiply Listed Option Symbols (Section II of the Exchange's Fee Schedule). Customers are not assessed a QCC Transaction Fee. The QCC Transaction Fees are subject to the Firm Related Equity Option Cap and the Monthly Cap. The Firm Related Equity Option Cap is currently $75,000.[17] ROTs and Specialists are currently subject to a Monthly Cap of $550,000.[18]

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act[19] in general, and furthers the objectives of Section 6(b)(4) of the Act[20] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members.

The Exchange believes that the proposed fees for Floor QCC Orders are equitable because the QCC Transaction Fees which would apply to Floor QCC Orders are currently applied to QCC Orders (electronic) today. For this reason, the Exchange believes that it is equitable to assess QCC Orders (electronic) and Floor QCC Orders the same rates.

Additionally, the Exchange believes that QCC Transaction Fees proposed to be applied to Floor QCC Orders are within the range of fees currently assessed in Section II for Multiply Listed equity options. Customers are not assessed a fee for options overlying equities which are Multiply Listed. Other market participants are assessed transaction fees, pursuant to Section II, which range from $.20 per contract to $.25 per contract, generally.[21] In addition, the Exchange is proposing to assess the same QCC Transaction Fee for Floor QCC Orders on all market participants uniformly, with the exception of Customers. The Exchange believes that its proposal to not assess Customers QCC Transaction Fees for Floor QCC Orders is not unfairly discriminatory because the Exchange is seeking to incentivize Broker-Dealers, Firms and Professionals to execute Customer Floor QCC Orders on the Exchange.

The Exchange believes that the proposed fees are reasonable because the fees are comparable to the Exchange's fees, as stated above, and because the fees are within the range of fees assessed by the International Securities Exchange, LLC (''ISE'') for

[4] Section I fees and rebates are applicable to certain select symbols which are defined in Section I (''Select Symbols'').

[5] Section II includes options overlying equities, ETFs, ETNs, indexes and HOLDRS which are Multiply Listed.

[6] A QCC Order is comprised of an order to buy or sell at least 1,000 contracts that is identified as being part of a qualified contingent trade, as that term is defined in Rule 1080(o)(3), coupled with a contra-side order to buy or sell an equal number of contracts. The QCC Order must be executed at a price at or between the National Best Bid and Offer and be rejected if a Customer order is resting on the Exchange book at the same price. A QCC Order shall only be submitted electronically from off the floor to the PHLX XL II System. *See* Rule 1080(o). *See also* Securities Exchange Act Release No. 64249 (April 7, 2011), 76 FR 20773 (April 13, 2011) (SR–Phlx–2011–47) (a rule change to establish a QCC Order to facilitate the execution of stock/option Qualified Contingent Trades (''QCTs'') that satisfy the requirements of the trade through exemption in connection with Rule 611(d) of the Regulation NMS).

[7] Floor QCC Orders must include data reflecting the number of shares of stock sold/purchased in the stock leg of the QCT trade. Floor QCC Orders lacking this data will be rejected by the Exchange system.

[8] Once entered into the FBMS by a Floor Broker, the execution will be executed electronically. Only Floor Brokers will be permitted to enter Floor QCC Orders. *See* Exchange Rule 1064. Exchange Rule 1064(e)(2) prohibits Options Floor Brokers from entering Floor QCC Orders for their own accounts, the account of an associated person, or an account with respect to which it or an associated person thereof exercises investment discretion.

[9] *See* Securities Exchange Act Release No. 64520 (May 19, 2011), 76 FR 30223 (May 24, 2011) (SR–Phlx–2011–66).

[10] A Directed Participant is a Specialist, Streaming Quote Trader (''SQT''), or Remote Streaming Quote Trader (''RSQT'') that receives a Directed Order that is directed to them by an Order Flow Provider. *See* Exchange Rule 1080(l).

[11] A Specialist is an Exchange member who is registered as an options specialist pursuant to Rule 1020(a).

[12] A Registered Options Trader (''ROT'') includes a SQT, a RSQT and a Non-SQT ROT, which by definition is neither a SQT or a RSQT. A ROT is defined in Exchange Rule 1014(b) as a regular member or a foreign currency options participant of the Exchange located on the trading floor who has received permission from the Exchange to trade in options for his own account. *See* Exchange Rule 1014(b)(i) and (ii).

[13] An SQT is defined in Exchange Rule 1014(b)(ii)(A) as an ROT who has received permission from the Exchange to generate and submit option quotations electronically in options to which such SQT is assigned.

[14] An RSQT is [sic] defined Exchange Rule in [sic] 1014(b)(ii)(B) as an ROT that is a member or member organization with no physical trading floor presence who has received permission from the Exchange to generate and submit option quotations electronically in options to which such RSQT has been assigned. An RSQT may only submit such quotations electronically from off the floor of the Exchange.

[15] The Exchange defines a ''professional'' as any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s) (hereinafter ''Professional'').

[16] Select Symbols are defined in Section I of the Exchange's Fee Schedule.

[17] Firm equity option transaction charges, in the aggregate, for one billing month will not exceed the Firm Related Equity Option Cap per member organization when such members are trading in their own proprietary account. The Firm equity options transaction charges will be waived for members executing facilitation orders pursuant to Exchange Rule 1064 when such members are trading in their own proprietary account. Firms that (i) are on the contra-side of an electronically-delivered and executed Customer complex order; and (ii) have reached the Firm Related Equity Option Cap will be assessed a $0.05 per contract fee. *See* Securities Exchange Act Release No. 63780 (January 26, 2011), 76 FR 5846 (February 2, 2011) (SR–Phlx–2011–07).

[18] The trading activity of separate ROTs and Specialist member organizations will be aggregated in calculating the Monthly Cap if there is at least 75% common ownership between the member organizations. In addition, ROTs and Specialists that (i) are on the contra-side of an electronically-delivered and executed Customer complex order; and (ii) have reached the Monthly Cap will be assessed a $0.05 per contract fee. *See* Securities Exchange Act Release No. 64113 (March 23, 2011), 76 FR 17468 (March 29, 2011) (SR–Phlx–2011–36).

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(4).

[21] A Broker-Dealer is the one exception to this range. A Broker-Dealer is assessed $.45 per contract for electronically submitted transactions in Penny Pilot and non-Penny Pilot options.

qualified contingent cross orders. ISE assesses $0.20 per contract for qualified contingent cross orders to all market participants [22] except the priority customer.[23]

The Exchange operates in a highly competitive market comprised of nine U.S. options exchanges in which sophisticated and knowledgeable market participants readily can, and do, send order flow to competing exchanges if they deem fee levels at a particular exchange to be excessive. The Exchange believes that the proposed QCC Transaction Fees for Floor QCC Orders it assesses must be competitive with fees assessed on other options exchanges. The Exchange believes that this competitive marketplace impacts the fees present on the Exchange today and influences the proposals set forth above.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[24] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2011–84 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2011–84. This file number should be included on the subject line if e-mail 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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2011–84 and should be submitted on or before July 29, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Cathy H. Ahn,

Deputy Secretary.

[FR Doc. 2011–17120 Filed 7–7–11; 8:45 am]

BILLING CODE 8011–01–P

[22] The fee for an ISE market maker is either $.18 or $.20 per contract, depending on the product. *See* ISE's Fee Schedule. *See also* Securities Release Act No. 64112 (March 23, 2011), 76 FR 17462 (March 29, 2011) (SR–ISE–2011–14).

[23] An ISE priority customer is not assessed a fee. *See* ISE's Fee Schedule.

[24] 15 U.S.C. 78s(b)(3)(A)(ii).

[25] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 7521]

Culturally Significant Objects Imported for Exhibition Determinations: ''Prints and the Pursuit of Knowledge in Early Modern Europe''

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236–3 of August 28, 2000, I hereby determine that the objects to be included in the exhibition ''Prints and the Pursuit of Knowledge in Early Modern Europe,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Harvard Art Museums, Cambridge, MA, from on or about September 6, 2011, until on or about December 10, 2011; The Mary and Leigh Block Museum of Art, Northwestern University, Evanston, IL, from on or about January 17, 2012, until on about April 8, 2012, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6467). The mailing address is U.S. Department of State, SA–5, L/PD, Fifth Floor (Suite 5H03), Washington, DC 20522–0505.

Dated: June 30, 2011.

Ann Stock,

Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2011–17212 Filed 7–7–11; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Reinstated Approval of Information Collection: Dealer's Aircraft Registration Certificate Application

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to reinstate a previously discontinued information collection. AC Form 8050–5 is an application for a dealer's Aircraft Registration Certificate which, under 49 United States Code 1404, may be issued to a person engaged in manufacturing, distributing, or selling aircraft.

DATES: Written comments should be submitted by September 6, 2011.

FOR FURTHER INFORMATION CONTACT: Carla Scott on (202) 385–4293, or by e-mail at: *Carla.Scott@faa.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0024.

Title: Dealer's Aircraft Registration Certificate Application.

Form Numbers: AC Form 8050–5.

Type of Review: Reinstatement of an information collection.

Background: Federal Aviation Regulation Part 47 prescribes procedures that implement Public Law 103–272, which provides for the issuance of dealer's aircraft registration certificates and for their use in connection with aircraft eligible for registration under this Act by persons engaged in manufacturing, distributing or selling aircraft. Dealer's certificates enable such persons to fly aircraft for sale immediately without having to go through the paperwork and expense of applying for and securing a permanent Certificate of Aircraft Registration. It also provides a system of identification of aircraft dealers.

Respondents: 2,135 aircraft dealers.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 45 minutes.

Estimated Total Annual Burden: 1,601.25 hours.

ADDRESSES: Send comments to the FAA at the following address: Ms. Carla Scott, Room 336, Federal Aviation Administration, AES–300, 950 L'Enfant Plaza, SW., Washington, DC 20024.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Issued in Washington, DC, on June 29, 2011.

Carla Scott,

FAA Information Collection Clearance Officer, IT Enterprises Business Services Division, AES–200.

[FR Doc. 2011–17208 Filed 7–7–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No FMCSA–2011–0097]

Pilot Program on the North American Free Trade Agreement (NAFTA) Long-Haul Trucking Provisions

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice; response to public comments.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) announces its intent to proceed with the initiation of a United States-Mexico cross-border long-haul trucking pilot program to test and demonstrate the ability of Mexico-domiciled motor carriers to operate safely in the United States beyond the municipalities in the United States on the United States-Mexico international border or the commercial zones of such municipalities (border commercial zones).

DATES: This notice is effective July 8, 2011.

ADDRESSES: You may search background documents or comments to the docket for this notice, identified by docket number FMCSA–2011–0097, by visiting the:

- *eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for reviewing documents and comments. Regulations.gov is available electronically 24 hours each day, 365 days a year; or.
- *DOT Docket Room:* Room W12–140 on the ground floor of the DOT Headquarters Building at 1200 New Jersey Avenue, SE., Washington, DC 20590 between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review DOT's Privacy Act System of Records Notice for the DOT Federal Docket Management System published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

FOR FURTHER INFORMATION CONTACT: Marcelo Perez, FMCSA, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001. Telephone (202) 366–9597; e-mail *marcelo.perez@dot.gov.*

SUPPLEMENTARY INFORMATION: On April 13, 2011, FMCSA published a notice in the **Federal Register** announcing its plans to initiate a pilot program as part of FMCSA's implementation of the NAFTA cross-border long-haul trucking provisions in compliance with section 6901(b)(2)(B) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, and requested public comments on those plans. FMCSA reviewed, assessed, and evaluated the required safety measures as noted in the notice, and considered all comments received on or before May 13, 2011, in response to the April 13, 2011, notice. Additionally, to the extent practicable, FMCSA considered comments received after May 13, 2011. Once the U.S. Department of Transportation's (DOT) Inspector General completes his report to Congress required by section 6901(b)(1) and the Agency completes any follow up actions needed to address issues raised in the report, FMCSA will proceed with the pilot program. FMCSA made changes and clarified elements of the program as a result of comments to the docket. For example, the Agency will include International Registration Plan (IRP) and International Fuel Tax Association (IFTA) information in its pre-authority safety audit (PASA) process; posted the Mexican regulations in both English and Spanish in the docket for this notice; elaborated on the inspection of available vehicles operating in the United States during

the compliance review (CR); and confirmed that the PASA information will be published in the **Federal Register**.

As indicated in the April 13, 2011, **Federal Register** notice, this pilot program will not include operations that transport placarded amounts of hazardous materials or passengers. In addition, on May 31, 2011, Mexico published its regulations that will govern a U.S. motor carrier's application for authority to operate in Mexico. In its regulations, Mexico specifies several types of transportation services, vehicles, and operations as ineligible for authority to operate into Mexico. These include oversized or overweight goods, industrial cranes, vehicle towing or rescue, or packaging and courier services. Mexico is allowing U.S. motor carriers of international freight to operate into Mexico. Mexico has excluded these services, vehicles, and operations from the program because they are not classified as, or pertinent to, freight operations in Mexico; rather these types of operations are subject to separate operating authority requirements than freight motor carriers. While the United States does not distinguish between these types of freight operations, in order to comply with the reciprocity requirements of section 6901(a)(3), the United States will not issue authority to Mexico-domiciled motor carriers to transport oversized or overweight goods, industrial cranes, or operate vehicle towing, rescue or packaging and courier services in this pilot program.

Legal Basis

Section 6901(a) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007 [Pub. L. 110–28, 121 Stat. 112, 183, May 25, 2007] (2007 Appropriations Act) provides that before DOT may obligate or expend any funds to grant authority for Mexico-domiciled trucks to engage in cross-border long-haul operations, DOT must first test granting such authority through a pilot program that meets the standards of 49 U.S.C. 31315(c). In accordance with 49 U.S.C. 31315(c)(2), in proposing a pilot program, the Secretary of Transportation (Secretary) has general authority to conduct pilot programs ''that are designed to achieve a level of safety that is equivalent to, or greater than, the level of safety that would otherwise be achieved * * *..''

In a pilot program, DOT typically collects specific data for evaluating alternatives to the regulations or innovative approaches to safety while ensuring that the goals of the regulations are satisfied. A pilot program may not last more than 3 years, and the number of participants in a pilot program must be large enough to ensure statistically valid findings. Pilot programs must include an oversight plan to ensure that participants comply with the terms and conditions of participation, and procedures to protect the health and safety of study participants and the general public. A pilot program may be initiated only after DOT publishes a detailed description of it in the **Federal Register** and provides an opportunity for public comment. Accordingly, on April 13, 2011, the Agency published a notice announcing its intention to conduct a pilot program and soliciting comment (76 FR 20807). This document responds to comments to the April 13, 2011 notice and provides additional information about the planned pilot program as requested by commenters. While a pilot program may provide temporary regulatory relief from one or more regulations to a person or class of persons subject to the regulations, or a person or class of persons who intends to engage in an activity that would be subject to the regulations (49 U.S.C. 31315(c)(1) and (2)), in this pilot program DOT does not propose to exempt or relieve Mexico-domiciled motor carriers from any FMCSA safety regulation or evaluate any less stringent alternatives to existing regulation. Mexico-domiciled motor carriers participating in the program will be required to comply with the existing motor carrier safety regulatory regime plus certain additional requirements associated with acceptance into and participation in the program.

Section 6901(a) of the 2007 Appropriations Act, the terms of which have been incorporated in each subsequent DOT appropriations act, also provides that this pilot program must comply with section 350 of the Department of Transportation and Related Agencies Appropriations Act, 2002 [Pub. L. 107–87, 115 Stat. 833, 864, December 18, 2001] (section 350). Section 350 prohibited FMCSA from using funds made available in the 2002 DOT Appropriations Act to review or process applications from Mexico-domiciled motor carriers to operate beyond the border commercial zones until certain preconditions and safety requirements were met. The terms of section 350 have also been incorporated in each subsequent DOT appropriations act. Section 350(a)(1) required FMCSA to perform a PASA of any Mexico-domiciled motor carrier before that motor carrier is allowed to engage in long-haul operations in the United States. Vehicles the motor carrier will operate beyond the border commercial zones that do not already have a Commercial Vehicle Safety Alliance (CVSA) decal are required to pass an inspection at the border port of entry and obtain a decal before being allowed to proceed. Section 350(a)(4) also required DOT to give a distinctive identification number to each Mexico-domiciled motor carrier that would operate beyond the border commercial zones to assist inspectors in enforcing motor carrier safety regulations. Additionally, every driver who will operate in the United States must have a valid commercial driver's license issued by Mexico. Section 350(c)(1) also required DOT's Office of the Inspector General (OIG) to conduct a comprehensive review of the adequacy of inspection capacity, information infrastructure, enforcement capability and other specific factors relevant to safe operations by Mexico-domiciled motor carriers; and section 350(c)(2) required the Secretary to address the OIG's findings and certify that the opening of the border poses no safety risk. The OIG was also directed to conduct similar reviews at least annually thereafter. A number of the section 350 requirements were addressed by FMCSA in rulemakings published on March 19, 2002 (67 FR 12653, 67 FR 12702, 67 FR 12758, 67 FR 12776) and on May 13, 2002 (67 FR 31978).

Section 136 of the Transportation, Housing and Urban Development, and Related Agencies Appropriations Act, 2009 [Division I of the Omnibus Appropriations Act, 2009, Pub. L, 111–8, 123 Stat. 524, 932, March 11, 2009] (2009 Appropriations Act) prohibited DOT from expending funds made available in the 2009 Appropriations Act to establish, implement, or continue a cross-border motor carrier pilot program to allow Mexico-domiciled motor carriers to operate beyond the border commercial zones. The Transportation, Housing and Urban Development, and Related Agencies Appropriations Act, 2010 [Division A of the Consolidated Appropriations Act, 2010, Pub. L. 111–117, 123 Stat. 3034, December 16, 2009] (2010 Appropriations Act) did not bar DOT or FMCSA from using funds on a cross-border long-haul program; but, pursuant to section 135 of the 2010 Appropriations Act (123 Stat. at 3053) did retain the requirements of section 6901 and section 350. Section 1101(a)(6) of the Full-Year Continuing Appropriations Act, 2011 [Pub. L. 112–10, division B, 125 Stat. 102, 103, April

15, 2011] (2011 Appropriations Act), makes funding available for DOT and other Federal agencies during Fiscal Year (FY) 2011 under the authority and conditions specified in the 2010 Appropriations Act.

Section 6901 of the 2007 Appropriations Act also provided that simultaneous and comparable authority to operate within Mexico must be made available to U.S. motor carriers. Further, before the required pilot program may begin, in accordance with section 6901(b)(1), the Department's OIG must submit a report to Congress verifying that DOT has complied with the requirements of section 350(a). DOT must take any actions that are necessary to address issues raised by the OIG and must detail those actions in a report to Congress. Section 6901(c) also directed the OIG to submit an interim report to Congress 6 months after the initiation of a cross-border long-haul Mexican trucking pilot program and a final report after the pilot program is completed. The statute further specified that the report address the program's adequacy as a test of safety. Also, as a precondition to beginning the pilot program, section 6901 of the 2007 Appropriations Act requires that DOT provide an opportunity for public comment by publishing in the **Federal Register** information on the PASAs conducted. DOT must also publish, for comment, the standards that will be used to evaluate the pilot program. The Agency must also provide a list of Federal motor carrier safety laws and regulations, including commercial driver's license (CDL) requirements, for which the Secretary will accept compliance with corresponding Mexican law or regulation as the equivalent to compliance with the U.S. law or regulation including an analysis of how the corresponding United States and Mexican laws and regulations differ. Further discussion of relevant U.S. and Mexican safety laws and regulations is provided later in this notice.

Background

Introduction

Before 1982, Mexico- and Canada-domiciled motor carriers could apply to the Interstate Commerce Commission (ICC), a former independent Federal agency responsible for regulating, *inter alia,* motor carrier operations and safety, for authority to operate within the United States. As a result of complaints that U.S. motor carriers were not allowed the same access to Mexican and Canadian markets that motor carriers from those nations enjoyed in this country, the Bus Regulatory Reform Act of 1982 [Pub. L. 97–261, 96 Stat. 2201, September 20, 1982] imposed a moratorium on the issuance of new operating authority to motor carriers domiciled, or owned or controlled by persons domiciled in Canada or Mexico. While the disagreement with Canada was quickly resolved, the issue of trucking reciprocity with Mexico was not.

Currently, most Mexico-domiciled motor carriers are allowed to operate only within the border commercial zones typically extending up to 25 to 50 miles into the United States. Every year, Mexico-domiciled commercial motor vehicles (CMVs) cross into the United States about 4.5 million times. Mexico granted reciprocal authority to 10 U.S.-domiciled motor carriers to operate throughout Mexico during the time of FMCSA's previous demonstration project, which was conducted between September 2007 and March 2009. Four of these motor carriers continue to operate in Mexico.

Trucking issues at the United States-Mexico border were not fully addressed until NAFTA was negotiated in the early 1990s. NAFTA required the United States to incrementally lift the moratorium on licensing Mexico-domiciled motor carriers to operate beyond the border commercial zones. On January 1, 1994, President Clinton modified the moratorium and the ICC began accepting applications from Mexico-domiciled passenger motor carriers to conduct international charter and tour bus operations in the United States (Memorandum for the Secretary of Transportation, ''Determination Under the Bus Regulatory Reform Act of 1982,'' 59 FR 653, January 6, 1994). On December 13, 1995, the ICC published a rule and a revised application form for the processing of Mexico-domiciled property motor carrier applications (Form OP–1(MX)) (60 FR 63981). The ICC rule anticipated the implementation of the second phase of NAFTA, providing Mexico-domiciled motor carriers of property access to California, Arizona, New Mexico and Texas, and the third phase, providing access throughout the United States. However, at the end of 1995, the United States announced an indefinite delay in opening the border to long-haul Mexico-domiciled long-haul motor carrier operations.

In 1998, Mexico filed a claim against the United States under NAFTA dispute resolution provisions alleging that the United States' refusal to grant authority to Mexico-domiciled trucking companies constituted a breach of the United States' NAFTA obligations. On February 6, 2001, the arbitration panel, convened pursuant to NAFTA dispute resolution provisions, issued its final report and ruled in Mexico's favor, concluding that the United States was in breach of its obligations and that Mexico could impose tariffs on U.S. exports to Mexico up to an amount commensurate with the loss of business resulting from the lack of U.S. compliance. The arbitration panel noted that the United States could establish a safety oversight regime to ensure the safety of Mexico-domiciled motor carriers entering the United States, but that the safety oversight regime could not be discriminatory and must be justified by safety data.

After President Bush announced the intent to resume the process for opening the border in 2001, Congress enacted section 350, as discussed in the ''Legal Basis'' section of this notice. FMCSA took various steps to comply with section 350, including the issuance of new regulations applicable to Mexico-domiciled long-haul motor carriers (67 FR 12702, 12758, March 19, 2002). These regulations were challenged on environmental grounds in litigation that was ultimately decided in FMCSA's favor by the U.S. Supreme Court (*Department of Transportation* v. *Public Citizen,* 541 U.S. 752 (2004)).

In November 2002, then Secretary Norman Mineta certified, as required by section 350(c)(2), that authorizing Mexico-domiciled motor carrier operations beyond the border commercial zones did not pose an unacceptable safety risk to the American public. Later that month, President Bush modified the moratorium to permit Mexico-domiciled motor carriers to provide cross-border cargo and scheduled passenger transportation beyond the border commercial zones. (Memorandum of November 27, 2002, for the Secretary of Transportation, ''Determination Under the Interstate Commerce Commission Termination Act of 1995,'' 67 FR 71795, December 2, 2002). The Secretary's certification was made in response to the June 25, 2002, DOT OIG report on the implementation of safety requirements at the United States-Mexico border. In a January 2005 follow-up report, the OIG concluded that FMCSA had sufficient staff, facilities, equipment, and procedures in place to substantially meet the eight section 350 requirements that the OIG was required to review. These reports are available in the docket for this notice.

Former Secretary Mary Peters and Mexico's former Secretary of the Secretaria de Communicaciones y Transportes (SCT) Luis Téllez Kuenzler

announced a demonstration project to implement certain trucking provisions of NAFTA on February 23, 2007. The demonstration project was initiated on September 6, 2007, after the DOT complied with the conditions imposed by section 6901 of the 2007 Appropriations Act, as discussed in the ''Legal Basis'' section of this notice. The demonstration project was initially expected to last 1 year (72 FR 23883, May 1, 2007). On August 6, 2008, FMCSA announced that the demonstration project was being extended from 1 year to the full 3 years allowed by 49 U.S.C. 31315(c)(2)(A) (73 FR 45796) after Secretaries Peters and Téllez exchanged letters on the extension.

On March 11, 2009, President Obama signed into law the 2009 Appropriations Act. Section 136 of the 2009 Appropriations Act provides that:

> [N]one of the funds appropriated or otherwise made available under this Act may be used, directly or indirectly, to establish, implement, continue, promote, or in any way permit a cross-border motor carrier pilot program to allow Mexican-domiciled motor carriers to operate beyond the commercial zones along the international border between the United States and Mexico, including continuing, in whole or in part, any such program that was initiated prior to the date of the enactment of this Act (123 Stat. at 932).

In accordance with section 136, FMCSA terminated the cross-border demonstration project that began on September 6, 2007. The Agency ceased processing applications by prospective project participants and took other necessary steps to comply with the provision. (74 FR 11628, March 18, 2009). In light of the termination, two consolidated lawsuits challenging the project and pending before the U.S. Court of Appeals for the Ninth Circuit were dismissed as moot.

On March 19, 2009, Mexico announced that it was exercising its rights under the 2001 NAFTA Arbitration Panel decision to impose retaliatory tariffs for the failure to allow Mexico-domiciled motor carriers to provide long-haul service into the United States. The tariffs affect approximately 90 U.S. export commodities at an estimated annual cost of $2.4 billion. The President directed DOT to work with the Office of the U.S. Trade Representative and the Department of State, along with leaders in Congress and Mexican officials, to propose legislation creating a new cross-border trucking program, and to address the legitimate safety concerns of Congress while fulfilling our obligations under NAFTA. Secretary Ray LaHood met with numerous members of Congress to solicit their input. FMCSA tasked its Motor Carrier Safety Advisory Committee (MCSAC) with providing advice and guidance on essential elements that the Agency should consider when drafting proposed legislation to permit Mexico-domiciled motor carriers beyond the border commercial zones. The MCSAC final report on this tasking is available on the FMCSA MCSAC Web page at *http://mcsac.fmcsa.dot.gov/Reports.htm.* Additionally, DOT formed a team to draft principles that would guide the creation of the draft legislation.

President Obama signed the 2010 Appropriations Act on December 16, 2009, which contained no prohibitions against using FY 2010 funds to conduct a cross border long-haul program (unlike the 2009 Appropriations Act) and retained requirements specified in section 350 and section 6901 of the 2007 Appropriations Act.

On April 12, 2010, Secretary LaHood met with Mexico's former Secretary of SCT, Juan Molinar Horcasitas, and announced a plan to establish a working group to consider the next steps in implementing a cross-border trucking program. On May 19, 2010, President Obama and Mexico's President Felipe Calderon Hinojosa issued a joint statement acknowledging that safe, efficient, secure, and compatible transportation is a prerequisite for mutual economic growth. They committed to continue their countries' cooperation in system planning, operational coordination, and technical cooperation in key modes of transportation.

The Initial Concept Document and the Preliminary Agreement

On January 6, 2011, Secretary LaHood shared with Congress and the Government of Mexico an initial concept document for a cross-border long-haul Mexican trucking pilot program that prioritizes safety, while satisfying the U.S. international obligations. On the same day, the Department posted the concept documents on its Web site for public viewing (*http://www.dot.gov/affairs/2011/dot0111.html*). The initial concept document was the starting point for renewed negotiations with Mexico; and the United States commenced discussions with the Government of Mexico on January 18, 2011. The preliminary agreement between DOT and SCT is reflected in the program description and described below.

On March 3, 2011, President Obama met with Mexico's President Calderon and announced that there is a clear path forward to resolving the trucking issues between the United States and Mexico.

On April 13, 2011, FMCSA published notice of the pilot program on NAFTA Long-Haul Trucking Provisions in the **Federal Register** (76 FR 20807) and the comment period ended May 13, 2011.

The Agency explained that the pilot program will allow Mexico-domiciled motor carriers to operate throughout the United States for up to 3 years, and that U.S.-domiciled motor carriers will be granted reciprocal rights to operate in Mexico for the same period. Participating Mexico-domiciled motor carriers and drivers must comply with all applicable U.S. motor carrier safety laws and regulations, as well as other applicable U.S. laws and regulations, *inter alia,* those concerned with customs, immigration, vehicle emissions, employment, vehicle registration, and vehicle/fuel taxation.

The Agency explained that the safety performance of the participating motor carriers will be tracked closely by FMCSA and its State partners, a Federal Advisory Committee Act group, and the OIG. The Agency will monitor and evaluate the data from the pilot program as a test of the granting of authority to Mexico-domiciled motor carriers to conduct long-haul operations in the United States. FMCSA indicated that it anticipated participating motor carriers may be able to convert their provisional status under the pilot program to ''permanent'' authority under the pilot program after operating 18 months and successfully completing a compliance review (CR). This ''permanent'' authority under the pilot program, in turn, may be converted into standard permanent authority upon completion or termination of the pilot program. It should be noted that the Agency will be maintaining its oversight strategies and resources that have been reviewed by the OIG during the previous demonstration project and the OIG's other reviews of the Agency's compliance with section 350. The April 13th notice outlined how the Agency would maintain those strategies and augment them with new strategies to address stakeholder input. This notice responds to comments on those previous and augmented strategies.

As indicated in the April 13, 2011, **Federal Register** notice, this pilot program will not include operations that involve the transport of placarded amounts of hazardous materials or passengers. As noted in the ''Summary'' section of this notice, Mexico's regulations identify other types of CMV operations and services as ineligible for authority to operate into Mexico. These include the transportation of oversized

or overweight goods, industrial cranes, vehicle towing or rescue, or packaging and courier services. Mexico is allowing U.S. motor carriers of international freight to operate into Mexico. In order to comply with the reciprocity requirements of section 6901(a)(3) of the 2007 Appropriations Act, the United States will not issue authority to Mexico-domiciled motor carriers to transport oversized or overweight goods, industrial cranes, or operate vehicle towing, rescue, or packaging and courier services in this pilot program.

Discussion of Comments

The notice and comment process for all pilot programs is required by statute (49 U.S.C. 31315) with the intent of providing all interested parties with the opportunity to review information published by the Agency and to comment on the specific details about any proposed pilot program. As of June 1, 2011, FMCSA received 2,254 comments or docket submissions in response to the April 13, 2011, notice. Over 1,000 comments were submitted by individuals on behalf of the International Brotherhood of Teamsters (Teamsters).

There were three recurring submissions from individuals that made up the majority of the comments. These commenters expressed concerns about the violence in Mexico and indicated that the pilot program will negatively impact U.S. jobs at a time when unemployment is high. Approximately 1,000 of the comments were submissions by individuals suggesting that the Agency should abandon the idea of a pilot program. Generally, these comments did not include information concerning the technical details of the Agency's proposal (*e.g.,* specific safety oversight procedures or processes), economic or legal aspects of the pilot program, or any other information supporting the view that the program should not be pursued. While FMCSA is not responding to these comments individually, the Agency believes that its responses to the substantive comments received address the brief comments submitted by these individuals.

Moreover, the purpose of this pilot program is to test the granting of authority to Mexico-domiciled motor carriers to conduct long-haul operation in the United States, in order to evaluate the ability of Mexico-domiciled motor carriers to operate safely in the United States beyond the border commercial zones as part of DOT's implementation of the NAFTA land transportation provisions. While FMCSA acknowledges these commenters' concerns, the issues are beyond the scope of the pilot project in that they do not relate to the safe operation of CMVs by Mexico-domiciled motor carriers or compliance with U.S. motor carrier safety regulations. Therefore, these comments will not be addressed in this notice.

The remaining comments were from members of Congress, companies, organizations, associations, and individuals expressing their views on specific details about the pilot program.

The Agency's announcement of its intent to proceed with the program is based on its consideration of all data and information currently available, including information submitted by the commenters.

The Agency received substantive comments from: Advocates for Highway and Auto Safety (Advocates); Teamsters; the American Trucking Associations (ATA); California Trucking Association (CTA); the Owner-Operator Independent Drivers Association (OOIDA); International Registration Plan (IRP), the Border Trade Alliance (BTA), the American Association for Justice (AAJ), Werner Enterprises, and the Truck Safety Coalition (Coalition)—a partnership with Citizens for Reliable and Safe Highways and Parents Against Tired Truckers. In addition, comments were received from several U.S. Representatives and Senators.

General Support for the Pilot Program

Many commenters supported the pilot program and recognized its importance in meeting U.S. obligations under NAFTA. U.S. companies and their representative associations that have been negatively impacted by the tariffs imposed by the Government of Mexico as a result of the termination of the previous demonstration project also expressed their strong support for the program. Companies negatively impacted by the tariffs included Oceanspray, Kraft Foods, Con Agra, Campbell Soup Company, American Frozen Foods Institute, National Cattlemen's Beef Association, National Potato Council, North American Equipment Dealers Association, the Grocery Manufacturers Association, Association of Food, Beverage and Consumer Products Companies, Distilled Spirits Council of the United States, Fresh Produce Association of the Americas, Mars, National Association of State Departments of Agriculture, the Snack Food Association, and Tysons Food. These commenters expressed their support for the pilot program as the means to remove the tariffs that have negatively impacted their industries.

Supporters of the pilot program include U.S. Representatives Mike Thompson and Reid Ribble. Representative Thompson stated,

> The proposal the Administration crafted includes important protections to ensure trucks crossing the border are operating safely on our roadways and under our environmental standards, allowing us to monitor and inspect vehicles before they are approved for cross-border trucking operations. I believe implementation of this revised pilot program provides a clear path toward the elimination of these harmful retaliatory tariffs and normalization of trade between our two countries, while also ensuring the integrity of our roadways.

Thirteen commenters—including the U.S. Apple Association, the National Council of Farmer Cooperatives and the National Association of State Departments of Agriculture—referenced the Congressional Research Service and/or OIG reports that concluded during the previous 18-month pilot program, Mexican trucks were as safe as—if not safer than—their U.S. counterparts and were subject to far more inspections.

U.S. Representative Doc Hastings and 29 congressional colleagues provided a letter in support of the pilot program, stating,

> As you know, Mexico imposed $2.6 billion in retaliatory tariffs on 99 U.S. agricultural and manufacturing products more than two years ago, after the United States halted a cross-border trucking program that was designed to bring the United States into compliance with our international obligations in a matter consistent with U.S. law. Since then, Mexico has rotated the tariffs to cover additional products, and Mexican officials have made clear they are prepared to do so yet again.
>
> These tariffs have already cost tens of thousands of U.S. jobs and over $4 billion to U.S. job creators, at a time when our economy is already struggling. It is imperative for U.S. workers and exporters that these tariffs be eliminated. Mexico has agreed to suspend fifty percent of the tariffs across the board once the new cross-border trucking pilot program is officially instituted and remaining tariffs once the first permit is issued under the program. The success of this pilot program is, thus, critical for U.S. workers and exporters—and for U.S. economic recovery.

This letter concluded with the statement that,

> In short, we have long believed that the United States can strengthen its economy by resolving this major issue with one of our largest trading partners—in a manner that fully ensures the safety of U.S. highways. This pilot program and its substantial safeguards are prudent and responsible. We strongly encourage you to move forward with finalizing and implementing this plan as soon as possible. These tariffs have done irreparable damage to our local economies, and U.S. workers, farmers, manufacturers,

and other exporters simply cannot afford any further delays.

The United States-Mexico Chamber of Commerce stated,

In 2010, Mexico and the United States enjoyed a nearly $400 billion trade relationship, and 70 percent of it travels by truck in an antiquated transportation system that requires three trucks and three drivers to do the job of one. This not only bloats producer and consumer prices by hundreds of millions of dollars a year. It also fails to fulfill the benefits (particularly lower transportation costs) that accrue from U.S.-Mexico proximity—a key NAFTA advantage. Doing so now clearly would boost U.S. and North American competitiveness against economic rivals and result in still more jobs.

The Cato Institute advised,

The failure of Congress to allow implementation of the NAFTA trucking provisions has proven costly to the United States in three important ways.

First, U.S. failure to comply has deprived our economy of the efficiencies of moving goods across our mutual border at lower cost. With the ban in place, trucks approaching the border are required to unload their cargo into warehouses in so-called commercial zones within 25 miles of the border, only to have that cargo reloaded onto short-haul vehicles and then onto domestic trucks for final delivery. This inefficient system causes delays, increased pollution and added costs at busy border crossings such as Calexico East; San Ysidro; Nogales, Ariz.; and Laredo, Texas. Because more than 70 percent of U.S. trade with Mexico travels by truck, the ban on cross-border trucking imposes an additional $200 million to $400 million in transportation costs each year, according to the U.S. Department of Transportation.

Second, failure to comply has exposed U.S. exporters to perfectly legal sanctions imposed by the Mexican government. Under the provisions of NAFTA, and after waiting patiently for more than a decade, the Mexican government imposed sanctions in 2009 on more than $2.4 billion in U.S. exports affect 100 products, from Washington apples to Iowa pork. The sanctions would be lifted in two stages as the U.S. government implements the proposed program to comply with Annex I.

Third, failure to comply has compromised the U.S. government's reputation as a good citizen of the global trading system. Simply put, the U.S. government has failed to keep its word to our Mexican neighbors. Our government has been in flagrant violation of a major trade agreement for more than 15 years. This breach of trust has undermined the U.S. government's standing to challenge other governments, from Mexico to China to the European Union, who may also be in violation of various trade agreements. The Obama administration's promise to more vigorously ''enforce'' our rights in the World Trade Organization and other agreements will lack credibility as long as the U.S. government fails to comply with such clear commitments as the trucking provisions of NAFTA.

For all these reasons, the U.S. government should act as quickly and as thoroughly as possible to implement the proposed regulations to bring our nation into compliance with our mutually beneficial agreement with our Mexican neighbors on cross-border trucking.

General Opposition to the Pilot Program

Most of the individual commenters to the April 13 notice expressed concerns about the following:

(1) The U.S. Government's funding of the electronic monitoring devices for participating Mexico-domiciled motor carriers;

(2) Mexico's standards for CDLs;

(3) The accuracy and completeness of Mexico's driver records;

(4) Compliance with hours-of-service requirements; and

(5) Comparable access for U.S. motor carriers.

U.S. Senator John D. Rockefeller and U.S. Representative Peter A. DeFazio both noted the economic impacts of NAFTA. Representative DeFazio expressed concern that ''the Administration is not launching a pilot program, but rather starting the full liberalization of cross-border trucking without having fully addressed the concerns raised by members of Congress surrounding safety, security, and job impacts that will necessarily arise.'' Representative DeFazio further suggested ''that the U.S. should renegotiate U.S. NAFTA Annex I (I–U–21) * * * thus eliminat[ing] the requirement to open our borders to Mexican trucks.''

U.S. Representative Bob Filner and U.S. Senator Mark Pryor also expressed concerns about the pilot program. Representative Filner's concerns included traffic congestion at our land port-of-entry and the impact on border wait times. He stated that, ''Many of my constituents already have to wait in lines several hours each day to cross the border * * *. We simply do not have enough Border Patrol and Immigration and Customs Enforcement agents at the border to deal with the existing traffic or the heavy burden of the proposed program.''

U.S. Representative Duncan Hunter, Jr. and 43 additional members of Congress co-signed a letter to the Secretary communicating their concerns about safety, the costs of electronic monitoring devices, and violence in Mexico. A copy of each congressional letter is available in the docket for this notice.

1. Operating Authority Under the Pilot Program

The Coalition stated that the pilot program participants should not be granted permanent authority before completion of the pilot program and evaluation of the results. The Coalition stated that, ''Granting permanent operating authority before the Pilot Program is completed undermines the purpose of the experiment and data collection and puts the public at serious risk.''

Representative DeFazio questioned how the Agency could comply with 49 U.S.C. 31315, which requires DOT to immediately revoke the participation of any motor carrier or driver who fails to comply with the terms and conditions of the pilot program, if the Agency is granting permanent authority.

OOIDA challenged the Agency's statutory authority for issuing operating authority. OOIDA averred that 49 U.S.C. 13902 precludes FMCSA from accepting compliance with certain Mexican laws and regulations in lieu of compliance with U.S. laws and regulations. OOIDA stated, ''FMCSA is simply not authorized to issue operating authority to any motor carrier (U.S. or Mexican) unless that carrier agrees to comply with applicable U.S. statutes and regulations.'' To support its position, OOIDA quoted a statement in the November 27, 2002, Memorandum of the President for the Secretary of Transportation, ''Determination Under the Interstate Commerce Commission Termination Act of 1995,'' (65 FR 71795, November 27, 2002), which terminated a moratorium on issuing operating authority to Mexico-domiciled motor carriers:

> Motor carriers domiciled in Mexico operating in the United States will be subject to the same Federal and State laws, regulations, and procedures that apply to carriers domiciled in the United States.

Advocates questioned whether FMCSA will be granting temporary operating authority to any participating Mexico-domiciled long-haul motor carriers before they are accepted into the pilot program. Advocates also stated that it opposes the granting of any operating authority, including temporary authority, in advance of FMCSA's publication of a notice in the **Federal Register** describing its data and information on completed PASAs and its analysis of public comments in response to the notice concerning the completed PASAs. Advocates also requested ''that the agency publish all the PASAs of all the participating motor carriers in advance of the start of the Pilot Program and before any motor carriers are granted temporary operating authority.''

FMCSA Response: FMCSA's Authority to Issue Operating Authority. Title 49 U.S.C. 13902(a) directs FMCSA

to grant operating authority to motor carriers that comply with all applicable safety regulations and financial responsibility requirements. As discussed in the ''Legal Basis'' section above, section 6901(a) of the 2007 Appropriations Act requires that before FMCSA may obligate or expend any funds to grant authority for Mexico-domiciled motor carriers to engage in cross-border long-haul operations, it is required to first test granting such authority through a pilot program that meets the standards of 49 U.S.C. 31315(c). By expressly providing for pilot programs in 49 U.S.C. 31315(c), and requiring FMCSA to first test the granting of long-haul authority to Mexico-domiciled motor carriers through a pilot program, Congress clearly contemplated that motor carriers participating in a test meeting the conditions of section 31315(c) would lawfully be granted operating authority under 49 U.S.C. 13902(a). Furthermore, the pilot program satisfies the fundamental statutory standard of equivalent safety protection and all other pilot program requirements. The safety-equivalence standard in section 31315(c) requires that the pilot program be designed to achieve a safety level equal to that prevailing under existing Federal Motor Carrier Safety Regulations (FMCSRs). The pilot program does not relax U.S. regulations for participants. Rather, it simply implements the presidential order lifting geographic limitations on cross-border trucking for a limited number of Mexico-domiciled motor carriers and imposes additional layers of safety monitoring upon those motor carriers. Existing Federal regulations already recognize and accept the Mexican Licencia Federal de Conductor (LFC) as equivalent to the U.S. CDL, (§ 383.23(b) and footnote) and pursuant to these regulations, thousands of LFC holders have driven Mexican trucks into the United States since their adoption in 1992 and continue to do so today. In all other significant respects, U.S. requirements apply with full force to participants in the pilot program. The Agency, by showing that the pilot program satisfies the standard of equivalent safety protection imposed by 49 U.S.C. 31315(c), satisfies the requirements of 49 U.S.C. 13902(a).

Permanent Operating Authority under the Pilot Program. Some commenters seemed to misapprehend the reference to ''pilot program permanent authority'' in the April 13, 2011 notice. That authority is not the same as standard permanent authority; will not continue after the expiration of the pilot program (unless converted into standard permanent authority); and may be revoked at any time if the operator fails to comply with the terms and conditions of the pilot program.

All operating authority granted under the pilot program will be subject to the terms and conditions of the pilot program. Under the pilot program, participating motor carriers will have the opportunity to operate under three successive stages of monitoring. Stage 1 will begin when the motor carrier is issued a provisional operating authority. The motor carrier's vehicles and drivers approved for long-haul transportation will be inspected each time they enter the United States for at least 3 months. This initial 3-month period may be extended if the motor carrier does not receive at least three vehicle inspections. FMCSA will also conduct an evaluation of the motor carrier's performance during Stage 1.

Mexico-domiciled motor carriers may be permitted to proceed to Stage 2 of the pilot program after FMCSA completes an evaluation of the motor carrier's performance in Stage 1. During Stage 2, the motor carrier's vehicles and drivers participating in the pilot program will be inspected at a rate comparable to other Mexico-domiciled motor carriers that cross the United States-Mexico border. The motor carrier's safety data will be monitored to assure the motor carrier is operating in a safe manner. Within 18 months after a Mexico-domiciled motor carrier is issued provisional operating authority, FMCSA will conduct a CR on the motor carrier. If the motor carrier obtains a satisfactory safety rating, has no pending enforcement or safety improvement actions, and has operated under provisional authority for at least 18 months, the provisional operating authority will become permanent, moving the motor carrier into Stage 3.

Stage 3 of the pilot program includes participating Mexico-domiciled motor carriers that have successfully operated for an 18-month monitoring period, have a satisfactory safety rating from a CR, and have no pending enforcement or safety improvement actions. Motor carriers that advance to Stage 3 of the pilot program will operate under permanent operating authority under, and fully subject to the requirements of, the pilot program. Granting this permanent operating authority under the pilot program does not restrict the Agency's authority to remove from the program any motor carrier that fails to comply with terms and conditions of the pilot program. Under 49 U.S.C. 31315, FMCSA may revoke participation in the pilot program of a motor carrier, CMV, or driver for failure to comply with the terms and conditions of the pilot program.

The successive stages in the pilot program are intended to be consistent with the Agency's regulations promulgated in 2002 related to Mexico-domiciled motor carriers operating beyond the border commercial zones (49 CFR part 365, subpart E). Those regulations provide for a Mexico-domiciled motor carrier to be initially granted provisional operating authority and be subject to increased monitoring. The authority, by definition, is provisional because it will be revoked if the motor carrier is not assigned a satisfactory safety rating following a CR conducted during an 18-month safety monitoring period established in the regulations. Under these regulations, if, at the end of 18-months of monitoring the motor carrier's most recent safety rating is satisfactory and the motor carrier does not have any pending enforcement or safety improvement actions, the Mexico-domiciled motor carrier's provisional operating authority becomes permanent. However, this authority is still subject to revocation as detailed above. Section 6901 requires FMCSA to first test the granting of operating authority for long-haul operation by Mexico-domiciled motor carriers through a pilot program. An important component and improvement of this pilot program is that by using the progressive stages of monitoring, the Agency is able to test the full range of its regulations while effectively monitoring Mexico-domiciled motor carriers to ensure the safety of long-haul operations and that such operations are conducted in compliance with all applicable laws and regulations.

In accordance with section 6901(c), within 60 days after the conclusion of the pilot program, the OIG is required to review the program and submit to Congress a final report addressing whether FMCSA has established sufficient mechanisms to determine whether the pilot program is having any adverse effects on motor carrier safety, and whether Federal and State monitoring and enforcement activities are sufficient to ensure that participants in the pilot program are in compliance with all applicable laws and regulations. Only at the conclusion of the pilot program will Mexico-domiciled motor carriers that participated in the pilot program and advanced to the Stage 3 permanent authority in the pilot program be eligible to convert their pilot program permanent authority to standard permanent authority. FMCSA has not yet developed the procedures for such conversions, but anticipates the

procedures will establish an administrative process that would occur once the pilot program ends.

Granting of Provisional Operating Authority. The Agency may have caused some confusion in the April 13, 2011, notice when it stated that ''the Agency will publish a summary of the application as a provisional grant of authority in the FMCSA Register.'' FMCSA will review and act on applications for authority in the pilot program in accordance with applicable regulations. The Agency's rules governing applications for authority are codified in 49 CFR part 365. FMCSA is required under its regulations to publish a summary of each application for motor carrier operating authority, regardless of the applicant's country of domicile, as a preliminary grant of operating authority for public notice in the FMCSA Register (49 CFR 365.109(b) and 365.507(d)). For prospective pilot program participants, such publication will occur only after the motor carrier successfully completes the PASA and FMCSA approves the application. Such publication of the application as a preliminary grant of authority in the FMCSA Register is not an issuance of temporary authority, but a notice to the public to permit interested parties wishing to oppose the authority to submit a protest to FMCSA. A preliminary grant of authority cannot become effective or active operating authority for a minimum of 10 days after publication. If a motor carrier successfully completes the PASA and FMCSA approves its application, the Agency will publish a summary of the application as a preliminary grant of authority in the FMCSA Register at: *http://li-public.fmcsa.dot.gov/LIVIEW/pkg_html.prc_limain.* To review these notices, select ''FMCSA Register'' from the pull down menu.

The FMCSA emphasizes that the public has the opportunity to comment in response to the FMCSA Register on every operating authority application that the Agency proposes to grant and that motor carriers may not operate during the comment period. Any member of the public may protest a motor carrier's application on the grounds that the motor carrier is not fit, willing, or able to provide the transportation services for which it has requested approval. FMCSA must consider all protests before determining whether to grant provisional operating authority to the motor carrier. The Agency's regulations regarding protests, codified at 49 CFR part 365 subpart B, set forth the procedures for protesting operating authority requests, including requests filed by U.S.- and Canada-domiciled motor carriers.

As required by section 6901(b)(2)(B)(i) of the 2007 Appropriations Act, 2007, FMCSA will also publish in the **Federal Register**, and solicit comment on comprehensive data and information relating to the PASAs of motor carriers domiciled in Mexico that are granted authority in the pilot program to operate beyond the border commercial zones. Therefore, the public has two opportunities to comment on Mexico-domiciled motor carriers' applications: (1) In response to the application summary information posted on the FMCSA Register, and in response to the **Federal Register** notice required by section 6901(b)(2)(B)(i) of the 2007 Appropriations Act. Provisional authority will not be granted until these processes and their respective notice periods are complete.

While FMCSA will publish information on the results of the PASA in the **Federal Register** for public comment for each motor carrier before granting the motor carrier provisional operating authority, FMCSA is not able to publish the results of the PASAs for all motor carriers that may ultimately apply to participate in the pilot program before the program begins. FMCSA will have no way of knowing at the beginning of the pilot program all of the motor carriers that may decide to apply to participate in the program during its three year duration and, therefore, could not publish the results of all PASAs before beginning the pilot program. Additional motor carriers that apply to participate in the pilot program after it begins will also be subject to PASAs, and the results of those PASAs will be published in the **Federal Register** before any such motor carrier is granted provisional operating authority.

2. Pilot Program Improperly Exempts Mexico-Domiciled Motor Carriers From Safety Laws and Regulations

OOIDA contends that accepting Mexican standards and regulations in lieu of U.S. statutes and regulations results in an exemption, and that FMCSA has failed to follow its authority and regulations for exemptions. OOIDA stated that, ''Excusing compliance with U.S. regulations for the duration of its pilot program certainly qualifies as 'temporary regulatory relief' for a person or class of persons subject to those regulations.'' OOIDA asserts that this, therefore, requires the Agency to follow the procedures for granting exemptions from U.S. regulations and deprives interested parties procedural protections.

FMCSA Response: This pilot program does not provide Mexico-domiciled motor carriers with exemptions from any statutory requirements or any of the Agency's regulations or make them eligible for any existing exemption. To the contrary, motor carriers participating in the program will be subject to existing statutory requirements and regulations, including the regulations mandating the PASA (49 CFR 365.507(c)). Additionally, because no exemptions from or new approaches to statutory requirements and safety regulations are being employed in the pilot program, the level of safety oversight that will be achieved in the program is the same or greater than would otherwise be achieved if Mexico-domiciled motor carriers were granted authority to operate beyond the border commercial zones outside of the context of a pilot program.

As to the issue of driver's license equivalency, the Agency has long recognized Mexico's LFC as equivalent to the CDL issued by U.S. State driver licensing agencies that follow the Federal standards under 49 CFR Parts 383 and 384. The Mexican LFC is recognized as a valid substitute for the CDL and is the basis for a signed international agreement under which the United States and Mexico have recognized each other's commercial driver's licenses, a decision that was upheld on judicial review (*Int'l. Brotherhood of Teamsters* v. *Peña,* 17 F.3rd 1478 (DC Cir. 1994)). The Agency has also long recognized Mexico's physical qualification standards. These are not exemptions, but well-established alternative means of meeting U.S. standards that pre-date the pilot program. Indeed, every day, thousands of Mexican drivers safely operate Mexico-domiciled trucks in the United States under these rules.

Neither the Government of Mexico nor any Mexico-domiciled motor carrier has requested that FMCSA consider granting an exemption from U.S. safety requirements for participating motor carriers, and the Agency is not seeking public comment on any forms of regulatory relief. The continued honoring of reciprocity agreements concerning the acceptance of the Mexican LFC and the medical certification should not be construed as granting regulatory relief. Nor is the allowance of specimen collections on the Mexican side of the border, in accordance with U.S. requirements, a form of regulatory relief.

All tests musts must be performed in accordance with the Department's controlled substances and alcohol testing regulations (49 CFR part 40),

which require that specimens be processed at U.S. laboratories certified to conduct such tests.

3. Equivalency of United States-Mexico Laws and Regulations Governing Safety

Advocates, Teamsters, the Coalition and OOIDA all challenged the equivalency of U.S. and Mexican safety laws. Advocates asserted that ''[r]egulatory differences that affect vehicle operation must be reconciled before commencement of Pilot Program.'' Advocates questioned the equivalence of CDLs, disqualification violations, and drug testing.

Several commenters requested clarification of the Agency's system to monitor performance of Mexico-licensed drivers and expressed concerns about the accuracy and completeness of the Mexican LFC and Mexican State license information.

Teamsters also noted that there are no drug testing laboratories in Mexico that are certified by the U.S. Department of Health and Human Services. OOIDA and Teamsters both requested additional information regarding the training regime for Mexican personnel to follow U.S. procedures for drug and alcohol testing collection and chain of custody.

Teamsters noted that the medical qualification standard for vision is different in Mexico than in the United States, as Mexico requires red-vision only. OOIDA encouraged the Agency to provide additional information on the Mexican medical certification requirements.

Multiple commenters asked how information about violations in personal vehicles in Mexico would be obtained and used by FMCSA.

OOIDA and Advocates both believe that FMCSA has an obligation to post more information about the equivalent laws and regulations and to provide copies of the Mexican regulations in English.

FMCSA Response: CDLs. As noted above, in 1991, the Secretary and his counterpart in Mexico entered into an agreement on the matter of driver license reciprocity. The agreement is in the form of a memorandum of understanding (MOU) and was reproduced as Appendix A to a final rule issued in 1992 by FMCSA's predecessor agency, the Federal Highway Administration (FHWA). (*Commercial Driver's License Reciprocity with Mexico,* 57 FR 31454 (July 16, 1992)). The primary purpose of the MOU was to establish reciprocal recognition of the CDL issued by the States to U.S. operators and the LFC issued by the government of the United Mexican States (*i.e.,* by the national government of Mexico, not by the individual Mexican states). In light of the agreement, the FHWA determined that an LFC meets the standards contained in 49 CFR part 383 for a CDL. (49 CFR 383.23(b)(1) and footnote) FHWA also stated in the July 16, 1992 final rule:

> It should be noted that Mexican drivers must be medically examined every 2 years to receive and retain the Licencia Federal de Conductor; no separate medical card [certificate] is required as in the United States for drivers in interstate commerce. As the Licencia Federal de Conductor cannot be issued to or kept by any driver who does not pass stringent physical exams, the Licencia Federal de Conductor itself is evidence that the driver has met medical standards as required by the United States. Therefore, Mexican drivers with a Licencia Federal de Conductor do not need to possess a medical card while driving a CMV in the United States.

(57 FR 31455)

The Agency's determination that a Mexico-domiciled driver with an LFC does not need to possess a separate medical certificate is based on the fact that the medical examination necessary to obtain the LFC meets the standards for an examination by a medical examiner in accordance with FMCSA regulations, and would therefore meet the requirements of 49 U.S.C. 31136(a)(3).

While FMCSA recognizes that U.S. CDL regulations have been amended since 1991, those changes relate almost exclusively to the types of offenses that would result in disqualification of licenses and to the administration of the licensing program (*i.e.,* how information is reported and shared among the States). There have been no major changes to the U.S. knowledge and skills testing until issuance of a May 9, 2011 final rule implementing the CDL Learner's Permit processes titled, ''Commercial Driver's License Testing and Commercial Learner's Permits Testing,'' (76 FR 26854). States have 3 years to implement the provisions of that rule. The United States will address the changes in U.S. CDL regulations with Mexico during the updating of the 1991 CDL MOU that is currently underway.

With respect to the changes relating to disqualifying offenses (49 CFR part 383, subpart D), FMCSA is not relying on Mexico's disqualifying offenses. During the PASA, FMCSA will review violation information from a driver's U.S. record, LFC record, and Mexican State license record to determine if the driver is qualified to drive in the United States, based on the current disqualification requirements for a U.S. CDL holder. FMCSA will also review Mexican State license records for violations in a personal vehicle that would result in suspension or revocation in the United States. After the PASA, these sets of records will be reviewed annually by FMCSA to ensure continued compliance.

FMCSA does, however, recognize the concern about the on-going acceptance of the existing CDL MOU. In the Agency's efforts to update the MOU, on February 16, 2011, a delegation of FMCSA and DOT representatives toured SCT's commercial driver's licensing office in Mexico City, Districto Federal, Mexico. The review of the commercial driver's licensing office showed that the LFC is issued in a manner similar to that employed by U.S. State commercial drivers licensing offices. Applicants are required to present documentation to verify their identity and place of residence. Additionally, applicants are required to provide documentation that they have passed the required psycho-physical examination. The drivers licensing office verifies this information by accessing the SCT's medical units' database. Applicants are also required to provide a training certificate from an SCT-certified training school.

On February 17, 2011, a delegation of FMCSA, CVSA, and the American Association of Motor Vehicle Administrators (AAMVA) representatives toured the commercial driver's licensing office in Monterrey, Nuevo Leon, Mexico. The delegation observed the same processes as were seen in Mexico City. In addition, the delegation toured an SCT-certified training school in Monterrey. The tour included a description of the classroom, simulator, maintenance shop, and behind the wheel training. The training school operator described the driver testing procedures.

FMCSA will be undertaking additional site visits to Mexican driver training, testing, and licensing locations prior to beginning the pilot program to review Mexico's on-going compliance with the terms of the current MOU. Reports of these visits will be posted on the FMCSA pilot program Web site at *http://www.fmcsa.dot.gov.*

FMCSA's statement that Mexico-domiciled drivers and motor carriers will be subject to the same standards as U.S. drivers and motor carriers does not mean that U.S. standards must be applied to Mexico-domiciled drivers and motor carriers while operating in Mexico. The Agency does not have authority to apply U.S. standards to driver or motor carrier actions occurring in Mexico, *i.e.,* it has no extraterritorial

jurisdiction to enforce FMCSA rules. If Mexico chooses to suspend or revoke a driver's LFC for violations committed in Mexico, the Licencia Federal Information System (LIFIS) will reflect that fact and FMCSA will refuse to let the driver operate in this country.

All drivers operating CMVs in the United States are subject to the same driver disqualification rules, regardless of the jurisdiction that issued the driver's license. The driver disqualification rules apply to driving privileges in the United States. Any convictions for disqualifying offenses that occur in the United States will result in the driver being disqualified from operating a CMV for the period of time prescribed in the FMCSRs.

In Mexico, in order to obtain the LFC, a driver must meet the requirements established by the Ley de Caminos, Puentes y Autotransporte Federal (Roads, Bridges and Federal Motor Carrier Transportation Act) Article 36, and Reglamento de Autotransporte Federal y Servicios Auxiliares (Federal Motor Carrier Transportation Act) Article 89, which state that a Mexican driver must pass the medical examination performed by Mexico's SCT, Directorship General of Protection and Prevention Medicine in Transportation (DGPMPT). While there is currently no government oversight of the proficiency and knowledge of medical examiners in the United States, the medical examinations in Mexico are conducted by government doctors or government-approved doctors instead of the private physicians who perform the examination on U.S. drivers.

The Agency emphasizes that drivers for Mexico-domiciled motor carriers have been operating within the border commercial zones for years with the medical certification provided as part of the LFC, and the Agency is not aware of any safety problems that have arisen as a result.

In response to the questions regarding how violations in personal vehicles will be handled and the quality of the Mexican databases, FMCSA notes that it and its Federal and State partners performed 254,397 checks of LFC holders in FY 2010. These LFC checks resulted in detection of a valid license 250,640 times, expired licenses 3,713 times, and disqualified licenses 44 times. While the Mexican State driving records systems vary significantly, FMCSA will be working with the applicant motor carriers, drivers, and SCT to secure valid copies of the State driving records for review.

FMCSA has satisfied the requirement of section 350(c)(1)(G) concerning an accessible database containing sufficiently comprehensive data to allow safety monitoring of motor carriers operating beyond the border commercial zones and their drivers. Looking specifically at driver monitoring, in 2002 FMCSA established a system known as the Foreign Convictions and Withdrawals Database (FCWD), which serves as the repository of the U.S. conviction history on Mexican CMV drivers. The system allows FMCSA to disqualify such drivers from operating in the United States if they are convicted of disqualifying offenses listed in the FMCSRs.

The FCWD is integrated into the Agency's gateway to the Commercial Driver's License Information System (CDLIS), allowing enforcement personnel performing a Mexican CDLIS-check to simultaneously query both the Mexican LIFIS and the FCWD. The response is a consolidated driver U.S./Mexican record showing the driver's status from the two countries' systems.

The States also have the capability to forward U.S. convictions of LFC holders, and other drivers from Mexico, to the FCWD via CDLIS. To accomplish this, the States implemented changes to their information systems and tested their ability to make a status/history inquiry and forward a conviction to the FCWD. All States except Oregon, (which does not electronically transmit any convictions) and the District of Columbia (which does not electronically transmit convictions of Mexico-domiciled CDL drivers) have successfully tested electronically forwarding convictions on Mexico-domiciled CMV drivers. Both jurisdictions, however, can manually transmit the information to FMCSA for uploading into the system.

As of May 31, 2011, the border States transmitted 46,065 convictions to the FCWD between 2002 and 2011. This averages 5,118 per year. Of that number, 41,118 were transmitted electronically and 4,947 were manually entered into the system. It should be noted that only 242 of these convictions were for major traffic offenses (as listed in 49 CFR 383.51(b)), and 1,709 were for serious traffic offenses (as listed in 49 CFR 383.51(c)). In comparison, between May 2010 and May 2011, the States transmitted 186,184 U.S. driver convictions through CDLIS.

The conviction data shows that the system is working, and States can both transmit the conviction data on Mexico-domiciled drivers and query the system to retrieve conviction data. FMCSA and its State partners have experience from providing safety oversight for Mexico-domiciled drivers currently operating within the border commercial zones. It is reasonable to believe that the small group of drivers who would be involved in the pilot program will be no more difficult to monitor than the much larger population of Mexico-domiciled drivers currently allowed to operate within the border commercial zones.

As an additional safety enhancement, compared to the previous demonstration project, the Agency will review the Mexican State license of a driver for violations that would result in a revocation or suspension in the United States. This will include violations in personal vehicles that would impact a CDL in the United States.

Drug and Alcohol Testing. Regarding the protocols for collection of specimens for drug and alcohol testing, FMCSA clarifies that Mexico is using procedures equivalent to those established by DOT regulations. A copy of the 1998 MOU between DOT and the Government of Mexico is included in the docket for this notice.

Urine specimens for controlled substances testing must be collected in a manner consistent with 49 CFR part 40, Procedures for Transportation Workplace Drug and Alcohol Testing Programs. During the 2007–2009 demonstration project, an independent evaluation panel conducted its own assessment of the urine collection procedures at four collection facilities in Mexico. The panel concluded that Mexico has a collection program with protocols that are at least equivalent to U.S. protocols found in 49 CFR part 40. Because there are no U.S.-certified laboratories in Mexico, Mexico-domiciled motor carriers must comply by ensuring that the specimens are tested in a U.S.-certified laboratory. The participants in the 2007–2009 demonstration project all had specimens tested in U.S.-certified laboratories located in the United States.

In the new pilot program, urine collection may continue to take place in Mexico. The specimens will be processed in accordance with U.S. requirements. Drivers who refuse to report to the collection facility in a timely manner will be considered to have refused to undergo the required random test, and the motor carrier would be required to address the issue in accordance with FMCSA's Controlled Substances and Alcohol Use and Testing regulations (49 CFR part 382).

Currently, Mexico-domiciled drivers operating within the border commercial zones use this approach to comply with the random testing requirements of 49 CFR 382.305. The random selection of drivers must be made by a scientifically valid method; each driver selected for

testing must have an equal chance (compared to the motor carrier's other drivers operating in the United States) of being selected, and drivers must be selected during a random selection period. Also, the tests must be unannounced, and the dates for administering random tests must be spread reasonably throughout the calendar year. Employers must require that each driver who is notified of selection for random testing proceed to the test site immediately.

In addition, through the PASA, the Agency will determine whether the motor carrier has a program in place to achieve full compliance with the controlled substances and alcohol testing requirements under 49 CFR parts 40 and 382. The ability of the border commercial zone motor carriers to follow these procedures further demonstrates that Mexico-domiciled motor carriers are capable of satisfying the Agency's drug and alcohol testing requirements. Based on FMCSA's experience enforcing the controlled substances and alcohol testing requirements on border commercial zone motor carriers, the Agency believes long-haul Mexico-domiciled motor carriers can and will comply with the random testing requirements, especially given that some of the anticipated participants in the pilot program may already have authority to conduct operations within the border commercial zones.

The Agency's experience in this area and the drug collection facility reviews performed during the previous demonstration project make us confident that testing is being conducted correctly. In addition, the Agency will be conducting collection facility reviews during the pilot program to verify specimens are being collected correctly.

Medical Qualifications. FMCSA has compared each of its physical qualifications standards with the corresponding requirements in Mexico and continues to believe acceptance of Mexico's medical certificate is appropriate, especially given that some Mexican medical standards are more stringent than their U.S. counterparts.

For example, one of the areas where Mexico's standards exceed those of the U.S. is in Body Mass Index (BMI) and the association between BMI and certain medical conditions that could increase the risk of a driver having difficulty operating a CMV safely. Mexico's regulations include certain limits on BMI, as it relates to medical conditions related to obesity, whereas FMCSA's regulations do not include such requirements.

Another area where Mexico's physical examination and qualifications process is more rigorous is vision testing. Mexico's examination process includes a measurement of intraocular pressure, a test that may be indicative of glaucoma, a disease characterized by a pattern of damage to the optic nerve. FMCSA's regulations do not require a measurement of intraocular pressure.

Finally, the medical certification for an LFC is part of Mexico's licensing process for commercial drivers. This means the license is not issued or renewed unless there is proof the driver has satisfied the physical qualifications standards. This is not the case in the United States, where medical certification is not currently posted on the CDL record. FMCSA has issued regulations to move towards this level of oversight (''Medical Certification Requirements as Part of the CDL,'' final rule, published at 73 FR 73096, December 1, 2008), but Mexico has more stringent requirements in effect at this time.

There are some areas where FMCSA's requirements are more stringent. Specifically, FMCSA requires drivers be capable of distinguishing between red, green and yellow, while Mexico limits the color recognition requirement to red. Additionally, the U.S. medical examination has standards for both systolic and diastolic blood pressure readings while Mexico only has a standard on the systolic reading. A finding of equivalency, however, does not require that both country's standards be identical. Here, it was FMCSA's considered judgment that these differences would not diminish safety and that, therefore, the Mexican requirements are equivalent to U.S. requirements.

FMCSA has prepared a table comparing the United States' and Mexico's physical qualifications standards. A copy of the table is provided in the docket for this notice.

To assist in the review of Mexican regulations, FMCSA has added English versions of the regulations to the docket for this notice. This includes the Mexican regulations for the Transportation Preventive Medicine Service Regulations, the Federal Motor Carrier Transportation and Auxiliary Services Regulations, and the Federal Roads, Bridges, and Motor Carrier Transportation Act.

4. Reciprocity With Mexico

The CTA, ATA, and numerous individual commenters stated that NAFTA reciprocity could not be achieved because of the current state of violence and corruption in Mexico. OOIDA also provided U.S. State Department alerts to travelers and instruction to U.S. government employees as documentation of the inability of Mexico to provide ''simultaneous and comparable'' authority and access.

The Teamsters elaborated that ''[s]ection 6901 limits funds to grant authority to Mexican-domiciled motor carriers to operate beyond the commercial zones to the extent that 'simultaneous and comparable authority to operating within Mexico is made available to motor carriers domiciled in the United States.' '' Teamsters further stated that ''[i]t is very clear that the safety of U.S. drivers traveling into Mexico cannot be ensured, and therefore simultaneous and comparable authority is not made available to U.S. motor carriers under the pilot program.''

Ron Cole pointed out that a Congressional Research Report dated February 1, 2010, notes ''[a]s of this writing the Mexican government has not begun accepting applications from U.S. trucking companies for operating authority in Mexico.'' The Texas Department of Motor Vehicles suggested that FMCSA provide detailed information on Mexico's regulatory requirements to the States and U.S. motor carriers that express an interest in participating in the program.

The ATA also endorsed allowing Mexico-domiciled motor carriers with U.S. investors to join the program as Mexico-domiciled motor carriers.

FMCSA Response: In response to the comments about reciprocity for U.S. motor carriers, FMCSA will continue to work closely with the Mexican government to ensure that U.S.-domiciled motor carriers are granted reciprocal authority to operate in Mexico during the pilot program. Mexico will publish rules for its current program before initiation of the program. Both English and Spanish versions of SCT's draft rules have been added to the docket for informational purposes.

In addition, the Department of Transportation is entering into a MOU with Mexico's SCT that requires that Mexico provide reciprocal authority.

The Agency will also work with the U.S. trucking industry to facilitate the exchange of information between the Mexican government and U.S. trucking companies interested in applying for authority to enter Mexico under this pilot program.

Both Teamsters and OOIDA commented on the ongoing violence in Mexico, and that it negatively impacts the possibility of U.S. motor carriers entering Mexico. Both cite to the U.S.

State Department travel advisory, and in turn point to a portion of section 6901 that states that ''simultaneous and comparable authority to operate within Mexico is made available to motor carriers domiciled in the United States.'' The reference to the section 6901 language speaks to the ability of U.S. motor carriers to receive comparable operating authority from Mexico's SCT. The MOU between DOT and SCT provides for reciprocal access to each country. The SCT has issued proposed rules outlining procedures for U.S. motor carriers to operate in Mexico. They will have the ability to apply for authority and operate within Mexico similar to that of Mexico-domiciled motor carriers in the United States. Therefore, the statutory requirement has been met. It is an independent business decision on the part of motor carriers as to whether or not they wish to apply for authority, or use it once obtained. Hundreds of companies are currently operating in the border region, and four U.S. motor carriers from the 2007 demonstration project continue to operate into Mexico. (Whereas the United States required Mexico-domiciled motor carriers participating in the 2007 demonstration project to relinquish their operating authority when the project was terminated, Mexico permitted the U.S.-domiciled motor carriers holding reciprocal authority to continue their operations in Mexico.)

OOIDA makes the claim that the violence in Mexico is a violation of the NAFTA as a nullification and impairment of U.S. motor carrier rights to engage in cross-border trade in services under Chapter 12 of the NAFTA. OOIDA contends that, ''Federal, state and local governments within Mexico are seen by many to be complicit'' in the drug-related violence. OOIDA quotes Annex 2004 of the NAFTA ''Nullification and Impairment'' language, including ''* * * being nullified or impaired as a result of *the application of any measure* that is not inconsistent with this Agreement * * *'' (emphasis added). The violence of the drug cartels, according to OOIDA, impairs U.S. motor carriers wishing to operate in Mexico. The fundamental error with this reasoning is that no measure has been put in place by the Government of Mexico that would prohibit U.S. motor carriers from doing business in Mexico, or would put U.S. motor carriers at such a competitive disadvantage that they are impaired. In order for Annex 2004 to apply, a State actor, such as SCT, must put in place ''measures not inconsistent with'' cross-border trade in services. It could constitute a violation of the NAFTA if a Mexican agency put in place restrictions on U.S. motor carriers that would on its face not be discriminatory but have the ultimate effect of denying the motor carriers the benefits they reasonably expected under Chapter 12. That, however, is not the case here. The application for authority and using it to operate into Mexico requires several business decisions on the part of the motor carrier, and it is ultimately the motor carrier's decision to operate into Mexico, as much as it would be for a motor carrier to expand its business from short-haul to long-haul.

FMCSA also notes that while Mexico has not begun accepting applications from U.S. trucking companies for operating authority in Mexico, neither has FMCSA begun accepting applications from Mexico-domiciled motor carriers for participation in the pilot program. Mexico, like the United States, is updating its application procedures for U.S. motor carriers to operate into Mexico. Following the publication of this notice, FMCSA will begin accepting applications from Mexico-domiciled motor carriers to participate in the pilot program. Mexico will begin accepting applications from U.S. motor carriers to operate in Mexico soon thereafter. When Mexico's new processes are finalized, FMCSA will post information regarding those requirements on our Web page related to this pilot program so that States and industry are aware of the requirements. In any case, the United States will not grant authority to operate beyond the border commercial zones to any Mexico-domiciled motor carriers under this pilot program unless and until Mexico is ready to provide authority to U.S. motor carriers. FMCSA also uses this notice to clarify that Mexico-domiciled motor carriers with U.S. investors are eligible to participate in the pilot program.

5. Pilot Program Requirements

The Agency received comments from the OOIDA, Teamsters, Advocates, and the Coalition regarding the requirements of FMCSA's pilot program authority.

OOIDA noted that, under 49 U.S.C. 31315(c)(2), a pilot program must include safety measures designed to achieve a level of safety that is ''equivalent to, or greater than'' the required level of safety. OOIDA also faulted the proposal for not elaborating on the countermeasures to protect the public health and safety of study participants and the general public.

FMCSA Response: The FMCSA and its State partners will ensure compliance with the requirements of the pilot program the same way the Agency and the States ensure that Mexico-domiciled motor carriers operating in and beyond the border commercial zones comply with the applicable safety regulations. There are currently 6,861 motor carriers with authority to operate within the border commercial zones and an additional 1,063 motor carriers with Certificates of Registration to operate beyond the commercial zones. FMCSA and the States have a robust safety oversight program for Mexico-domiciled motor carriers that are currently allowed to operate CMVs in the United States. In FY 2010, FMCSA and its State partners conducted over 256,000 commercial vehicle inspections on vehicles operated by Mexico-domiciled motor carriers in the border commercial zones. Further, in order to assist in ensuring compliance, FMCSA imposed the following pre-requisites for Mexico-domiciled motor carriers to participate in the pilot program: (1) The application for long-haul operating authority, which includes requirements for proof of a continuous valid insurance with an insurance company licensed in the United States, in contrast to trip insurance used by motor carriers that operate solely within the border commercial zones; (2) successful completion of the PASA prior to being granted provisional authority; (3) the continuous display of a valid CVSA decal; and (4) a special designation in their USDOT Numbers to allow enforcement officials to readily distinguish between vehicles permitted to operate solely within the border commercial zone and those authorized to operate beyond the border commercial zones.

In addition, section 350 and 49 CFR 385.707 require that a CR be conducted within 18 months of the motor carrier being granted provisional operating authority. In the context of the pilot, FMCSA will prioritize long-haul Mexico-domiciled motor carriers for CRs based on a number of factors, such as the motor carrier's safety performance as measured through roadside inspections and crash involvement and the Agency's Safety Measurement System.

The vehicles and drivers will be monitored through data collected from electronic monitoring devices with GPS. In addition, the drivers' complete driving records will be reviewed in advance of participation and then annually thereafter. Also, during the first stage, the vehicles and drivers will be subjected to more inspections.

The FMCSA and its State partners have for many years provided safety

oversight under the same regulations for a much larger population of Mexico-domiciled motor carriers operating in U.S. border commercial zones and motor carriers with Certificates of Registration than the group that will participate in the pilot program. As a result, the Agency has a well-established and effective enforcement program in place to ensure that participants comply with the terms and conditions of the program. Moreover, full compliance with existing U.S. safety regulations and domestic point-to-point transportation prohibitions will be required, as is the case with Mexico-domiciled motor carriers operating in the border commercial zones and certificated motor carriers already operating beyond the border commercial zones.

As discussed in this section, FMCSA has taken necessary steps to comply with the requirement to provide an equivalent or greater level of safety, and countermeasures are therefore not required.

6. PASA Requirements

Commenters, including Teamsters and Advocates, recommended that information about the PASAs be posted in the **Federal Register** rather than the FMCSA Register.

Teamsters recommended that the PASA also include a spot check of vehicles other than those to be used in the long-haul program to gather more information on the carrier's operations.

OOIDA, Advocates and Teamsters requested additional information on the Agency's standards for evaluating English language proficiency and one association submission indicated the English language screening and should be a component of the initial screening.

Advocates requested that the violation histories of applicant motor carriers, and their driver convictions records in both Mexico and the U.S. should be disclosed in the **Federal Register** publication as part of the PASA information disclosure. OOIDA requested additional information about participating motor carrier's past operations within the United States.

The IRP requested that the Agency use the PASA as an opportunity to reiterate the requirements for IRP and IFTA registrations.

OOIDA also recommended that PASAs be conducted again on motor carriers that participated in the previous demonstration project to ensure they are still safe motor carriers.

FMCSA Response: There appears to have been some confusion about where the PASA information will be published. The results of the PASAs will be posted in the **Federal Register**. This was where the PASA information was posted during the previous demonstration project, and FMCSA will follow this protocol again in this pilot program. The operating authority application information will also continue to be posted in the FMCSA Register as required by applicable regulations.

If the motor carrier has passed the PASA, FMCSA will publish the motor carrier's request for authority in the FMCSA Register. The FMCSA Register can be viewed by going to: *http://li-public.fmcsa.dot.gov/LIVIEW/pkg_html.prc_limain* and then selecting ''FMCSA Register'' from the drop-down box in the upper right corner of the screen. Any member of the public may protest the motor carrier's application on the grounds that the motor carrier is not fit, willing, or able to provide the transportation services for which it has requested approval. FMCSA will consider all protests before determining whether to grant provisional operating authority. Under FMCSA regulations, all motor carriers receive provisional new entrant authority for 18 months after receiving a USDOT Number and are subject to enhanced safety scrutiny during the provisional operating period.

Regarding the Teamster's request that additional vehicles in the motor carrier's fleet be inspected during the PASA, the Agency points out that all available vehicles that are used in U.S. operations will be subject to review during the CR. Additionally, vehicles operated in the U.S. by Mexico-domiciled motor carriers also regularly cross the border, where the vehicle inspection rate is 13 times higher than that of vehicles in the interior of the U.S. As a result, the Agency does not believe it is necessary to inspect vehicles other than the participating vehicles during the PASA.

FMCSA will check participating Mexico-domiciled drivers during the PASA through an interview in English. The interview will include a variety of operational questions, which may include inquiries about the origin and destination of the driver's most recent trip; the amount of time spent on duty, including driving time, and the record of duty status; the driver's license; and vehicle components and systems subject to the FMCSRs. The driver will also be asked to recognize and explain U.S. traffic and highway signs in English.

If the driver successfully completes the interview, FMCSA has confidence that the driver can sufficiently communicate in English to converse with the general public, understand traffic signs and signals in English, respond to official inquiries and make entries on reports and records required by FMCSA.

Regarding Advocates' request that additional information be published about the history of Mexico-domiciled motor carriers and drivers, FMCSA is committed to publishing the results of the PASAs as required by section 6901(b)(2)(B) of the 2007 Appropriations Act. FMCSA will not publish violation data on individual Mexican drivers as protection of their personal privacy. FMCSA, however, will make additional information about all participating motor carriers' past U.S. performance available through its Safety Management System (SMS) as requested by OOIDA.

FMCSA agrees with the IRP's suggestion that information regarding the requirements for registration and fuel taxes be provided during the PASA. The Agency is revising its PASA procedures to include this information.

In regard to motor carriers that participated in the previous demonstration project that choose to apply to participate in the pilot program, it has always been in FMCSA's plan that PASAs will be completed on these motor carriers. FMCSA recognizes that there may have been changes in the motor carrier's operations since the demonstration project ended in 2009 and that a current PASA is needed.

7. Credit to Demonstration Project Participants

Most commenters did not agree with the Agency's plans to give credit to motor carriers that participated in the demonstration project for the amount of time they operated safely. The Teamsters specifically contended that providing credit to previous participants was a violation of section 6901.

FMCSA Response: It appears that there was some confusion about how these motor carriers, if they chose to participate in the new pilot program, would enter the program, and how their safety would be evaluated. As noted above, it has always FMCSA's plan and responsibility to conduct PASAs on all motor carriers applying for authority under the pilot program including motor carriers that participated in the prior demonstration project. As a result, the motor carrier's safety management controls will be assessed again in advance of participation. The only distinction that is being made for motor carriers that previously participated in the demonstration project is to give them credit for the amount of time they operated under the project in completing the 18 months of provisional authority before being eligible to

advance to Stage 3 in this pilot program. FMCSA believes this is consistent with section 6901 because the previous demonstration project was subject to the same pilot program statute and regulations. While it was ultimately determined that the previous project did not have sufficient participation to allow for a statistically valid demonstration that Mexico-domiciled motor carriers as a whole could comply with U.S. safety standards and this program has added additional safeguards, reports from both the OIG and the Independent Panel documented that motor carriers in the previous program had safety records that were comparable or better than the U.S. fleet averages.

As a result, if a motor carrier from the demonstration project chooses to apply to participate in the pilot program, it will be subject to the security check by the Department of Homeland Security, PASA, financial responsibility, CVSA decal, and CR requirements. If a motor carrier operated for 5 months under the demonstration project, it would then only need to operate safely for an additional 13 months under the pilot program before being eligible to advance to Stage 3 in the program.

8. Use of Electronic Monitoring Devices and Compliance With Hours-of-Service Requirements

The majority of commenters did not support FMCSA funding the installation of electronic monitoring devices on Mexican trucks participating in the pilot program. Representative Peter A. DeFazio stated that, ''it is outrageous that U.S. truckers, through the Federal fuel tax, will subsidize the cost of doing business for these Mexican carriers.'' Representative Reid J. Ribble articulated his understanding of his colleagues' disapproval of using the Highway Trust Fund to cover the costs of the electronic monitoring devices, but ''recognize[d] that DOT cannot require Mexican motor carriers to cover these expenses because there is no similar requirement for U.S. carriers.''

The BTA pointed out that the hours-of-service requirements for drivers of Mexico-domiciled motor carriers participating in the program must include the driver's on-duty and driving time in Mexico before reaching the Southern border. In addition, Teamsters asserted that electronic monitoring devices do not measure ''on-duty/not driving'' time and, as a result, Mexican drivers need to provide logs and supporting documents.

Several commenters did not understand if the data from the electronic monitoring devices would be processed in real-time or at the conclusion of the program. In addition, there were several questions about who would be reviewing the data.

FMCSA Response: FMCSA developed guidelines for this new pilot program after extensive engagement with members of Congress and other stakeholders to better understand the strengths and weaknesses of the prior demonstration project that ended in March 2009. Using that valuable input, we worked with the Government of Mexico to craft a more robust program. As described in the April 13, 2011, **Federal Register** notice, all participating Mexican trucks will be required to be equipped with electronic monitoring devices with GPS capabilities so that FMCSA is able to monitor the vehicle and use the data to address hours-of-service and domestic point-to-point transportation concerns. Stakeholders felt strongly that FMCSA include this as an element of the new pilot program.

FMCSA will own the monitoring equipment and thereby will have access and control of the data provided by the electronic monitoring devices and GPS units and will be able to customize reports and alerts from the system of the vendor that will collect the data. This proposed approach is necessary to address concerns expressed by members of Congress and others regarding hours-of-service and domestic point-to-point compliance. The most the Agency would spend on electronic monitoring devices for purchase, installation, and monitoring over the life of the 3-year program is $2.5 million—less than 0.1 percent of the costs borne by U.S. firms subject to the tariffs imposed by Mexico in a 12-month period. As a result, we believe this is not only in the public interest to require and provide the electronic monitoring devices, but is also a good investment for the country. Moreover, as stated above, the in-truck equipment will be the property of the United States.

In addition, the electronic monitoring devices that FMCSA will install will have functionality to allow on-duty start and end times to be entered and tracked. As a result, FMCSA will be monitoring on-duty time in Mexico to ensure that drivers comply with FMCSA hours-of-service regulations while operating in the United States. FMCSA agrees, however, that the participating motor carriers will be expected to maintain the appropriate supporting documents for review by FMCSA during the safety and compliance reviews.

It is FMCSA's intention to acquire devices and monitoring software that will allow the Agency to develop alerts and reports of the vehicles and drivers' information. These reports will be reviewed by FMCSA at least weekly to identify compliance issues. If there are any indicators of problems, FMCSA will initiate an investigation. FMCSA expects to use staff to conduct the analysis, but acknowledges that the conversion of the electronic data to a format usable for analysis may require some processing by a third party. Finally, once the pilot program is terminated, the program participants must return the equipment to FMCSA.

9. Federal Motor Vehicle Safety Standards (FMVSS) and Emissions Issues

Commenters on this issue all supported the requirement that the equipment must meet the FMVSS or Canadian Motor Vehicle Safety Standards (CMVSS) at the time of manufacturing. However, Teamsters believe that the Agency's proposal that model years 1996 and newer do not need a label constitutes a waiver and that FMCSA does not have the authority to waive this requirement.

ATA argued that the vehicles should not have to comply with the FMVSS, but instead with the FMCSRs.

ATA and CTA stressed that all equipment operating in the United States must comply with Federal emissions standards. Both also expressed concern about the limited availability of low-sulfur fuels in Mexico and the impact on vehicle emissions.

Werner Enterprises requested clarification on the requirement that the vehicles meet the EPA requirements at the time of manufacturing.

FMCSA Response: Participating Mexico-domiciled motor carriers, the drivers they employ, and the vehicles they operate in the United States must comply with all applicable Federal and State laws and regulations, including those concerning customs, immigration, vehicle emissions, employment, vehicle registration and taxation, and fuel taxation.

Environmental Issues. First, Mexico-domiciled motor carriers operating in the United States must ensure compliance with all applicable Federal and State laws related to the environment. FMCSA has no reason to doubt that its sister Federal and State agencies will enforce their laws and regulations as they apply to long-haul Mexico-domiciled motor carriers, just as they have done for years with respect to the border commercial zone motor carriers as well as U.S.- and Canada-domiciled motor carriers.

Second, FMCSA does not have the statutory authority to enforce Federal

environmental laws and regulations, with the exception of those concerning vehicle noise emissions (49 CFR part 325). The Agency cannot, for example, condition the grant of operating authority to a motor carrier on the motor carrier's demonstration that its truck engines comply with EPA engine standards. FMCSA does not construe section 6901 as expanding the scope of the Agency's regulatory authority into environmental regulation or any other new area of regulation. Section 6901 makes no mention of environmental regulation, and FMCSA construes the reference to ''measures * * * to protect public health and safety'' in section 6901(b)(2)(B)(ii) of the 2007 Appropriations Act as within the context of the scope of the Agency's existing statutory authority. Moreover, because FMCSA is a safety rather than an environmental regulatory agency, the pilot program is appropriately focused on evaluating the safety of long-haul Mexican truck operations in the United States, consistent with the scope of 49 U.S.C. 31315(c). However, vehicle data is being collected to assist with determining the potential environmental impacts of the pilot program (and for any further actions concerning the border) in accordance with the National Environmental Policy Act of 1969 (NEPA) and the Council on Environmental Quality's (CEQ) NEPA implementing regulations (40 CFR part s1500–1508) and FMCSA's NEPA Order 5610.1 as this program is not exempt from NEPA review.

Third, the Agency is conducting an Environmental Assessment (EA) in accordance with NEPA, CEQ implementing regulations, and FMCSA's NEPA Order 5610.1 to examine the potential impacts of this pilot project on the environment. It is important to note that the EA is limited to the environmental impacts of this particular pilot project. FMCSA will announce availability of the draft Environmental Assessment in a separate **Federal Register** notice and place a copy in the docket for this rulemaking.

Finally, EPA, in partnership with Mexico and other governments on both sides of the border, has conducted numerous diesel emissions reduction projects. These include vehicle testing, monitoring, and tracking, diesel retrofitting, accelerated use of ultra-low sulfur diesel fuel, and anti-idling programs. In addition, the State of California regulates particulate matter emissions from trucks through roadside emissions testing conducted throughout the State, including in its border commercial zones. California has also issued regulations requiring truck engines, including those in Mexican trucks, to have proof that they were manufactured in compliance with the EPA emissions standard in effect on the date of their manufacture and will be able to conduct inspections of these vehicles while they are in California. Motor carriers are subject to penalties for the violation of these regulations. In addition, FMCSA considers these issues in its NEPA review for the pilot program.

Regarding the availability of low sulfur fuels, it is our understanding that low sulfur fuels are available in the border areas and large cities, so access should not limit participation in the project.

FMVSS Compliance. With regard to concerns about compliance with the FMVSSs, the Agency already requires Mexico-domiciled motor carriers to certify on their applications for operating authority that CMVs used in the United States meet the applicable FMVSSs in effect on the date of manufacture. While there is no requirement that the vehicles display an FMVSS certification label, the Agency believes the concerns about displaying a certification label have been adequately addressed by the Department through a notice-and-comment rulemaking proceeding.

On March 19, 2002, FMCSA and NHTSA published four notices requesting public comments on regulations and policies directed at enforcement of the statutory prohibition on the importation of CMVs that do not comply with the applicable FMVSSs. The notices were issued as follows: (1) FMCSA's notice of proposed rulemaking (NPRM) proposing to require motor carriers to ensure their vehicles display an FMVSS certification label (67 FR 12782); (2) NHTSA's proposed rule to issue a regulation incorporating a 1975 interpretation of the term ''import'' (67 FR 12806); (3) NHTSA's draft policy statement providing that a vehicle manufacturer may, if it has sufficient basis for doing so, retroactively certify a motor vehicle complied with all applicable FMVSSs in effect at the time of manufacture and affix a label attesting this (67 FR 12790); and 4) NHTSA's proposed rule concerning recordkeeping requirements for manufacturers that retroactively certify their vehicles (67 FR 12800).

After reviewing the public comments in response to those notices, FMCSA and NHTSA withdrew their respective proposals on August 26, 2005 (70 FR 50269). NHTSA withdrew a 1975 interpretation in which the agency had indicated that the Vehicle Safety Act is applicable to foreign-based motor carriers operating in the United States. Accordingly, it is the Department's position that the FMVSSs do not obligate foreign-domiciled trucks engaging in cross-border trade to bear a certification label. Although FMCSA withdrew its NPRM, the Agency indicated that it would continue to uphold the operational safety of CMVs on the nation's highways, including that of Mexico-domiciled CMVs operating beyond the United States-Mexico border commercial zones, through continued vigorous enforcement of the FMCSRs, many of which cross-reference specific FMVSSs.

FMCSA explained in its withdrawal notice that Mexico-domiciled motor carriers are required under 49 CFR 365.503(b)(2) and 368.3(b)(2) to certify on the application form for operating authority that all CMVs they intend to operate in the United States were built in compliance with the FMVSSs in effect at the time of manufacture. These vehicles will be subject to inspection by enforcement personnel at U.S.-Mexico border ports of entry and at roadside inspection sites in the United States to ensure their compliance with all applicable FMCSRs, including those that cross-reference the FMVSSs.

For vehicles lacking a certification label, enforcement officials could, as necessary, refer to the VIN (vehicle identification number) in various locations on the vehicle. The VIN will assist inspectors in identifying the vehicle model year and country of manufacture to determine compliance with the FMVSSs based on guidance provided by FMCSA. Based on information provided by the Truck Manufacturers Association in a September 16, 2002, letter to NHTSA and FMCSA, FMCSA believes model year 1996 and later CMVs manufactured in Mexico meet the FMVSSs. The Agency continues to believe this information is an appropriate basis for considering whether a vehicle is likely to have been manufactured in compliance with the FMVSSs because most of the members of TMA have truck manufacturing facilities in Mexico that are used to build vehicles for both the United States and Mexico markets.

Therefore, FMCSA continues to use its August 26, 2005 guidance, ''Enforcement of Mexico-Domiciled Motor Carriers' Self-Certification of Compliance with Motor Vehicle Safety Standards,'' which provides technical assistance to Federal and State enforcement personnel on this issue. The guidance indicates that if FMCSA finds, during the PASA or subsequent inspections, that a Mexico-domiciled motor carrier has falsely certified on the

application for authority that its vehicles are FMVSS compliant, that the Agency may use this information to deny, suspend, or revoke the motor carrier's operating authority or certificate of registration or take enforcement action for falsification, if appropriate. A copy of the Agency's guidance is included in the docket referenced at the beginning of this notice.

Although Mexico-domiciled vehicles may be less likely to display FMVSS certification labels, FMCSA believes continued strong enforcement of the FMCSRs in real-world operational settings, coupled with existing regulations and enhanced enforcement measures, will ensure the safe operation of Mexico-domiciled CMVs in interstate commerce. As the Agency stated in the 2005 withdrawal notice, FMCSR enforcement, and by extension the FMVSSs they cross-reference, is the bedrock of these compliance assurance activities. The Agency continues to believe it is not necessary to require participating motor carriers to ensure their CMVs display an FMVSS certification label. Requiring CMVs to have FMVSS certification labels would not ensure their operational safety. The American public is better protected by enforcing the FMCSRs than by a label indicating a CMV was originally built to certain manufacturing performance standards. See 70 FR at 50287.

There appeared to be some confusion about when the vehicles would be checked for FMVSS or CMVSS certification. During the PASA, the Agency will check those vehicles identified for the long-haul trucking program to determine whether the vehicle displays an FMVSS or CMVSS certification label, or whether the vehicle is a 1996 model year or newer truck. Alternatively, if there is no label, the motor carrier may present a certificate or other documentation from the manufacturer confirming that the vehicle was built to the appropriate standard.

FMCSA understands ATA's position that the safety of the participating vehicles should be determined based on compliance with the FMCSRs, rather than the FMVSSs. FMCSA acknowledges that vehicle manufacturers must comply with the FMVSSs at the vehicle manufacturing state and that the vehicles may not meet the FMVSSs after they are placed in service. However, the Agency's inspection of participating vehicles during the PASA, inspections, and CR will confirm compliance with the FMCSRs, as is required by 49 CFR 390.3.

10. Statistical Validity

Teamsters asserted that the Agency's evaluation plan was flawed because the statute requires evaluation based on participants, not the number of inspections.

Advocates challenged the Agency's null hypothesis and asserted that the evaluation plan does not conform to established scientific research methodology.

Advocates also requested additional information on how the rate of violations per type of inspection performed will be calculated. Advocates further requested information on the specific statistical tests or methods of analysis to be used, and suggested that a peer review panel review the study design. Specifically, Advocates noted that ''the elements contained in the pilot program statutory provision under 49 U.S.C. 31315(c) require more specific and detailed information about the experimental design of the Pilot Program than the agency has provided.''

FMCSA Response: Section 31315(c)(2)(C) of title 49, United States Code, requires a pilot program to have a sufficient number of participants to allow for statistically valid findings. Given that the majority of statistical comparisons between the Mexico-domiciled and U.S.-domiciled motor carriers will focus on roadside inspection data, the relevant question becomes whether or not the total number of inspections performed on the pilot program participants will be sufficient to allow for valid statistical comparisons. The Agency believes that the sample size targets presented in the April 13, 2011, **Federal Register** notice will ensure that the number of motor carrier participants will be sufficient for achieving this objective. As discussed in that notice, based on the results of the application and vetting process from previous border demonstration project, the Agency estimates an upper limit for the total number of Mexico-domiciled motor carriers both capable and interested in taking advantage of the NAFTA cross border provisions at 316 motor carriers. Thus, if 46 motor carriers were to participate in the current effort, the sample would represent 15 percent of this population.

The Agency acknowledges, however, that the statistical validity of the findings also hinges upon the representativeness of the study data. For example, if most of the inspection data collected in the pilot program were to come from just a few of the Mexico-domiciled motor carriers, the question of sample bias becomes a legitimate concern when producing survey estimates. To mitigate the effect of this potential bias, the Agency plans to calculate the various violation rates both for the population of program participants as a whole, as well as for individual program participants. Thus, for each metric in question, the violation rates for each of the program participants will be averaged to give an alternate violation rate for the program participant population. This alternate violation rate calculation will help to minimize the effect of inspection data being potentially dominated by a small number of motor carriers. Comparison of the original population violation rate to this alternate violation rate calculation will give the Agency an indication of the magnitude of this problem.

With regard to the United States' obligations under NAFTA, FMCSA does not have reason to deny Mexico-domiciled motor carriers from operating in the United States unless it can demonstrate that the motor carriers pose a safety threat to the American public. Thus, the null hypothesis for the study begins with a presumption that Mexico-domiciled motor carriers are as safe as U.S. motor carriers. The data from the study will be used to determine whether this assumption should be rejected or not. While the term ''null hypothesis'' can be used for any hypothesis set up primarily to see whether it can be rejected, the more common statistical practice is to hypothesize that two methods, populations, or processes are the same and then determine if there is sufficient statistical evidence to reject this null hypothesis. If one can demonstrate definitively from the pilot program data that Mexico-domiciled motor carriers are inherently less safe than U.S. motor carriers, then the Agency would be justified in rejecting this null hypothesis and restricting Mexico-domiciled motor carrier operations in the United States. If, on the other hand, the Agency cannot establish as a fact, there would be no justification for denying these motor carriers full access to our roadways as guaranteed under NAFTA. Had the null hypothesis for the study begun with the assumption that Mexico-domiciled motor carriers were inherently less safe than U.S. motor carriers (as recommended by the commenter), then all non-statistically significant results from the study would imply that Mexico-domiciled motor carriers are less safe than U.S. motor carriers, since this initial assumption would not be rejected. In contrast, the approach taken by FMCSA is a prudent one, and is similar to the scientific approach used

in virtually all medical research examining safety risk. In such studies, the null hypothesis assumes that a particular food, chemical, or activity poses no safety risk, or no safety benefit. In other words, the null hypothesis always assumes that the item or activity in question has absolutely no effect. The results of the study are used to determine whether one can reject this null hypothesis, to identify a clear risk or clear benefit attributable to the item or activity. Additionally, the null hypothesis is supported by the safety data on border commercial zone motor carriers and the Mexico-domiciled motor carriers that participated in the previous demonstration project.

With regard to the Advocates' reference to 49 U.S.C. 31315(c), the Agency believes the commenter's interpretation of this section is incorrect. The section does not speak to the findings of a program or the conclusions to be drawn from them. Rather, the section simply states that a pilot program must be designed to ensure that public safety is not compromised while the study is being conducted. All of the safeguards put in place by the Agency, such as requiring pilot program participants to achieve a specified level of safety performance at various stages of the pilot in order to continue with their participation (as stipulated in the original notice requesting public comment), speak directly to this issue.

On a routine basis, program participant vehicles will be inspected at border crossings and other roadside inspection stations. Additionally, under section 350, each participating motor carrier will, within 18 months of being granted provisional operating authority, be subject to a full CR. During the CR, the Agency plans to inspect both ''program participating'' and ''nonparticipating'' vehicles of a Mexico-domiciled motor carrier that operate in the United States.

Concerning how the violation rates obtained from the study will be used, these rates will be directly compared to similar rates from U.S. motor carriers. Although a motor carrier's crash history is a good predictor of future crashes, given the relatively short time frame of the pilot study, it is anticipated that participating motor carriers will have very few, if any, crashes while operating in the United States. Thus, violation rates based on inspection data will be used to assess the safety performance of each participating motor carrier. This same approach is used to evaluate U.S. motor carriers. For example, six of the seven performance metrics used to assess a motor carrier's safety risk under the Agency's Compliance, Safety, Accountability (CSA) program are based on data collected from the roadside.

Inspection data used in the study will be based on Level 1, 2, and 3 inspections. The Agency anticipates that inspections performed on program participants' trucks will be, on average, as thorough and rigorous as those performed on U.S. motor carriers. For those violations only observable by a Level 1 inspection, such as brake violations, only Level 1 inspection data will be used when making comparisons between program participants and U.S. motor carriers.

The Agency plans to evaluate the safety performance of the Mexico-domiciled motor carriers participating in the pilot project by looking at a variety of metrics and comparing their performance on these metrics with the performance of U.S. motor carriers. All of these metrics represent proportions of some type (proportion of inspections having a particular violation, or the proportion of motor carriers having a particular violation), and, as such, statistical tests designed for comparing proportions from two populations can be used. The metrics to be evaluated are discussed below.

Vehicle Out of Service (OOS) Rate. The vehicle OOS rate will be calculated in two different ways for the Mexico-domiciled motor carriers. First, the rate will be calculated in the standard manner, summing up all vehicle OOS violations found from all vehicles belonging to Mexico-domiciled motor carrier participants, divided by the total number of vehicle inspections performed in the United States on these vehicles during the study.

In addition, a vehicle OOS rate will be calculated for each participating motor carrier based upon the data collected during the duration of the pilot program. Using these carrier-level OOS rates, the average value for these carrier-level vehicle OOS rates will then be computed by summing up the individual vehicle OOS rates and dividing by the number of motor carriers having an OOS rate assigned to them. This last statistic, which is the average value of each motor carrier's OOS rate, will be used as a check to determine if the standard vehicle OOS rate calculated for the Mexican trucks participating in the pilot program is dominated by data from a small number of carriers. If it is, then more emphasis will be placed on the average OOS rate in the analysis.

Vehicle Violation Rate. The vehicle violation rate is similar to the vehicle OOS rate, except that all violations will be considered, rather than just OOS violations.

Driver OOS Rate. The driver OOS rate for the Mexico-domiciled drivers participating in the pilot program will be calculated in the same manner as the vehicle OOS rates. First, the rate will be calculated in the standard manner, summing up all driver OOS violations found from all Mexico-domiciled drivers participating in the pilot, divided by the total number of driver inspections performed on these drivers during the study. In addition, the driver OOS rate will be calculated for each Mexico-domiciled motor carrier in the pilot, and these carrier-level driver OOS rates will next be averaged over all participating motor carriers.

Driver Violation Rate. The driver violation rate is similar to the driver OOS rate, except that all violations will be considered, rather than just OOS violations.

Safety Audit Pass Rate. The percentage of motor carriers in the pilot program that pass the PASA will be calculated and compared to the percentage of U.S.-domiciled motor carriers that pass the new entrant safety audit. The Agency recognizes that there are differences in these two types of reviews. However, they both evaluate success at meeting the established safety standards.

Crash Rate. Because crashes are relatively rare events, FMCSA will likely have insufficient crash data to evaluate safety performance of Mexico-domiciled motor carriers in this area. However, if sufficient data are available to produce meaningful statistical results, crash rate comparisons will be produced. It is anticipated that motor carriers participating in the pilot program will be involved in a wide variety of trucking operations, and many, if not most, of them will not be operating their vehicles full-time in the United States. For this reason, crash rates for carriers participating in the pilot program will be calculated in terms of crashes per million miles, and not crashes per power unit. All crashes that have a severity level of towaway or higher will be included in the crash count.

Crash rates will be calculated based on crashes occurring within both the United States and Mexico, and on mileage accumulated within both countries.

Specific Violation Rates. In addition to overall vehicle and driver violation and OOS rates, violation rates for study participants will be calculated for specific types of violations, including traffic enforcement, driver fitness, and hours of service. These violation rates

measure safety performance in subject areas considered key by Agency's CSA program. The purpose of this is to see whether there are specific types of violations that are more common among the Mexico-domiciled carriers than their U.S. counterparts.

Traffic Enforcement. Of particular interest are traffic enforcement violations pertaining to local laws, including, but not limited to, speeding, reckless driving, or driving too fast for conditions. Because traffic enforcement pertaining to driving only occurs when a violation is suspected, the exposure measure for these violation rates will not be total inspections, but, rather, the total number motor carrier trucks participating in the program, prorated by the number of months each motor carrier is in the pilot program. This traffic enforcement violation rate will be compared to a similar rate for US.-domiciled motor carriers, based on 36 months of data.

Driver Fitness. A driver fitness violation rate will be calculated for the motor carriers participating in the pilot program by summing-up all of the driver fitness-related violations detected during the program for participating motor carriers, divided by their total number of inspections. This statistic will be compared to this same rate for U.S.-domiciled motor carriers.

Hours-of-Service. An hours-of-service violation rate will be calculated for the motor carriers participating in the pilot program by summing-up all of the hours-of-service violations detected during the program for participating motor carriers, divided by their total number of inspections. This statistic will be compared to this same rate for U.S.-domiciled motor carriers.

The Agency will conduct a peer review to assess the study design. Upon its conclusion, we will submit the results of the peer review to the docket for this notice. If the peer review results in recommended changes, the Agency will publish a notice in the **Federal Register** explaining the change.

Regarding the assertion that Mexico-domiciled drivers are not cited for violations in the United States, FMCSA does not have any information available that would corroborate this statement.

11. Minimum Levels of Financial Responsibility

The Coalition requested that the minimum insurance requirements for all CMVs, domestic and foreign, be increased before conducting the pilot program.

The American Association for Justice interpreted the Agency's regulations as allowing participating motor carriers to self insure and suggested that all Mexican motor carriers carry insurance at all times.

FMCSA Response: FMCSA does not agree with the Coalition's suggestion that motor carriers transporting general freight should be required to have a greater level of financial responsibility. Mexico-domiciled motor carriers must establish financial responsibility, as required by 49 CFR part 387, through an insurance carrier licensed in a State in the United States. Based on the terms provided in the required endorsement, FMCSA Form MCS–90, if there is a final judgment against the motor carrier for loss and damages associated with a crash in the United States, the insurer must pay the claim. The financial responsibility claims would involve legal proceedings in the United States and an insurer based here. There is no reason that a Mexico-domiciled motor carrier, insured by a U.S.-based company, should be required to have a greater level of insurance coverage than a U.S.-based motor carrier.

Increasing the minimum levels of financial responsibility for all motor carriers is beyond the scope of this notice and would require a rulemaking.

In accordance with section 350(a)(1)(B)(iv), FMCSA must verify participating motor carriers' proof of insurance through a U.S., State-licensed insurer. As a result, participating motor carriers may not self-insure.

12. Vehicle Inspection and Fleet Safety

Teamsters expressed concern that only the segment of the motor carrier's fleet participating in long-haul trucking would be inspected. They also questioned how inspections at ''a rate comparable to other Mexico-domiciled motor carriers'' will be effective. Additionally, several commenters questioned what level of inspections would be conducted during each phase of the pilot program.

FMCSA Response: As noted previously, while only participating vehicles will be inspected during the PASA, the maintenance of all of the motor carrier's available vehicles that operate in the United States will be subject to inspection during the CR. Additionally, motor carriers currently operating within the border commercial zone are subject to inspections on a routine basis. The inspection rate of border commercial zone motor carriers is significantly higher than the average U.S. motor carrier. As a result, at all stages of the program, the participating motor carriers' drivers and vehicles are expected to be inspected more frequently than those of the average U.S. motor carrier.

In FY 2010, FMCSA and its State partners conducted 2,614,052 commercial vehicle inspections on U.S.-based motor carriers with 4,125,778 CMVs. FMCSA and its State partners conducted 256,151 CMV inspections on Mexico-domiciled motor carriers within the border commercial zones with 29,566 CMVs. Thus, the inspections rates for U.S.-based motor carriers and Mexico-domiciled motor carriers are 0.636336% and 8.6337% respectively. At an inspection rate that is 13 times greater for Mexico-domiciled motor carriers, FMCSA is confident that the inspections performed on motor carriers during Stages 2 and 3 should be sufficient to ensure continued safe operations. Additionally, Mexico-domiciled motor carriers that are in Stages 2 and 3 of the pilot program are required to be inspected at least once every 90 days in order to maintain a valid CVSA safety decal.

FMCSA will use all available inspection levels as well as license/insurance check inspections on the vehicles during the program. The level of inspection chosen will depend on a number of factors including the presence of a CVSA decal, previous history, and other observations by the inspector. At a minimum, a Level I inspection will be conducted if a CVSA decal has expired or will soon expire.

It must also be noted that participating vehicles will be required to maintain a current CVSA decal and must be inspected every 90 days. This is not a requirement for U.S. motor carriers or border commercial zone motor carriers.

13. Transparency

Advocates requested that all of the Agency's agreements with Mexico be subject to notice and comment and that each step in the pilot program be subject as well.

Advocates and ATA advised that the monitoring group should be independent from the Agency's Motor Carrier Safety Advisory Committee (MCSAC), and Advocates further indicated that under the Federal Advisory Committee Act (FACA), the use of a subcommittee of a Federal advisory committee to provide consensus advice and recommendations to a Federal official is prohibited. Advocates questioned whether the MCSAC participants comprised persons with backgrounds in basic research and statistical analysis who can offer advice on how decisions made by the monitoring group will affect the research design. Advocates requested that FMCSA provide all reports to the

appropriate congressional authorities and the public in a timely fashion.

The Coalition requested that monthly or quarterly reports of data collection be made available to the public.

FMCSA Response: The FMCSA has added copies of the 1991 MOU regarding CDL reciprocity and the 1998 MOU regarding drug and alcohol testing protocols to the docket for this notice. However, these documents are for informational purposes only and are not the subject of comments as they were negotiated by the Governments of the United States and Mexico more than a decade ago. The MOU between DOT and SCT that has been under negotiation since January 2011, is not subject to public comment, and the terms of that MOU have been explained in the April 13, 2011, **Federal Register** notice. The terms for U.S.-domiciled motor carriers wishing to travel south can be found in the draft rules proposed by SCT, which have been placed in the docket.

The FMCSA provided the opportunity for notice and comment on all steps of this pilot program through the notice published on April 13, 2011, and will not be providing another notice.

Regarding the monitoring groups, FMCSA clarifies that there will be a government monitoring group to discuss bi-lateral operational issues. In addition, there will be an independent monitoring group.

The FMCSA agrees that the group must be independent from the Agency. As a result, FMCSA continues to believe that the most efficient and effective process is to establish a subcommittee of the MCSAC. The MCSAC has proven itself to be independent of the Agency. We, however, want to clarify that the subcommittee would be able to invite input from individuals outside the MCSAC itself and would report out through the Committee. As a result, consistent with FACA requirements, only the MCSAC will transmit recommendations and advice to the FMCSA Administrator. FMCSA will make reports of the monitoring group available to the appropriate congressional committees and the public in a timely manner.

The FMCSA will maintain a comprehensive Web site dedicated to this pilot program to keep the public informed about how the program progresses. In addition to the specific information mentioned within this notice, FMCSA will publish the name and DOT Number of each participating motor carrier, the Vehicle Identification Numbers (VIN) of all vehicles approved for long-haul transportation, details on the driver/vehicle inspections the motor carrier has received, and details on any crashes involving the motor carrier. FMCSA will also publish aggregate data regarding the number of trips taken by participating motor carriers and the destinations of those trips.

14. Resources

Senator John D. Rockefeller expressed a concern about the adequacy of FMCSA, State law enforcement, and Immigration and Customs Enforcement (ICE) resources to support the program. Representative Hunter indicated he believed the Agency had gaps in its ability to properly manage the previous program. OOIDA indicated that based on contacts at the International Association of Chiefs of Police, more training on cabotage is needed.

The Texas Department of Motor Vehicles recommends that FMCSA provide financial assistance to the Border States to off-set the Border States' administrative and enforcement expenses related to the pilot program.

FMCSA Response: The FMCSA notes that the number of Mexico-domiciled motor carriers and vehicles that will participate in the pilot program is extremely small compared to the population of motor carriers and vehicles currently operating within the border commercial zones. Most of the motor carriers that would participate in the pilot program already have authority to operate in the border commercial zones, so their participation in the program would not result in a significant increase in the population of Mexico-domiciled motor carriers operating in the United States. Further, as to concerns regarding possible strains on border inspection facility capacity, it should be noted that FMCSA has no reason to believe the number of Mexican trucks crossing the border during the pilot program will increase significantly because the cargo carried by the long-haul trucks would have crossed the border in any event via short-haul, border commercial zone trucks.

The FMCSA and its State partners have sufficient staff, facilities, equipment, and procedures in place to meet the requirements of this pilot program. This conclusion is based on the Agency's experience providing safety oversight for Mexico-domiciled motor carriers currently authorized to operate within the border commercial zones and on its regular liaison with its State enforcement partners with whom the Agency has worked for years in anticipation of the opening of the border to long-haul Mexico-domiciled motor carriers. In fact, during the previous program, FMCSA was able to confirm that over 99 percent of the participating vehicles received an inspection at the border. Further, FMCSA can find no evidence that the remaining less than one percent of the vehicles were not inspected as they crossed the border, and neither the OIG, nor the Independent Panel, nor any other entity has identified any vehicles that crossed without an inspection. FMCSA currently employs 260 Federal personnel dedicated to border enforcement activities.

In response to the OOIDA's concerns about the burden on the States for providing safety oversight for Mexico-domiciled motor carriers and the Texas Department of Motor Vehicles comment regarding making funding available to Border States, FMCSA is authorized under 49 U.S.C. 31107 to provide border enforcement grants for carrying out CMV safety programs and related enforcement activities and projects and has $32 million available in FY2011 for this purpose. The Agency's State partners along the border employ 456 State officials for this purpose. Therefore, the Congress has provided funding for enforcement resources dedicated exclusively to ensuring the safe operation of foreign-domiciled motor carrier operations.

The FMCSA works with the States to ensure that motor carrier safety enforcement personnel receive extensive training. From 2008 to date, over 5,800 State motor carrier safety inspectors have received North American Standard (NAS) inspection procedures training. The NAS training course is designed to provide State motor carrier safety enforcement personnel with the basic knowledge, skills, practices, and procedures necessary for performing inspections under the Motor Carrier Safety Assistance Program (MCSAP).

Additionally, through the Agency's partnership with the International Association of Chiefs of Police (IACP), four Foreign CMV Awareness Training sessions have been conducted on a recurring basis including a session that covers cabotage laws. Approximately 215 officers were certified to train law enforcement officers throughout the United States using this course which includes cabotage information.

The training these officers will provide to other law enforcement officials will ensure patrol officers are informed about potential safety and enforcement issues involving foreign-based CMVs and drivers operating beyond the border commercial zones. Therefore, not only has FMCSA provided funding resources to support the States' role in providing Safety oversight for Mexico-domiciled motor

carriers operating in the United States, the Agency has provided training. Presently, 1,755 law enforcement officers have received such training.

Finally, during the program, FMCSA will monitor for domestic point-to-point transportation violations using the information obtained from the GPS feature of the electronic monitoring devices installed on the vehicles and during CRs.

15. Impact on Truck Drivers, Small Fleets and Businesses

Over 1,000 commenters felt that this pilot program would have a negative economic impact on the United States at a time when unemployment was high.

FMCSA Response: The FMCSA does not believe the pilot program will have a significant adverse impact on U.S. motor carriers or drivers. As an initial matter, however, it is important to note that FMCSA lacks the authority to alter the terms under which Mexico-domiciled motor carriers operate in the United States based on the possible economic impact of those motor carriers on U.S. motor carriers. FMCSA's responsibility, pursuant to the November 2002 presidential order, is to implement NAFTA's motor carrier provisions in a manner consistent with the motor carrier safety laws.

While the wages for a Mexico-domiciled driver may differ from those of a U.S.-domiciled driver, wages represent only one factor in the cost of a trucking operation. The costs for safety management controls to achieve full compliance with U.S. safety requirements, equipment maintenance, fuel, taxes and insurance costs must also be considered. Therefore, driver wages alone should not be considered the determining factor for an economic advantage.

Also, Mexico-domiciled motor carriers cannot compete against U.S.-domiciled motor carriers for point-to-point deliveries of domestic freight within the United States. Section 365.501(b) of title 49, Code of Federal Regulations, provides that ''a Mexico-domiciled motor carrier may not provide point-to-point transportation services, including express delivery services, within the United States for goods other than international cargo.'' FMCSA notes that engaging in domestic point-to-point transportation in the U.S. is operating beyond the scope of a Mexico-domiciled motor carrier's authority, and FMCSA and its State partners are actively engaged in enforcing this regulation. Vehicles caught in this practice will be placed out-of-service, participating motor carriers may be subject to civil penalties of up to $11,000 and more comprehensive review of operations by FMCSA, and they could be removed from the pilot program.

16. Concerns About Furthering Illegal Activity

Numerous commenters noted the existence of drug cartels in Mexico and expressed concern that the long-haul program would increase drug trafficking.

FMCSA Response: The FMCSA disagrees with the commenters on this issue. FMCSA is not aware of any information that would suggest the pilot program will increase the extent to which illegal activities occur. Mexico-domiciled motor carriers are already allowed to operate in border commercial zones. Many of the motor carriers that may apply for authority to operate beyond the border commercial zones and participate in the pilot program are already conducting CMV operations in the U.S., albeit limited to the border commercial zones. Moreover, as noted above, FMCSA does not anticipate that the pilot program will result in a substantial increase in the number of Mexican trucks crossing the border. It follows that the pilot program will not increase instances of cross-border drug smuggling in any significant way.

Finally, as the U.S. Immigration and Customs Enforcement's inspections of long-haul trucks will not change as a result of this pilot, we do not believe this program introduces any new risks.

FMCSA's Intent To Proceed With Pilot Program

In consideration of the above, FMCSA believes it is appropriate to commence the pilot program after the Department's Inspector General completes his report to Congress, as required by section 6901(b)(1) of the 2007 Appropriations Act, and the Agency completes any follow-up actions needed to address any issues that may be raised in the report. FMCSA reiterates that before an applicant Mexico-domiciled motor carrier may receive operating authority, it must submit a complete and accurate application; complete the DHS security review process; successfully complete the PASA; and file with FMCSA evidence of adequate insurance from a U.S. company. In addition, as stated above, FMCSA will complete reviews of Mexican licensing facilities to ensure compliance with the 1991 MOU before granting authority. FMCSA does not anticipate that any Mexico-domiciled motor carrier seeking participation in the pilot program will receive its provisional operating authority before the first weeks of August 2011.

Issued on: June 29, 2011.

William Bronrott,

Deputy Administrator.

[FR Doc. 2011–16886 Filed 7–7–11; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2011–0145]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA).

ACTION: Notice of applications for exemption from the diabetes mellitus standard; request for comments.

SUMMARY: FMCSA announces receipt of applications from 22 individuals for exemption from the prohibition against persons with insulin-treated diabetes mellitus (ITDM) operating commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals with ITDM to operate CMVs in interstate commerce.

DATES: Comments must be received on or before August 8, 2011.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2011–0145 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or

Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 22 individuals listed in this notice have recently requested such an exemption from the diabetes prohibition in 49 CFR 391.41(b)(3), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by the statutes.

Qualifications of Applicants

Bryan K. Aaron

Mr. Aaron, age 44, has had ITDM since 2011. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Aaron understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a Commercial Motor Vehicle (CMV) safely. Mr. Aaron meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he has nonproliferative stable diabetic retinopathy. He holds a Class A Commercial Driver's License (CDL) from Utah.

Michael A. Anderson

Mr. Anderson, 48, has had ITDM since 2006. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Anderson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Anderson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Kansas.

Donald M. Bergman

Mr. Bergman, 49, has had ITDM since 1993. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bergman understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bergman meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class D operator's license from Minnesota.

Ronald J. Boehm

Mr. Boehm, 47, has had ITDM since 2006. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Boehm understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Boehm meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Indiana.

Ernest E. Bogan

Mr. Bogan, 61, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bogan understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bogan meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Michigan.

Eric B. Bratanich

Mr. Bratanich, 36, has had ITDM since 1985. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bratanich understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bratanich meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he has stable

proliferative diabetic retinopathy. He holds a Class A CDL from Wisconsin.

Jerry A. Campbell

Mr. Campbell, 49, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Campbell understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Campbell meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Ohio.

Paul Dessesow

Mr. Dessesow, 63, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Dessesow understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Dessesow meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Maryland.

Vernon W. Elmore

Mr. Elmore, 68, has had ITDM since 2009. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Elmore understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Elmore meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Mississippi.

Michael J. Gilbert

Mr. Gilbert, 40, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Gilbert understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Gilbert meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Washington.

William D. Hanam

Mr. Hanam, 64, has had ITDM since 2005. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hanam understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hanam meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Steven S. Hanna

Mr. Hanna, 44, has had ITDM since 2007. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hanna understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hanna meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from Ohio.

Michael M. Harms

Mr. Harms, 42, has had ITDM since 2000. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Harms understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Harms meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he has stable proliferative diabetic retinopathy. He holds a Class A CDL from Nebraska.

Johnathan R. Hartman

Mr. Hartman, 31, has had ITDM since 2004. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hartman understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hartman meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Oklahoma.

Devon K. Johnson

Mr. Johnson, 47, has had ITDM since 2005. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Johnson understands diabetes management and monitoring,

has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Johnson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Indiana.

Andrew W. Richey

Mr. Richey, 49, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Richey understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Richey meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Mississippi.

Rob T. Romans

Mr. Romans, 53, has had ITDM since 2005. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Romans understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Romans meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from South Dakota.

Thomas M. Shafer

Mr. Shafer, 51, has had ITDM since 1984. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Shafer understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Shafer meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Indiana.

Allen D. Stevenson

Mr. Stevenson, 45, has had ITDM since 2008. His endocrinologist examined him in 2010 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Stevenson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Stevenson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New Jersey.

Oleg Tarasov

Mr. Tarasov, 44, has had ITDM since 2011. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Tarasov understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Tarasov meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New Jersey.

Richard H. Willis

Mr. Willis, 64, has had ITDM since 2010. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Willis understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Willis meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2011 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Wisconsin.

Harvey N. Woody

Mr. Woody, 60, has had ITDM since 2006–2007. His endocrinologist examined him in 2011 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Woody understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Woody meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2010 and certified that he does not have diabetic retinopathy. He holds a Class A CDL license from Iowa.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

FMCSA notes that section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users requires the Secretary to revise its diabetes exemption program established on September 3, 2003 (68 FR 52441).[1] The revision must provide for individual assessment of drivers with diabetes mellitus, and be consistent with the criteria described in section 4018 of the Transportation Equity Act for the 21st Century (49 U.S.C. 31305).

Section 4129 requires: (1) Elimination of the requirement for 3 years of experience operating CMVs while being

[1] Section 4129(a) refers to the 2003 notice as a ''final rule.'' However, the 2003 notice did not issue a ''final rule'' but did establish the procedures and standards for issuing exemptions for drivers with ITDM.

treated with insulin; and (2) establishment of a specified minimum period of insulin use to demonstrate stable control of diabetes before being allowed to operate a CMV.

In response to section 4129, FMCSA made immediate revisions to the diabetes exemption program established by the September 3, 2003 notice. FMCSA discontinued use of the 3-year driving experience and fulfilled the requirements of section 4129 while continuing to ensure that operation of CMVs by drivers with ITDM will achieve the requisite level of safety required of all exemptions granted under 49 U.S.C. 31136(e).

Section 4129(d) also directed FMCSA to ensure that drivers of CMVs with ITDM are not held to a higher standard than other drivers, with the exception of limited operating, monitoring and medical requirements that are deemed medically necessary.

The FMCSA concluded that all of the operating, monitoring and medical requirements set out in the September 3, 2003 notice, except as modified, were in compliance with section 4129(d). Therefore, all of the requirements set out in the September 3, 2003 notice, except as modified by the notice in the **Federal Register** on November 8, 2005 (70 FR 67777), remain in effect.

Issued on: July 1, 2011.

Larry W. Minor,

Associate Administrator.

[FR Doc. 2011–17185 Filed 7–7–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2011–0102]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of applications from 16 individuals for exemption from the vision requirement in the Federal Motor Carrier Safety Regulations. If granted, the exemptions would enable these individuals to qualify as drivers of commercial motor vehicles (CMVs) in interstate commerce without meeting the Federal vision standard.

DATES: Comments must be received on or before August 8, 2011.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2011–0102 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowldgment page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf*.

FOR FURTHER INFORMATION CONTACT: Dr. Mary D. Gunnels, Director, Medical Programs, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.'' FMCSA can renew exemptions at the end of each 2-year period. The 16 individuals listed in this notice have each requested such an exemption from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

Qualifications of Applicants

Stanley C. Anders

Mr. Anders, age 58, has had amblyopia in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/80. Following an examination in 2011, his optometrist noted, ''His right eye provides the necessary vision for him to perform the driving task of operating a commercial vehicle.'' Mr. Anders reported that he has driven tractor-trailer combinations for 38 years, accumulating 2.7 million miles. He holds a Class A Commercial Driver's License (CDL) from South Dakota. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Joel A. Cabrera

Mr. Cabrera, 31, has a prosthetic left eye due to retinoblastoma that occurred at age 2. The corrected visual acuity in his right eye is 20/15 and in his left eye, no light perception. Following an examination in 2011, his optometrist noted, ''On the basis of my clinical observations, Joel meets all the visual requirements to drive a commercial vehicle.'' Mr. Cabrera reported that he has driven tractor-trailer combinations for 3 years, 63,000 miles. He holds a Class A CDL from Florida. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Sherman W. Clapper

Mr. Clapper, 50, has had amblyopia in his right eye since childhood. The best corrected visual acuity in his right eye is count-finger vision and in his left eye, 20/20. Following an examination in

2011, his ophthalmologist noted, ''He should have sufficient vision to perform his tasks as a commercial driver.'' Mr. Clapper reported that he has driven straight trucks for 15 years, accumulating 7,500 miles and tractor-trailer combinations for 4 years, accumulating 400 miles. He holds a Class A CDL from Idaho. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Eric C. Esplin

Mr. Esplin, 46, has loss of vision in his right eye due to a traumatic injury that occurred in 1994. The best corrected visual acuity in his right eye is hand motion vision and in his left eye, 20/20. Following an examination in 2011, his optometrist noted, ''It is my opinion that Eric has adapted well to the loss of sensitivity in that right eye and is capable of maintaining commercial driver's license privileges.'' Mr. Esplin reported that he has driven straight trucks for 30 years, accumulating 180,000 miles and tractor-trailer combinations for 26 years, accumulating 260,000 miles. He holds a Class A CDL from Utah. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Ronald R. Fournier

Mr. Fournier, 52, has amblyopia in his right eye due to anisometropia since birth. The best corrected visual acuity in his right eye is 20/70 and in his left eye, 20/20. Following an examination in 2011, his optometrist noted, ''It is my opinion, Ronald Fournier has sufficient vision to perfrom the driving tasks requried to operate a commercial vehicle.'' Mr. Fournier reported that he has driven straight trucks for 28 years, accumulating 154,000 miles and tractor-trailer combinations for 19 years, accumulating 104,500 miles. He holds a Class A CDL from New York. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Ronald D. Jackman, II

Mr. Jackman, 44, has had ambylopia in his right eye since childhood. The visual acuity in his right eye is 20/50 and in his left eye, 20/20. Following an examination in 2011, his optometrist noted, ''In my medical opinion, this patient has adequate vision to operate a commercial vehicle.'' Mr. Jackman reported that he has driven straight trucks for 22 years, accumulating 286,000 miles and tractor-trailer combinations for 22 years, accumulating 286,000 miles. He holds a Class A CDL from Nevada. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Thomas W. Kent

Mr. Kent, 53, has central scotoma in his left eye due to a traumatic injury sustained in 1982. The visual acuity in his right eye is 20/20 and in his left eye, hand motion vision. Following an examination in 2011, his optometrist noted, ''My medical opinion is that the patient does have adequate vision to perfrom the driving tasks requried to operate a commercial vehicle.'' Mr. Kent reported that he has driven straight trucks for 32 years, accumulating 960,000 miles and tractor-trailer combinations for 10 years, accumulating 200,000 miles. He holds an operator's license from Indiana. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Brian L. Keszler

Mr. Keszler, 33, has had amblyopia in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/70. Following an examination in 2011, his optometrist noted, ''It is my professional opinion that Mr. Keszler has sufficient vision to perform the driving tasks required to operate a commerical vehicle, considering the requirements are fulfilled of wearing glasses at all times and using a working, correctly adjusted left/driver's side mirror required at all times.'' Mr. Keszler reported that he has driven straight trucks for 15 years, accumulating 150,600 miles. He holds a Class R operator's license from Colorado. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Gerald Kortesmaki

Mr. Kortesmaki, 48, has a congenital cataract in his left eye. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/50. Following an examination in 2010, his optomerist noted, ''It is my opinion that Mr. Kortesmaki has sufficient vision to operate a commercial vehicle.'' Mr. Kortesmaki reported that he has driven straight trucks for 32 years, accumulating 640,000 miles. He holds a Class D operator's license from Minnesota. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Craig C. Lowry

Mr. Lowry, 39, has loss of vision in his right eye due to a retinal detachment that occurred in 2006. The visual acuity in his right eye is 20/200 and in his left eye, 20/20. Following an examination in 2010, his optometrist noted, ''I believe Craig has sufficient vision to perfrom the driving tasks requried to operate a commercial vehicle.'' Mr. Lowry reported that he has driven straight trucks for 11 years, accumulating 440,000 miles and tractor-trailer combinations for 17 years, accumulating 1 million miles. He holds a Class A CDL from Montana. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Robert J. MacInnis

Mr. MacInnis, 58, has had amblyopia in his right eye since birth. The best corrected visual acuity in his right eye is 20/50 and in his left eye, 20/20. Following an examination in 2010, his optometrist noted, ''His vision is stable and sufficient to perform the driving tasks requried to operate a commercial motor vehicle.'' Mr. MacInnis reported that he has driven straight trucks for 5 years, accumulating 13,500 miles and tractor-trailer combinations for 21 years, accumulating 2 million miles. He holds a Class A CDL from Massachusetts. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Gordon S. Newman

Mr. Newman, 50, has no light perception in his left eye due to a traumatic injury that occurred eight years ago. The best corrected visual acuity in his right eye is 20/200 and in his left eye, no light perception. Following an examination in 2010, his optometrist noted, ''In my medical opinion, Mr. Newman has sufficient vision to perform the driving tasks required of him.'' Mr. Newman reported that he has driven straight trucks for 18 years, accumulating 270,000 miles. He holds a Class A CDL from Illinois. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Adolph L. Romero

Mr. Romero, 48, has had refractive amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/20 and in his left eye, 20/80. Following an examination in 2011, his ophthalmologist noted, ''I certify that in my medical opinion the patient's visual acuity is adequate for both daylight and nighttime driving and the visual acuity is sufficient to perform the driving tasks

required to operate a commercial vehicle.'' Mr. Romero reported that he has driven straight trucks for 25 years, accumulating 112,500 miles and tractor-trailer combinations for 10 years, accumulating 20,000 miles. He holds a Class E operator's license from Florida. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Rodney W. Sukalski

Mr. Sukalski, 54, has had amblyopia in his right eye since childhood. The best corrected visual acuity in his right eye is 20/200 and in his left eye, 20/15. Following an examination in 2010, his optometrist noted, ''Yes, in my opinion I feel that Rodney Sukalski has adequate vision to drive a commercial vehicle.'' Mr. Sukalski reported that he has driven straight trucks for 15 years, accumulating 45,000 miles. He holds a Class A CDL from Minnesota. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Sherman W. Clapper

Mr. Clapper, 50, has had amblyopia in his right eye since childhood. The best corrected visual acuity in his right eye is count-finger vision and in his left eye, 20/20. Following an examination in 2011, his ophthalmologist noted, ''He should have sufficient vision to perform his tasks as a commercial driver''. Mr. Clapper reported that he has driven straight trucks for 15 years, accumulating 7,500 miles and tractor-trailer combinations for 4 years, accumulating 400 miles. He holds a Class A CDL from Idaho. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Larry D. Warneke

Mr. Warneke, 49, has had exotropia and ambylopia in his left eye since birth. The visual acuity in his right eye is 20/15 and in his left eye, 20/200. Following an examination in 2011, his optometrist noted, ''It is my opinion that this man has sufficient vision to drive as he has proved within Washington State since 1987 when driving commercial vehicles.'' Mr. Warneke reported that he has driven straight trucks for 20 years, accumulating 800,000 miles and tractor-trailer combinations for 23 years, accumulating 115,000 miles. He holds a Class A CDL from Washington. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Lonnie D. Wendinger

Mr. Wendinger, 56, has had retinal scars in both eyes due to toxoplasmosis since birth. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/70. Following an examination in 2010, his optometrist noted, ''In my medical opinion, Lonnie has sufficient vision to perform the driving tasks necessary to operate the commercial vehicle.'' Mr. Wendinger reported that he has driven straight trucks for 40 years, accumulating 1 million miles and tractor-trailer combinations for 20 years, accumulating 600,000 miles. He holds a Class A CDL Minnesota. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. The Agency will consider all comments received before the close of business August 8, 2011. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will file comments received after the comment closing date in the public docket, and will consider them to the extent practicable.

In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should monitor the public docket for new material.

Issued on: June 29, 2011.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2011–17183 Filed 7–7–11; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2011–0141]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of applications from 9 individuals for exemption from the vision requirement in the Federal Motor Carrier Safety Regulations. If granted, the exemptions would enable these individuals to qualify as drivers of commercial motor vehicles (CMVs) in interstate commerce without meeting the Federal vision standard.

DATES: Comments must be received on or before August 8, 2011.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2011–0141 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' FMCSA can renew exemptions at the end of each 2-year period. The 9 individuals listed in this notice have each requested such an exemption from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

Qualifications of Applicants

Joe M. Flores

Mr. Flores, age 34, has had a macular hole in his left eye since 2006. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/200. Following an examination in 2011, his optometrist noted, ''Joe has sufficient vision peripherally in both eyes and centrally in his right eye to operate a commercial vehicle.'' Mr. Flores reported that he has driven tractor-trailer combinations for 4 years, accumulating 180,000 miles. He holds a Commercial Driver's License (CDL) Class A from New Mexico. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a Commercial Motor Vehicle (CMV).

Matthew K. Hagge

Mr. Hagge, 31, has had optic atrophy in his right eye since 2007 due to multiple sclerosis. The visual acuity in his right eye is 20/250 and in his left eye, 20/20. Following an examination in 2011, his ophthalmologist noted, ''Visual acuity fine for performing commercial vehicle driving.'' Mr. Hagge reported that he has driven straight trucks for 4 years, accumulating 20,000 miles and tractor-trailer combinations for 7 years, accumulating 420,000 miles. He holds a CDL Class A from North Dakota. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

James O. Howard

Mr. Howard, 48, has had amblyopia in his left eye since age 6. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/100. Following an examination in 2011, his optometrist noted, ''Mr. James Howard has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Howard reported that he has driven straight trucks for 14 years, accumulating 291,200 miles. He holds a Class C operator's license from California. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Ramon Melendez

Mr. Melendez, 57, has had amblyopia in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/200. Following an examination in 2011, his ophthalmologist noted, ''certified by David Lichtenstain to have sufficient vision to operate a commercial vehicle and do driving tasks.'' Mr. Melendez reported that he has driven tractor-trailer combinations for 14 years, accumulating 1.1 million miles. He holds a Class A CDL from New Jersey. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Matthew D. Nelson

Mr. Nelson, 27, has had refractive amblyopia in his left eye since birth. The best visual acuity in his right eye is 20/20 and in his left eye, 20/50. Following an examination in 2011, his optometrist noted, ''Matthew's vision is sufficient to perform the driving tasks required to operate a commercial vehicle.'' Mr. Nelson reported that he has driven straight trucks for 3½ years, accumulating 56,000 miles. He holds a Class A CDL from Florida. His driving record for the last 3 years shows no crashes, but one conviction for a moving violation in a CMV; failure to observe a stop sign.

Jesse A. Nosbush

Mr. Nosbush, 31, has complete loss of vision in his left eye due to a work related accident in 1998. The visual acuity in his right eye is 20/20. Following an examination in 2011, his optometrist noted, ''It is in my opinion that Jesse, even knowing that he has one eye, should not have any difficulty when it comes to operating a commercial motor vehicle.'' Mr. Nosbush reported that he has driven tractor-trailer combinations for 9 years, accumulating 495,000 miles. He holds a Class A CDL from Minnesota. His driving record for the last 3 years shows one crash, for which he was cited, and no convictions for moving violations in a CMV.

Richard E. Purvenas, Jr.

Mr. Purvenas, 51, has a prosthetic left eye. The visual acuity in his right eye is 20/20. Following an examination in 2011, his optometrist noted, ''It is my understanding that Mr. Purvenas has maintained a safe driving record for many years and has always driven without having any vision in the left eye. Since it has always been non-existent, he has functioned well, and his peripheral visual acuity is excellent there is no reason to believe that he cannot continue to operate commercial vehicles.'' Mr. Purvenas reported that he has driven buses for 5 years, accumulating 400,000 miles. He holds a Class D operator's license from Delaware. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Wilfred E. Sweatt

Mr. Sweatt, 50, has had amblyopia in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/50. Following an examination in 2011, his optometrist noted, ''He has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Sweatt reported that he has driven straight trucks for 8 years, accumulating 176,000 miles. He holds an operator's license from New Hampshire. His driving record for the last 3 years shows no crashes and no conviction for moving violations in a CMV.

Thomas L. Swatley

Mr. Swatley, 55, has had amblyopia in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20 and in his left eye, 20/50. Following an examination in 2011, his optometrist noted, ''Mr. Swatley appears to have stable visual function at the present time that is not an impediment to his operating commercial vehicles.'' Mr. Swatley reported that he has driven straight trucks for 35 years, accumulating 1.1 million miles and tractor-trailer combinations for 3 years, accumulating 450,000 miles. He holds a Class A CDL from Tennessee. His driving record for the last 3 years shows

no crashes and no conviction for moving violations in a CMV.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. The Agency will consider all comments received before the close of business August 8, 2011. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will file comments received after the comment closing date in the public docket, and will consider them to the extent practicable.

In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should monitor the public docket for new material.

Issued on: June 29, 2011.

Larry W. Minor,

Associate Administrator.

[FR Doc. 2011–17184 Filed 7–7–11; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[Docket No. FTA–2011–0031]

Notice of Proposed Buy America Waiver To Allow Bidder To Certify Compliance

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of proposed Buy America waiver to allow bidder to certify compliance; Request for comment.

SUMMARY: The New York Metropolitan Transportation Authority (MTA) has asked the Federal Transit Administration (FTA) to waive its Buy America requirements on the basis of public interest to permit the low bidder for a contract to construct the 86th Street Station for the Second Avenue Subway project to certify compliance with Buy America. The bidder certified non-compliance based on a misunderstanding of how FTA would apply its rules to certain construction materials. In fact, the low bidder is willing and able to comply with the Buy America rules. Without a waiver, MTA may spend an additional $32.9 million on the 86th Street Station without furthering the goals of Buy America. FTA seeks public comment before deciding whether to grant MTA's request. This Notice sets forth the justification for a public interest waiver in this instance.

DATES: Comments must be received by July 15, 2011. Late-filed comments will be considered to the extent practicable.

ADDRESSES: Please submit your comments by only one of the following means, identifying your submissions by docket number FTA–2011–0031. All electronic submissions must be made to the U.S. Government electronic site at *http://www.regulations.gov.* Commenters should follow the instructions below for mailed and hand-delivered comments.

(1) *Web site: http://www.regulations.gov.* Follow the instructions for submitting comments on the U.S. Government electronic docket site;

(2) *Fax:* (202) 493–2251;

(3) *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue, SE., Docket Operations, M–30, Room W12–140, Washington, DC 20590–0001.

(4) *Hand Delivery:* Room W12–140 on the first floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must make reference to the ''Federal Transit Administration'' and include docket number FTA–2011–0031. Due to security procedures in effect since October 2001, mail received through the U.S. Postal Service may be subject to delays. Parties making submissions responsive to this notice should consider using an express mail form to ensure the prompt filing of any submissions not filed electronically or by hand. Note that all submissions received, including any personal information therein, will be posted without change or alteration to *http://www.regulations.gov.* For more information, you may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jayme L. Blakesley at (202) 366–0304 or *jayme.blakesley@dot.gov.*

SUPPLEMENTARY INFORMATION:

The purpose of this notice is to seek public comment on whether the Federal Transit Administration should waive its Buy America requirements of 49 CFR Part 661 to permit a low bidder to re-submit its Buy America certificate in connection with its bid to construct the 86th Street Station for the Second Avenue Subway project. If granted, this waiver would be limited to the procedural aspects of the Buy America rule. The low bidder will need to certify compliance with Buy America and will be required to comply will all of the substantive Buy America requirements.

In February 2011, MTA received bids for a contract to construct the 86th Street Station for its Second Avenue Subway project, a $4.8 billion project for 2.3 miles of new subway on the East Side of Manhattan. Five parties submitted bids, ranging from $301,860,000 to $460,443,000. The low bid of $301,860,000, submitted by Skanska/Traylor JV, is $32.9 million lower than the next lowest bidder and almost $100 million lower than MTA's budget for the contract.

Skanska/Traylor JV signed and submitted a Certificate of Non-Compliance with its bid, based on its understanding that certain construction materials—shotcrete steel fibers and Polyvinyl Choride (PVC) membrane—would need to be produced in the United States in order to comply with FTA's Buy America requirements.

Except for items made primarily of iron and steel, FTA treats the procurement of construction projects as the procurement of a manufactured end product subject to the requirements of 49 CFR 661.5. The main elements incorporated into the project at the job site are the components. As with all manufactured products, Buy America requires all of the manufacturing processes to take place in the United States and all of the components of the product to be of U.S. origin. A component is considered of U.S. origin if it is manufactured in the United States, regardless of the origin of its subcomponents. 49 CFR 661.5(d).

Skanska/Traylor JV certified non-compliance based on its understanding that shotcrete was subject to the steel and iron requirements of 49 CFR 661.5(b) and (c), not the manufactured product requirements of § 661.5(d), and PVC membrane would be considered a component. As such, Skanska/Traylor JV would have needed to obtain each item from a domestic source. According to Skanska/Traylor JV and MTA, neither shotcrete nor the type of PVC membrane called for in MTA's specification is produced in the United States.

FTA and MTA engineers examined the materials in question and determined that shotcrete is a manufactured product and that shotcrete steel fibers and PVC membrane are subcomponents of the waterproofing system that will be constructed around the tunnel for the 86th Street Station. As such, FTA's Buy America rules do not require shotcrete or PVC membrane to be produced in the

United States. This determination indicates that Skanska/Traylor JV certified non-compliance in error.

Notwithstanding the above interpretation and Skanska/Traylor JV's willingness and ability to comply with Buy America, the procedural portion of FTA's Buy America regulations prohibit Skanska/Traylor JV from modifying its Buy America certificate unless it submitted an incorrect certificate based on inadvertent or clerical error. 49 CFR 661.13(a)(1). In the case of a sealed bid procurement, a bidder or offeror is bound by its original certification. 49 CFR 661.13(c).

In this instance, FTA proposes to waive the restrictions of 49 CFR 661.13 to allow Skanska/Traylor JV to certify compliance with Buy America. Unlike other requests for public interest waivers, the granting of which enable an otherwise non-compliant bidder to purchase foreign products that the Buy America provisions would otherwise require to be produced in the United States, in this circumstance a waiver would allow MTA to award a contract to a low bidder that will perform wholly in compliance with the substantive Buy America requirements. Without a waiver, MTA may spend an additional $32.9 million for the Second Avenue Subway project without furthering the goals of Buy America.

FTA may waive its rules if applying the Buy America requirements ''would be inconsistent with the public interest.'' 49 U.S.C. 5323(j)(2)(A). Before granting such waiver, FTA must issue a detailed written statement justifying why the waiver is in the public interest, and must publish this justification in the **Federal Register**, providing the public with a reasonable time for notice and comment of not more than seven calendar days. 49 CFR 661.7(b). This notice satisfies the aforementioned requirement.

Before deciding whether to grant MTA's request, FTA seeks comment from all interested parties. In the interest of transparency, FTA has published copies of MTA's request to the docket. Interested parties may access these materials by visiting the docket site at *http://www.regulations.gov,* docket number FTA–2011–0031. Please submit comments by July 15, 2011. Late-filed comments will be considered to the extent practicable.

Issued this 1st day of July 2011.

Dorval R. Carter, Jr,

Chief Counsel.

[FR Doc. 2011–17182 Filed 7–7–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. EP 682 (Sub-No. 2)]

2010 Tax Information for Use in the Revenue Shortfall Allocation Method

AGENCY: Surface Transportation Board.

ACTION: Notice.

SUMMARY: The Board is publishing, and providing the public an opportunity to comment on, the 2010 weighted average state tax rates for each Class I railroad, as calculated by the Association of American Railroads (AAR), for use in the Revenue Shortfall Allocation Method (RSAM).

DATES: Comments are due by August 8, 2011. If any comment opposing AAR's calculations is filed, AAR's reply will be due August 29, 2011. If no comments are filed by the due date, AAR's calculation of the 2010 weighted average state tax rates will be automatically adopted by the Board, effective August 9, 2011.

ADDRESSES: Comments may be submitted either via the Board's e-filing format or in traditional paper format. Any person using e-filing should attach a document and otherwise comply with the instructions at the E-FILING link on the Board's Web site at *http://www.stb.dot.gov.* Any person submitting a filing in the traditional paper format should send an original and 10 copies referring to Docket No. EP 682 (Sub-No. 2) to: Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001.

FOR FURTHER INFORMATION CONTACT: Valerie O. Quinn (202) 245–0382. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The RSAM figure is one of three benchmarks that together are used to determine the reasonableness of a challenged rate under the Board's *Simplified Standards for Rail Rate Cases,* EP 646 (Sub-No. 1) (STB served Sept. 5, 2007),[1] as further revised in *Simplified Standards for Rail Rate Cases—Taxes in Revenue Shortfall Allocation Method,* EP 646 (Sub-No. 2) (STB served Nov. 21, 2008). RSAM is intended to measure the average markup that the railroad would need to collect from all of its ''potentially captive traffic'' (traffic with a revenue-to-variable-cost ratio above 180%) to earn adequate revenues as measured by the Board under 49 U.S.C. § 10704(a)(2) (*i.e.,* earn a return on investment equal to the railroad industry cost of capital). *Simplified Standards—Taxes in RSAM,* slip op. at 1. In *Simplified Standards—Taxes in RSAM,* slip op. at 3, 5, the Board modified its RSAM formula to account for taxes, as the prior formula mistakenly compared pre-tax and after-tax revenues. In that decision, the Board stated that it would institute a separate proceeding in which Class I railroads would be required to submit the annual tax information necessary for the Board's annul RSAM calculation. *Id.* at 5–6.

In *Annual Submission of Tax Information for Use in the Revenue Shortfall Allocation Method,* EP 682 (STB served Feb. 26, 2010), the Board adopted rules to require AAR—a national trade association—to annually calculate and submit to the Board the weighted average state tax rate for each Class I railroad. *See* 49 CFR 1135.2(a). On May 27, 2011, AAR filed its calculation of the weighted average state tax rates for 2010, listed below for each Class I railroad:

WEIGHTED AVERAGE STATE TAX RATES

[In percent]

Railroad	2010	2009	% Change
BNSF Railway Company	5.572	5.665	−0.093
CSX Transportation, Inc.	5.575	5.578	−0.003
Grand Trunk Corporation	7.634	7.590	0.044
The Kansas City Southern Railway	6.070	6.434	−0.364
Norfolk Southern Combined	5.819	5.803	0.016
Soo Line Corporation	7.305	8.651	−1.346

[1] *Aff'd sub nom. CSX Transp., Inc.* v. *STB,* 568 F.3d 236 (DC Cir. 2009), *and vacated in part on reh'g, CSX Transp., Inc.* v. *STB,* 584 F.3d 1076 (DC Cir. 2009).

WEIGHTED AVERAGE STATE TAX RATES—Continued

[In percent]

Railroad	2010	2009	% Change
Union Pacific Railroad Company	5.922	6.051	−0.129

Any party wishing to comment on AAR's calculation of the 2010 weighted average state tax rates should file a comment by August 8, 2011. *See* 49 CFR 1135.2(c). If any comment opposing AAR's calculations is filed, AAR's reply will be due by August 29, 2011. *Id.* If any comments are filed, the Board will review AAR's submission, together with the comments, and serve a decision within 60 days of the close of the record that either accepts, rejects, or modifies AAR's railroad-specific tax information. *Id.* If no comments are filed by August 8, 2011, AAR's submitted weighted average state tax rates will be automatically adopted by the Board, effective August 9, 2011. *Id.*

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

Decided: July 5, 2011.

Joseph H. Dettmar,

Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2011–17238 Filed 7–7–11; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–106010–98]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning information collection requirements related to qualified lessee construction allowances for short-term.

DATES: Written comments should be received on or before September 6, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of Evelyn J. Mack, at (202) 622–7381, or at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the internet, at *Evelyn.J.Mack@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Qualified Lessee Construction Allowances for Short-Term Leases.

OMB Number: 1545–1661.

Regulation Project Number: REG–106010–98, (TD 8901).

Abstract: The regulations provide guidance with respect to § 110, which provides a safe harbor whereby it will be assumed that a construction allowance provided by a lessor to a lessee is used to construct or improve lessor property when long-term property is constructed or improved and used pursuant to a short-term lease. The regulations ensure that both the lessee and the lessor consistently treat the property subject to construction allowance as nonresidential real property owned by the lessor.

Current Actions: There is no change to these existing regulations.

Type of review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 10,000.

Estimated Average Time per Respondent: 1 hour.

Estimated Total Annual Reporting Burden Hours: 10,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 28, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–17129 Filed 7–7–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Forms 12339, 12339–B, and 13775

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Forms 12339, Internal Revenue Service Advisory Council Membership Application; 12339–B, Information Reporting Program Advisory Committee

Membership Application and 13775, Tax Check Waiver.

DATES: Written comments should be received on or before September 6, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Evelyn J. Mack at (202) 622–7381, or at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the Internet at *Evelyn.J.Mack@Iirs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Tax Check Waiver.

OMB Number: 1545–1791.

Form Numbers: 12339, 12339–B, & 13775.

Abstract: Form 12339 and Form 12339–B were created to better solicit and maintain all of the applicant information for those interested in becoming members of the Internal Revenue Service Advisory Council (IRSAC) and the Information Reporting Program Advisory Council (IRPAC).

Form 12339 must be completed by those individuals interested in applying for IRSAC. Form 12339–B must be completed by those interested in applying for IRPAC. Each form is submitted in conjunction with Form 13775.

Current Actions: Form 13775 replaces Form 12339–A.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households, and businesses or other for-profit organizations.

Estimated Number of Respondents: 500.

Estimated Time per Response: 50 min.

Estimated Total Annual Burden Hours: 417.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 28, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–17131 Filed 7–7–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Notice 2008–56

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). The IRS is soliciting comments concerning information collection requirements related to relief from certain low-income housing credit requirements due to severe storms and flooding in Indiana.

DATES: Written comments should be received on or before September 6, 2011 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette B. Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Evelyn J. Mack, (202) 622–7381, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or through the internet at *Evelyn.J.Mack@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Relief from Certain Low-Income Housing Credit Requirements Due to Severe Storms and Flooding in Indiana.

OMB Number: 1545–2105.

Form Number: Notice 2008–56.

Abstract: This notice provides guidance to the Indiana Housing and Community Development Authority regarding the suspension of certain income limitation requirements under section 42 of the Internal Revenue Code for certain low-income housing tax credit properties as a result of the devastation caused by Severe Storms and Flooding in Indiana.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations, Farms.

Estimated Number of Respondents: 500.

Estimated Time per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 125.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection

techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 28, 2011.

Yvette B. Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2011–17130 Filed 7–7–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0086]

Agency Information Collection (Request for a Certificate of Eligibility) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 8, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0086'' in any correspondence

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, fax (202) 461–0966 or e-mail *denise.mclamb@va.gov.* Please refer to ''OMB Control No. 2900–0086.''

SUPPLEMENTARY INFORMATION:

Title: Request for a Certificate of Eligibility, VA Form 26–1880.

OMB Control Number: 2900–0086.

Type of Review: Extension of a currently approved collection.

Abstract: The data collected on VA Form 26–1880 is used to determine a claimant's eligibility for home loan guaranty benefits. Claimants also use VA Form 26–1880 to request restoration of entitlement previously used, or a duplicate Certificate of Eligibility due to the original being lost or stolen.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on May 2, 2011, at pages 24568–24569.

Affected Public: Individuals or households.

Estimated Annual Burden: 62,500 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 250,000

Dated: July 5, 2011.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–17166 Filed 7–7–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0503]

Agency Information Collection (Veterans Mortgage Life Insurance—Change of Address Statement) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 8, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov;* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0503'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, fax (202) 461–0966 or e-mail *denise.mclamb@va.gov.* Please refer to ''OMB Control No. 2900–0503.''

SUPPLEMENTARY INFORMATION:

Title: Veterans Mortgage Life Insurance—Change of Address Statement, VA Form 29–0563.

OMB Control Number: 2900–0503.

Type of Review: Extension of a currently approved collection.

Abstract: The data collected on VA Form 29–0563 will be used to inquire about a veteran's continued ownership of property issued under Veterans Mortgage Life Insurance when an address change for the veteran is received. VA uses the data collected to determine whether continued Veterans Mortgage Life Insurance coverage is applicable since the law granting this insurance provides that coverage terminates if the veteran no longer owns the property.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on May 2, 2011, at page 24570.

Affected Public: Individuals or households.

Estimated Annual Burden: 20 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 240.

Dated: July 5, 2011.

By Direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–17167 Filed 7–7–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0166]

Agency Information Collection (Application for Ordinary Life Insurance) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995

(44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 8, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov;* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0166'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, fax (202) 273–0966 or e-mail *denise.mclamb@va.gov.* Please refer to ''OMB Control No. 2900–0166.''

SUPPLEMENTARY INFORMATION:

Titles

a. Application for Ordinary Life Insurance, Replacement Insurance for Modified Life Reduced at Age 65, National Service Life Insurance, VA Form 29–8485.

b. Application for Ordinary Life Insurance, Replacement Insurance for Modified Life Reduced at Age 70, National Service Life Insurance, VA Form 29–8485a.

c. Application for Ordinary Life Insurance, Replacement Insurance for Modified Life Reduced at Age 65, National Service Life Insurance, VA Form 29–8700.

d. Application for Ordinary Life Insurance, Replacement Insurance for Modified Life Reduced at Age 65, National Service Life Insurance, VA Forms 29–8700a–e.

e. Application for Ordinary Life Insurance, Replacement Insurance for Modified Life Reduced at Age 70, National Service Life Insurance, VA Form 29–8701.

f. Application for Ordinary Life Insurance, Replacement Insurance for Modified Life Reduced at Age 70, National Service Life Insurance, VA Form 29–8701a–e.

OMB Control Number: 2900–0166.

Type of Review: Extension of a currently approved collection.

Abstract: Policyholder's use the forms to apply for replacement of Modified Life insurance. Modified Life insurance coverage is reduced automatically by one–half from its present face value on the day before a policyholder's 65th and 70th birthdays. Policyholder's who wish to maintain the same amount of coverage must purchase whole life insurance prior to their 65th and 70th birthdays to replace the coverage that will be lost when the Modified Life insurance is reduce.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on May 2, 2011, at pages 24572–24573.

Affected Public: Individuals or households.

Estimated Annual Burden: 1,284 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 15,400.

Dated: July 5, 2011.

By Direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–17168 Filed 7–7–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0120]

Agency Information Collection (Report of Treatment by Attending Physician) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 8, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov;* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0120'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, fax (202) 461–0966 or e-mail *denise.mclamb@va.gov.* Please refer to ''OMB Control No. 2900–0120.''

SUPPLEMENTARY INFORMATION:

Title: Report of Treatment by Attending Physician, VA Form 29–551a.

OMB Control Number: 2900–0120.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 29–551a is used to collect information from attending physician to determine a claimant's eligibility for disability insurance benefits.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on May 2, 2011, at page 24572.

Affected Public: Individuals or households.

Estimated Annual Burden: 5,069 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 20,277.

Dated: July 5, 2011.

By Direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–17169 Filed 7–7–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0492]

Agency Information Collection (VA MATIC Authorization) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits

Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 8, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov;* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0492'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, fax (202) 461–0966 or e-mail *denise.mclamb@va.gov.* Please refer to ''OMB Control No. 2900–0492.''

SUPPLEMENTARY INFORMATION:

Title: VA MATIC Authorization, VA Form 29–0532–1.

OMB Control Number: 2900–0492.

Type of Review: Extension of a currently approved collection.

Abstract: Veteran policyholders complete VA Form 29–0532–1 to authorize deduction of Government Life Insurance premiums from their bank account.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on May 2, 2011, at page 24567–24568.

Affected Public: Individuals or households.

Estimated Annual Burden: 1,500 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 3,000.

Dated: July 5, 2011.

By Direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–17174 Filed 7–7–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0024]

Agency Information Collection (Insurance Deduction Authorization (for Deduction from Benefit Payments)) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 8, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov;* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0024'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, fax (202) 461–0966 or e-mail *denise.mclamb@va.gov.* Please refer to ''OMB Control No. 2900–0024.''

SUPPLEMENTARY INFORMATION:

Title: Insurance Deduction Authorization (For Deduction from Benefit Payments), VA Form 29–888.

OMB Control Number: 2900–0024.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 29–888 is completed by the insured or their representative to authorize deduction from their compensation check to pay premiums, loans and/or liens on his or her insurance contract.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on May 2, 2011, at page 24567.

Affected Public: Individuals or households.

Estimated Annual Burden: 622 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 3,732.

Dated: July 5, 2011.

By Direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–17170 Filed 7–7–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0154]

Agency Information Collection (Application for VA Education Benefits) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 8, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0154'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, FAX (202) 461–0966 or e-mail *denise.mclamb@va.gov.* Please refer to ''OMB Control No. 2900–0154.''

SUPPLEMENTARY INFORMATION:

Titles:

a. Application for VA Education Benefits, VA Form 22–1990.

b. Application for Family Member to Use Transferred Benefits, VA Form 22–1990E.

c. Application for VA Education Benefits Under the National Call to Service (NCS) Program, VA Form 22–1990N.

OMB Control Number: 2900–0154.

Type of Review: Extension of a currently approved collection.

Abstract:

a. Claimants complete VA Form 22–1990 to apply for education assistance allowance.

b. Claimants who signed an enlistment contract with the Department of Defense for the National Call to Service program and elected one of the two education incentives complete VA Form 22–1990E.

c. VA Form 22–1990N is completed by claimants who wish to transfer his or her Montgomery GI Bill entitlement their dependents.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on May 2, 2011, at pages 24570–24571.

Affected Public: Individuals or households.

Estimated Annual Burden: 206,919 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: One-time.

Estimated Number of Respondents: 671,087.

Dated: July 5, 2011.

By Direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–17171 Filed 7–7–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0710]

Proposed Information Collection (VSO Access to VHA Electronic Health Records) Activity; Comment Request

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Health Administration (VHA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to establish computer accounts for Veteran Service Officers (VSO) to access VA's Veterans Health Information Systems Technology Architecture (VistA).

DATES: Written comments and recommendations on the proposed collection of information should be received on or before September 6, 2011.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *http://www.Regulations.gov* or to Cynthia Harvey-Pryor, Veterans Health Administration (193E1), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420; or e-mail: *cynthia.harvey-pryor@va.gov.* Please refer to ''OMB Control No. 2900–0710'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Cynthia Harvey-Pryor at (202) 461–5870 or FAX (202) 273–9381.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501—3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: VSO Access to VHA Electronic Health Records, VA Form 10–0400.

OMB Control Number: 2900–0710.

Type of Review: Extension of a currently approved collection.

Abstract: VSO's complete VA Form 10–0400 to request authorization to access VA VistA database. VA will use the data collected to establish an account for VSO's who were granted power of attorney by veterans who have medical information recorded in VHA electronic health records system.

Affected Public: Individuals or households.

Estimated Total Annual Burden: 400 hours.

Estimated Average Burden per Respondent: 2 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 12,000.

Dated: July 5, 2011.

By Direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–17172 Filed 7–7–11; 8:45 am]

BILLING CODE 8302–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0469]

Agency Information Collection (Certificate Showing Residence and Heirs of Deceased Veteran or Beneficiary) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 8, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov;* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0469'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, fax (202) 461–0966 or e-mail

denise.mclamb@va.gov. Please refer to ''OMB Control No. 2900–0469.''

SUPPLEMENTARY INFORMATION:

Title: Certificate Showing Residence and Heirs of Deceased Veteran or Beneficiary, VA Form 29–541.

OMB Control Number: 2900–0469.

Type of Review: Extension of a currently approved collection.

Abstract: VA uses the information collected on VA Form 29–541 to establish a claimant's entitlement to Government Life Insurance proceeds in estate cases when formal administration of the estate is not required.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on May 2, 2011, at page 24566.

Affected Public: Individuals or households.

Estimated Annual Burden: 1,039 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 2,078.

Dated: July 5, 2011.

By Direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–17173 Filed 7–7–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0501]

Agency Information Collection (Veterans Mortgage Life Insurance Inquiry) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 8, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov;* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0501'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, fax (202) 461–0966 or e-mail *denise.mclamb@va.gov.* Please refer to ''OMB Control No. 2900–0501.''

SUPPLEMENTARY INFORMATION:

Title: Veterans Mortgage Life Insurance Inquiry, VA Form 29–0543.

OMB Control Number: 2900–0501.

Type of Review: Extension of a currently approved collection.

Abstract: Veterans whose mortgage is insured under Veterans Mortgage Life Insurance (VMLI) completes VA Form 29–0543 to report any recent changes in the status of their mortgage. VMLI coverage is automatically terminated when the mortgage is paid in full or when the title to the property secured by the mortgage is no longer in the veteran's name.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on May 2, 2011, at page 24571.

Affected Public: Individuals or households.

Estimated Annual Burden: 45 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 540.

Dated: July 5, 2011.

By Direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–17175 Filed 7–7–11; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0131]

Agency Information Collection (Request for Supplemental Information on Medical and Nonmedical Applications) Activity Under OMB Review

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3521), this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden; it includes the actual data collection instrument.

DATES: Comments must be submitted on or before August 8, 2011.

ADDRESSES: Submit written comments on the collection of information through *http://www.Regulations.gov;* or to VA's OMB Desk Officer, OMB Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 (202) 395–7316. Please refer to ''OMB Control No. 2900–0131'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Denise McLamb, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–7485, fax (202) 273–0966 or e-mail *denise.mclamb@va.gov.* Please refer to ''OMB Control No. 2900–0131.''

SUPPLEMENTARY INFORMATION:

Title: Request for Supplemental Information on Medical and Nonmedical Applications, VA Form Letter 29–615.

OMB Control Number: 2900–0131.

Type of Review: Extension of a currently approved collection.

Abstract: VA Form 29–615 used by the insured to apply for new issue, reinstatement or change of plan on Government Life Insurance policies.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on May 2, 2011, at pages 24571–24572.

Affected Public: Individuals or households.

Estimated Annual Burden: 3,000 hours.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 9,000.

Dated: July 5, 2011.

By direction of the Secretary.

Denise McLamb,

Program Analyst, Enterprise Records Service.

[FR Doc. 2011–17176 Filed 7–7–11; 8:45 am]

BILLING CODE 8320–01–P

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Part II

Department of Health and Human Services

45 CFR Parts 160 and 162

Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Health Care Claim Status Transactions; Interim Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 162

[CMS–0032–IFC]

RIN 0938–AQ12

Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Health Care Claim Status Transactions

AGENCY: Office of the Secretary, HHS.

ACTION: Interim final rule with comment period.

SUMMARY: Section 1104 of the Administrative Simplification provisions of the Patient Protection and Affordable Care Act (hereafter referred to as the Affordable Care Act) establishes new requirements for administrative transactions that will improve the utility of the existing HIPAA transactions and reduce administrative costs. Specifically, in section 1104(b)(2) of the Affordable Care Act, Congress required the adoption of operating rules for the health care industry and directed the Secretary of Health and Human Services to ''adopt a single set of operating rules for each transaction * * * with the goal of creating as much uniformity in the implementation of the electronic standards as possible.''

This interim final rule with comment period adopts operating rules for two Health Insurance Portability and Accountability Act of 1996 (HIPAA) transactions: eligibility for a health plan and health care claim status. This rule also defines the term ''operating rules'' and explains the role of operating rules in relation to the adopted transaction standards. In general, transaction standards adopted under HIPAA enable electronic data interchange through a common interchange structure, thus minimizing the industry's reliance on multiple formats. Operating rules, in turn, attempt to define the rights and responsibilities of all parties, security requirements, transmission formats, response times, liabilities, exception processing, error resolution and more, in order to facilitate successful interoperability between data systems of different entities.

DATES: *Effective Date:* These regulations are effective on June 30, 2011. The incorporation by reference of the publications listed in this interim final rule is approved by the Director of the Office of the Federal Register June 30, 2011.

Compliance Date: The compliance date for this regulation is January 1, 2013.

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 6, 2011.

ADDRESSES: In commenting, please refer to file code CMS–0032–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0032–IFC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0032–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–1066 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Shannon Whetzel (410) 786–3267. Matthew Albright (410) 786–2546. Denise Buenning (410) 786–6711.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Introduction

The background discussion below presents a partial statutory and regulatory history related only to the statutory provisions and regulations that are important and relevant for purposes of this interim final rule with comment period. For further information about electronic data interchange, the complete statutory background, and the regulatory history, see the proposed rule entitled ''Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards,'' published in the **Federal Register** on August 22, 2008 (73 FR 49742).

Congress addressed the need for a consistent framework for electronic health care transactions and other administrative simplification issues through the Health Insurance Portability and Accountability Act of 1996 (HIPAA), (Pub. L. 104–191), enacted on August 21, 1996. HIPAA amended the

Social Security Act (hereinafter referred to as the Act) by adding Part C—Administrative Simplification—to Title XI of the Act requiring the Secretary of the Department of Health and Human Services (hereinafter referred to as the Secretary) to adopt standards for certain transactions to enable health information to be exchanged electronically and to achieve greater uniformity in the transmission of health information. Electronic Data interchange (EDI) enables providers and payers to process financial and administrative transactions faster and at a lower cost than manual transactions.

In the August 17, 2000 **Federal Register** (65 FR 50312) we published a final rule entitled ''Health Insurance Reform: Standards for Electronic Transactions'' (hereinafter referred to as the Transactions and Code Sets rule). This rule implemented some of the HIPAA Administrative Simplification requirements by adopting standards for electronic health care transactions developed by standard setting organizations (SSOs), and medical code sets to be used in those transactions. Accordingly, we adopted the Accredited Standards Committee (ASC) X12 standards Version 4010 and the National Council for Prescription Drug Programs (NCPDP) Telecommunication standard Version 5.1, which are specified at 45 CFR part 162, subparts K through S. All health plans, health care clearinghouses, and health care providers who transmit health information in electronic form (referred to as covered entities) are required to comply with these adopted standards.

In the January 16, 2009 **Federal Register**, we published a final rule entitled, ''Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards'' (74 FR 3296) (hereinafter referred to as the Modifications final rule), that, among other things, adopted updated versions of the standards [(ASC X12 Version 5010 (hereinafter referred to as Version 5010)] and NCPDP Version D.0) for the electronic health care transactions originally adopted in the Transactions and Code Sets final rule. Covered entities are required to comply with the updated standards for electronic health care transactions on January 1, 2012. Table 1 lists HIPAA standard transactions.

TABLE 1—CURRENT ADOPTED STANDARDS FOR HIPAA TRANSACTIONS

Standard	Transaction
ASC X12 837 D	Health care claims—Dental.
ASC X12 837 P	Health care claims—Professional.
ASC X12 837 I	Health care claims—Institutional.
NCPDP D.0	Health care claims—Retail pharmacy drug.
ASC X12 837 P and NCPDP D.0	Health care claims—Retail pharmacy supplies and professional services.
NCPDP D.0	Coordination of Benefits—Retail pharmacy drug.
ASC X12 837 D	Coordination of Benefits—Dental.
ASC X12 837 P	Coordination of Benefits—Professional.
ASC X12 837 I	Coordination of Benefits—Institutional.
ASC X12 270/271	Eligibility for a health plan (request and response)—dental, professional, and institutional.
NCPDP D.0	Eligibility for a health plan (request and response)—Retail pharmacy drugs.
ASC X12 276/277	Health care claim status (request and response).
ASC X12 834	Enrollment and disenrollment in a health plan.
ASC X12 835	Health care payment and remittance advice.
ASC X12 820	Health plan premium payment.
ASC X12 278	Referral certification and authorization (request and response).
NCPDP D.0	Referral certification and authorization (request and response)—retail pharmacy drugs.
NCPDP 5.1 and D.0	Retail pharmacy drug claims (telecommunication and batch standards).
NCPDP 3.0	Medicaid pharmacy subrogation (batch standard).

In general, the transaction standards adopted under HIPAA enable electronic data interchange using a common interchange structure, thus minimizing the industry's reliance on multiple formats. While the standards significantly decrease administrative burden on covered entities by creating greater uniformity in data exchange, and reduce the amount of paper forms needed for transmitting data, gaps created by the flexibility in the standards permit each health plan to use the transactions in very different ways, which remains an obstacle to achieving greater health care industry administrative simplification. These gaps include all of the following:

• Performance and system availability. Because the standards permit the flexibility of conducting the transactions in batch mode or real-time, in order to minimize the number of different implementations, some submitters have resorted to contracting with clearinghouses for transaction exchanges that require batch submissions, and simultaneously are utilizing internal resources for real-time submissions. Some batch submissions are only conducted overnight. Typically batch submissions can be substantially slower than real-time transmissions, and systems may be available only at certain times for conducting certain transactions.

• Connectivity and transportation of information. In traditional trading partner agreements, health plans specify their connectivity options for conducting the standard transactions. These options can vary from plan to plan. For example, some payers only conduct the transactions through a contracted clearinghouse. Others offer a direct connection to their system. Still others use both—contract with a clearinghouse for some transactions, and offer direct connect solutions for other transactions. Also, there are some plans that offer a number of options, and negotiate a choice with each trading partner, including providers.

• Security and authentication. Currently, security standards do not prescribe requirements for levels of security and authentication when conducting the standard transactions and accessing protected health information. A covered entity's level of security and authentication requirements is determined by the individual entity's periodic assessments for security risk and vulnerabilities. Organizations have latitude to determine and document the number and types of security safeguards that they implement. Although this flexibility supports the implementation

of security safeguards that are consistent with the uniqueness of various organizations, it also limits standardization for security compliance.

• Business scenarios and expected responses. The standards do not define methods by which trading partners, including providers, establish electronic communication links, or types of hardware and software to exchange EDI data. Each trading partner, including providers, separately provides specific requirements; for example, the number of transactions that are submitted in a file. Transaction processing in each entity's system will vary from one trading partner, including providers, to another. The responses to compliantly implementing these various transaction processing systems are identified by trading partners, including providers, in documentation that is in addition to the adopted implementation guides. These types of documented business requirements can vary in terms of number and complexity.

• Data content refinements. In accordance with trading partner agreements, plans can ignore certain data that are submitted if not needed by them to conduct the transaction. They also can refine certain data elements and require their submission. Trading partner agreements and additional documentation that plans develop permit plans to define specific types of data and to clarify the specific data that is required to be submitted for successful completion of a transaction. Although the standards limit the number of data elements that can be defined or optionally submitted, a plan's individual business flow and operations may impose specific data definition and submission requirements.

These gaps, among other challenges in the implementation of the standards, have spurred the creation of companion guides by health plans. Health plans have created these companion guides to describe their unique implementation of HIPAA transactions and how they will work with their business partners. Historically, companion guides have been used to establish business practices such as response time, system availability, communication protocols, hours of operation, amount of claim history available for inquiries and real-time adjustments, security practices, and more. Health plans' companion guides vary in format and structure. Such variance can be confusing to trading partners (those entities, including providers, who exchange HIPAA compliant electronic transactions), who must implement them in addition to the specifications in the transaction standard implementation guides. Further, each companion guide is unique for each different health plan.

Currently, according to the American Medical Association (AMA) there are over 1,200 such companion guides in existence (*http://www.ama-assn.org/ama1/pub/upload/mm/368/hipaa-tcs.pdf*). As mentioned previously, companion guides require providers and trading partners, including providers, to adhere to different transaction implementation rules for different health plans. Therefore, the widespread proliferation of health plan companion guides is particularly burdensome to health care providers, and we believe has subverted the goal of administrative simplification.

Over the past 5 years, this proliferation of health plan companion guides has given rise to the development of operating rules. To facilitate successful interoperability between data systems of different entities, operating rules more clearly define the rights and responsibilities of all parties, security requirements, transmission formats, response times, liabilities, exception processing, error resolution and more. Operating rules have been shown to reduce costs and administrative complexities as will be described later in this interim final rule with comment period.

The use of operating rules is widespread and varied among other industries. For example, uniform operating rules for the exchange of Automated Clearing House (ACH) payments among ACH associations are used in compliance with U.S. Federal Reserve regulations (12 CFR Part 370), and maintained by the Federal Reserve and the Electronic Payments Network. Additionally, credit card issuers employ detailed operating rules (for example, Cirrus Worldwide Operating Rules) describing types of members, their responsibilities and obligations, licensing and display of service marks, *etc.*

B. Operating Rules Mandated by the Affordable Care Act

Congress sought to address the aforementioned problems in the health care industry by requiring the adoption of operating rules for the health care industry as outlined in the Patient Protection and Affordable Care Act (Pub L. 111–148), enacted on March 23, 2010, and by the Health Care and Education Reconciliation Act of 2010, (Pub. L. 111–152), which was enacted on March 30, 2010 (hereinafter referred to as the Affordable Care Act). Section 1173(g)(1) of the Act, as added by section 1104(b)(2) of the Affordable Care Act, requires the Secretary to ''adopt a single set of operating rules for each transaction * * * with the goal of creating as much uniformity in the implementation of the electronic standards as possible.''

The role of operating rules is to support the adopted standards for health care transactions in order to foster and enhance uniform use of the adopted standards and implementation guides across the health care industry. Standards and operating rules overlap in their functions to increase uniformity, but differ in their purposes. While standards are mainly concerned with the content transmitted in a transaction, operating rules provide for the method of how the information should be transmitted, as well as the elimination of certain situationality in the use of data content contained in the standards. Situationality refers to the fact that many transaction requirements only apply if the situation is presented. For example, in the 271 eligibility response transaction, the health plan name is only required when a specific plan name exists for the plan for which the individual has coverage.

Operating rules augment the standards in the following three important ways:

• They contain additional requirements that help implement the standard for a transaction in a more consistent manner across health plans. For example, when a provider currently sends an eligibility for a health plan inquiry to a health plan, the standard allows responses ranging from a simple ''yes'' or ''no'', to the inclusion of a complete range of information. The operating rule requires the health plan to return patient eligibility and financial responsibility for a specified list of service type codes including, but not limited to, dental, vision, medical, hospital inpatient, and emergency care. This requirement ensures that a provider, who submits the same inquiry to multiple payers, receives a consistent response for an eligibility for a health plan inquiry. This reduces the number of customized transactions when dealing with multiple health plans, thus saving both time and money.

• They address ambiguous or conditional requirements in the standard and clarify when to use or not use certain data elements or code values. For example, the standard may leave it to the discretion of the health plan whether or not to return the health plan's name in a particular field, creating the possibility of inconsistency in health plan responses. An operating rule may require that the health plan name always be returned and that it

always be returned in one particular specified manner. This encourages uniformity and alleviates the problem of providers receiving inconsistent information.

• They specify how trading partners, including providers, should communicate with each other and exchange patient information, with the goal of eliminating connectivity inconsistencies. Currently, individual health plans specify the transmission methods they expect each of their trading partners, including providers, to use for electronic transactions. Mandating one uniform method decreases the amount of work and inconsistencies providers experience when dealing with multiple payers with differing transmission methods.

The Affordable Care Act presents a definition of operating rules and provides a great deal of guidance about the role Congress envisioned for operating rules in relation to the standards. Operating rules are defined by section 1171(9) of the Act (as added by section 1104(b)(1) of the Affordable Care Act) as ''the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.'' Additionally, section 1173(a)(4)(A) of the Act (as added by section 1104(b)(2) of the Affordable Care Act) requires that—

> The standards and associated operating rules adopted by the Secretary shall—
> (i) to the extent feasible and appropriate, enable determination of an individual's eligibility and financial responsibility for specific services prior to or at the point of care;
> (ii) be comprehensive, requiring minimal augmentation by paper or other communications;
> (iii) provide for timely acknowledgment, response, and status reporting that supports a transparent claims and denial management process (including adjudication and appeals); and
> (iv) describe all data elements (including reason and remark codes) in unambiguous terms, require that such data elements be required or conditioned upon set values in other fields, and prohibit additional conditions (except where necessary to implement State or Federal law, or to protect against fraud and abuse).''

Section 1104(b)(2) of the Affordable Care Act also amended section 1173 of the Act by adding new subsection (a)(4)(B), which states that, ''[i]n adopting standards and operating rules for the transactions* * *, the Secretary shall seek to reduce the number and complexity of forms (including paper and electronic forms) and data entry required by patients and providers.''

Section 1104(b)(2) of the Affordable Care Act added section 1173(g)(1) to the Act, which states that, ''[s]uch operating rules shall be consensus-based and reflect the necessary business rules affecting health plans and health care providers and the manner in which they operate pursuant to standards issued under Health Insurance Portability and Accountability Act of 1996.''

New sections 1173(g)(2)(D), (g)(3)(C), and (g)(3)(D) of the Act also clarify the scope of operating rules. They provide that,

> In adopting operating rules under this subsection, the Secretary shall consider recommendations for operating rules developed by a qualified nonprofit entity that meets the following requirements * * * (D) The entity builds on the transactions issued under Health Insurance Portability and Accountability Act of 1996. * * * The National Committee on Vital and Health Statistics shall * * * (C) determine whether such operating rules represent a consensus view of health care stakeholders and are consistent with and do not conflict with other existing standards; (D) evaluate whether such operating rules are consistent with electronic standards adopted for health information technology

We take from the statutory context the following information about operating rules to be adopted under HIPAA:

• They are business rules and guidelines;
• They are necessary for the electronic exchange of information;
• They are not defined by a standard;
• They do not conflict with the existing HIPAA standards;
• They are consensus based;
• They are consistent with HIPAA and Health Information Technology (HIT) standards adopted by the Secretary; and
• Together with standards they encourage the use of electronic transactions by reducing ambiguities currently permitted by the standard, resulting in better-defined inquiries and responses that add value to provider practice management and health plan operations.

II. Provisions of the Interim Final Rule With Comment Period

A. Definition of Operating Rules

Section 1171(9) of the Act, as added by section 1104(b)(1) of the Affordable Care Act, defines operating rules as ''the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.'' We are adding the term ''operating rules'' to the definitions in regulations at 45 CFR 162.103, and defining it just as it appears in the statute. We note that, in the statutory reference, ''this part'' refers to Part C of Title XI of the Act, Administrative Simplification. In the regulation at 45 CFR 162.103, ''this part'' refers to Part 162 of the CFR, the part in which the definition appears, which contains the regulations that pertain to, among other things, the HIPAA transactions and code sets. The following discussion further explains operating rules and their scope, in light of their relationship to the standards.

Business rules and guidelines are not defined by the statute, nor has the health care industry specifically defined business rules or guidelines for itself. These are very broad terms and there are many ways to define them. Generally, business rules and guidelines are statements that refine and specify. For purposes of operating rules, business rules and guidelines are statements that refine and specify.

While operating rules may have a very broad scope as business rules and guidelines in order to cover the full spectrum of data content, from data elements to standards, we believe there are limitations. To meet the definition of operating rules, business rules and guidelines must be ''*necessary* * * * for the electronic exchange of information that are not defined by a standard or its implementation specifications.'' We interpret the term ''necessary'' to be those operating rules needed to facilitate better communication between trading partners, including providers, to fill gaps in the standards, and to fulfill the purposes and principles set out in sections 1173(a)(4)(A)(i) through (iv) and (B) of the Act.

If a business rule or guideline is necessary for the electronic exchange of information, it must also be one that is ''not defined by'' a HIPAA standard or its implementation specifications in order to meet the definition of an operating rule. We consider a business rule or guideline that does not duplicate what is in the standard to be one that is not defined by the standard. Business rules and guidelines that duplicate what is in the standard are not operating rules under our interpretation.

The National Committee on Vital and Health Statistics (NCVHS) is tasked with reviewing any operating rule developed and recommended to the Secretary for adoption. The NCVHS is to make recommendations to the Secretary and determine whether such operating rules represent a consensus view of the health care stakeholders and are consistent with and do not conflict with other

existing standards under section 1173(g)(3)(C) of the Act. The NCVHS must also determine if such operating rules are consistent with electronic standards adopted for health information technology under section 1173(g)(3)(D) of the Act. From these statutory provisions, we understand that operating rules should be consistent with and not be in conflict with the adopted HIPAA standards and HIT standards (for example, those standards that address governance, funding and infrastructure of controlled vocabularies, value sets and vocabulary subsets to be used primarily to further interoperability between providers and systems). We believe that, if an operating rule imposes a requirement that would make it impossible for a party to comply with both the associated HIPAA standard and the operating rule, then the operating rule conflicts with the standard. This interpretation is consistent with fundamental principles and precedents regarding when a conflict exists. If a party is able to satisfy both the requirements of the standard and the requirements of the operating rule, there is no conflict and the operating rule is consistent with the standard. Table 2 illustrates what we consider to be a conflict by presenting hypothetical scenarios that illustrate when an operating rule could or could not conflict with a standard.

TABLE 2—COULD AN OPERATING RULE CONFLICT WITH A STANDARD?

Statement in the standard	Statement in the operating rule	Does the operating rule's statement conflict with the standard's statement?	Justification
"X is recommended."	"X is "required."	No	It is possible for an entity to comply with both the standard and the operating rule.
"X is not required."	"X is required."	No	It is possible for an entity to comply with both the standard and the operating rule.
"X cannot be required."	"X is required."	Yes	It is impossible for an entity to comply with both the standard and the operating rule.
"X is required."	"X is required."	No	It is possible for an entity to comply with both the standard and the operating rule. (However, to the extent that the statement in the operating rule duplicates the statement in the standard, the operating rule statement would not be considered an operating rule.)
"X is at the discretion of person #1. Person #2 cannot require it."	"X is required."	No	It is possible for an entity to comply with both the standard and the operating rule.
"X is required."	"X is required, so is Y."	No	It is possible for an entity to comply with both the standard and the operating rule.
"X is required. No other can be required."	"X is required, so is Y."	Yes	It is impossible for an entity to comply with both the standard and the operating rule.

Our current definition of standard at 45 CFR 160.103 is very broad. In fact, it is so broad that it could include operating rules as we are defining that term at § 162.103. Therefore, we are revising the definition of standard at § 160.103 to be clear that standards and operating rules are separate and distinct. See the ''Additional Requirements'' section for discussion of this change.

B. National Committee on Vital and Health Statistics and the Affordable Care Act

The National Committee on Vital and Health Statistics (NCVHS) was established by Congress to serve as an advisory body to the Department of Health and Human Services (DHHS) on health data, statistics and national health information policy, and has been assigned a significant role in the Secretary's adoption of operating rules under section 1173(g)(3) of the Act (as added by section 1104(b)(2) of the Affordable Care Act).

In July 2010, the NCVHS' Subcommittee on Standards convened a hearing to discuss the Affordable Care Act's provisions pertaining to operating rules for the eligibility for a health plan and health care claim status transactions. Section 1173(g)(3) requires the NCVHS to do the following:

- Advise the Secretary whether a nonprofit entity meets the requirements for development of operating rules.
- Review the operating rules developed and recommended by such nonprofit entity.
- Determine whether such operating rules represent a consensus view of the health care stakeholders and are consistent with and do not conflict with other existing standards.
- Evaluate whether such operating rules are consistent with electronic standards adopted for health information technology.
- Submit to the Secretary a recommendation as to whether the Secretary should adopt such operating rules.

The NCVHS engaged in a comprehensive review of health care operating rules and their authors, with the goal of determining whether an entity was qualified to develop operating rules for transactions and to evaluate existing operating rules for purposes of making a recommendation to the Secretary as to whether those operating rules should be adopted. The process consisted of a full day of public testimony on July 20, 2010, with participation by more than 20 stakeholders representing a cross section of the health care industry, including health plans, provider organizations, health care clearinghouses, pharmacy industry representatives, health care industry associations, standards developers, professional associations, representatives of Federal and State health plans, the banking industry, and the entities proposing to serve as operating rules authoring entities.

During the hearing, testifiers reiterated the need for greater consistency and standardization in HIPAA transactions consistent with the Affordable Care Act amendments to the HIPAA, which highlight the need to improve the use of standard transactions, increase industry adherence to the implementation specifications of the standards, encourage greater adoption of electronic transactions, and enable more timely

updates and adoption of the HIPAA standards. Testifiers claimed that all of these could help reduce the clerical burden on the industry in the use of paper and the non-standard use of the current transaction standards.

We believe that the considerable public participation in the NCVHS hearings for adoption of operating rules demonstrates an increasing level of support and interest from broader segments of the health care industry. Per the NCVHS' recommendation, we will work with industry to continue this public exchange of information regarding operating rules, standards and their respective roles in administrative simplification.

Based on the NCVHS testimony (*http://www.ncvhs.hhs.gov/100719ag.htm*) and the NCVHS' analysis of the operating rules and qualifications of the candidate authoring entities, the NCVHS developed a set of recommendations to the Secretary, which are outlined in the following discussions.

C. Operating Rules Authoring Entities

Section 1173(g)(3)(A) of the Act charges the NCVHS with advising the Secretary as to whether a nonprofit entity meets the statutory requirements for developing the operating rules to be adopted by the Secretary. Those requirements, at section 1173(g)(2) of the Act, include all of the following:

- The entity focuses its mission on administrative simplification.
- The entity demonstrates a multi-stakeholder and consensus-based process for development of operating rules, including representation by or participation from health plans, health care providers, vendors, relevant Federal agencies, and other standards development organizations.
- The entity has a public set of guiding principles that ensure the operating rules and process are open and transparent, and supports nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory practices.
- The entity builds on the transaction standards issued under the Health Insurance Portability and Accountability Act of 1996.
- The entity allows for public review and updates of its operating rules.

Of those organizations testifying at the July 2010 NCVHS hearing, two organizations formally requested to be considered authoring entities for operating rules. These entities were the Council for Affordable Quality Healthcare's (CAQH) Committee on Operating Rules for Information Exchange (CORE) and the National Council for Prescription Drug Programs (NCPDP).

The CAQH, a nonprofit alliance of health plans and trade associations, supports industry collaboration on initiatives that simplify health care administration (*http://www.caqh.org/about.php*). The CAQH launched the CORE with the goal of giving providers access to eligibility and benefits information before or at the time of service. The CAQH CORE is engaged in the development of voluntary operating rules for the facilitation of administrative health care transactions. It has already developed operating rules for the eligibility for a health plan and health care claim status transactions. The CAQH CORE has also demonstrated that the use of these rules yields a return on investment for both business operations and systems within today's complex health care environment (*http://www.caqh.org/COREIBMstudy.php*).

The NCPDP is a not-for-profit standards development organization (SDO) accredited by the American National Standards Institute (ANSI), with over 1,500 members representing the pharmacy services industry (*http://ncpdp.org/WP.aspx*). It is one of several SDOs involved in health care information technology and standardization, with a focus on retail pharmacy services, and has member representation from the pharmacy services sector of health care (*http://ncpdp.org/about.aspx*). The operating rules the NCPDP brought forth to NCVHS focus on the retail-pharmacy sector.

The July 2010 NCVHS hearings were followed by a request from the NCVHS Subcommittee on Standards to both the CAQH CORE and the NCPDP as authoring entity candidates, to respond to detailed questionnaires about their ability to meet the statutory requirements of the Affordable Care Act as authoring entities for health care operating rules. The NCVHS request solicited specific documentation from the two candidates to validate their previous testimony, including minutes, voting records and copies of bylaws. Both the CAQH CORE and the NCPDP responded to the Subcommittee's request and submitted their respective applicable materials. A synopsis of the candidates' responses can be found on the Internet at *http://www.ncvhs.hhs.gov/100930lt2.pdf.*

Upon review of the CAQH CORE's and the NCPDP's respective responses to the NCVHS questionnaire, the NCVHS determined that both organizations met the statutory requirements to be an operating rules authoring entity. The NCVHS noted, however, that there are still adjustments to process and procedures that may be required of both organizations to enhance transparency, citing the need for more formalized relations with each other and with other SDOs, inclusion of a more diverse cadre of stakeholders, and a more formal public review process. Both the CAQH CORE and the NCPDP acknowledged these issues in their submitted responses to the NCVHS (*http://www.ncvhs.hhs.gov/100930lt2.pdf*).

The NCVHS advised the Secretary in its letter dated September 30, 2010, (*http://www.ncvhs.hhs.gov/100930lt2.pdf*) that the CAQH CORE meets the requirements of section 1173(g)(2) of the Act to be the operating rules authoring entity for the non-retail pharmacy-related eligibility for a health plan and health care claim status standard transactions with additional qualifying requirements. In the same letter, the NCVHS stated that the NCPDP met the requirements to be the authoring entity for operating rules for retail pharmacy-related eligibility transactions (as outlined in the Telecommunications Standard Implementation Guide Version D.0) also with additional qualifying requirements. Those requirements for both the CAQH CORE and the NCPDP are as follows:

- Require authoring entities to maintain minutes, attendance, voting records, and other appropriate documentation that will help the NCVHS conduct verification that the authoring entities have utilized an open, consensus-driven process with broad stakeholder participation and provided an opportunity for public comment in authoring any new operating rules or new versions of existing operating rules, consistent with such processes followed by ANSI-accredited standards development organizations.
- Continue to use the NCVHS and its open process to evaluate, select, and recommend any new qualifying operating rules authoring entities when it comes time to adopt operating rules for other transactions, or for newer versions of the operating rules for the transactions for which the CAQH CORE and the NCPDP are being recommended to be named authoring entities at this time.

After our own review and analysis of the CAQH CORE and the NCPDP applications for consideration to be authoring entities for their respective developed operating rules, and the NCVHS' recommendation, we have determined that the CAQH CORE is qualified to be the operating rules authoring entity for non-retail

pharmacy-related eligibility for a health plan and health care claim status standard transactions per section 1173(g)(2) of the Act.

At the time of the hearing, the NCVHS based its recommendation to appoint the NCPDP as an operating rules authoring entity on the testimony presented. However, upon further review and consultation, we have determined that the NCPDP's standard provides enough detail and clarity to operationalize the standards to the point where no gaps exist that operating rules would need to fill and no further infrastructure or data content rules need to be adopted. (For a more detailed discussion, see section III. of this interim final rule with comment period).

D. Adoption of Operating Rules

1. Adoption of the CAQH CORE Phase I and Phase II Operating Rules for the Non-Retail Pharmacy Eligibility for a Health Plan and Health Care Claim Status Transactions (Updated for Version 5010)

The CAQH CORE builds consensus among health care industry stakeholders on a set of operating rules that facilitate administrative interoperability between health plans and providers by building on applicable HIPAA transaction requirements, enabling providers to submit transactions from any system, and facilitating administrative and clinical data integration. The CAQH CORE uses a phased approach for developing operating rules. This approach allows for developing rules and implementing them via incremental, achievable milestones, and helps to maximize rule adoption. The CAQH CORE Phase I operating rules were developed in 2006 and focused on the eligibility for a health plan transaction. The CAQH CORE Phase II rules, developed in 2008, added operating rules for the health care claim status transaction, and more rules for the eligibility for a health plan transaction that were not included in Phase I. Both the CAQH CORE Phase I and Phase II operating rules were updated to accommodate the Version 5010 HIPAA standards, which were adopted by the Secretary via the final rule published in the **Federal Register** on January 16, 2009 (74 FR 3296) and with which HIPAA covered entities must be compliant on January 1, 2012.

The CAQH CORE operating rules (updated for Version 5010) include both infrastructure rules and data content rules. The infrastructure rules help improve data content flow between provider and payer. They improve interoperability by addressing all of the following:

- Connectivity—provide a uniform way for stakeholders to connect (through the Internet).
- Response Times—specify that information will be available in real time.
- System Availability—specify systems delivering information be available a certain amount of time.
- Patient Identification—help assure patient matching/identification can occur.

The CAQH CORE's first set of operating rules (updated for Version 5010) are Phase I rules for eligibility for a health plan transaction. They help electronically confirm patient benefit coverage, copay, coinsurance, and base deductible. In addition, through requirements to use common Internet protocols, they allow providers to access needed patient information prior to or at the point of care. The CAQH CORE's second set of operating rules (updated for Version 5010) are the Phase II rules for the eligibility for a health plan and health care claim status transactions. They expand on the first set by adding a requirement for transaction recipients to send back patient remaining deductible amounts, rules to improve patient matching, health care claim status infrastructure requirements (for example, response time) and more prescriptive connectivity requirements.

We have examined each of the CAQH CORE Phase I and Phase II operating rules and are adopting those that we believe further enhance the HIPAA transactions by better facilitating communication between trading partners, including providers, filling gaps in the associated standards, and fulfilling the requirements, purposes, and principles set out in the statute at sections 1173(a)(4)(A)(i through iv) and (B). Of the eight CAQH CORE Phase I operating rules (updated for Version 5010), we are adopting the following six:

- Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, and CORE Version 5010 Master Companion Guide Template, 005010, 1.2, March 2011.
- Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011.
- Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011.
- Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version 1.1.0, March 2011.
- Phase I CORE 156: Eligibility and Benefits Real Time Response Time Rule, version 1.1.0, March 2011.
- Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011.

We are adopting all five of the CAQH CORE Phase II operating rules (updated for Version 5010). They include the following:

- Phase II CORE 250: Claim Status Rule, version 2.1.0, March 2011, and CORE Version 5010 Master Companion Guide Template, 005010, 1.2, March 2011.
- Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011.
- Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0, March 2011.
- Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011.
- Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011.

Both the CAQH CORE Phase I and Phase II operating rules (updated for Version 5010) that we are adopting in this interim final rule with comment period can be found on the CAQH CORE Web site at *http://www.caqh.org/COREVersion5010.php.* Below we briefly describe those operating rules.

The Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule (updated for Version 5010) and CORE Version 5010 Master Companion Guide Template provide a standardized format for health plan companion guides. As mentioned previously, health plans have the option of creating a companion guide that describes the specifics of how they implement the HIPAA transactions. Currently, health plans have independently created companion guides that vary in format and structure, which can be confusing to trading partners, including providers, and providers who must review numerous companion guides along with the Version 5010 Implementation Guides. To address this issue, the CAQH CORE developed the CORE Version 5010 Master Companion Guide Template to ensure that the structure of each health plan's companion guide is similar to every other health plan's companion guide, making it easier for providers to find information quickly.

Developed with input from multiple health plans, system vendors, provider representatives and healthcare and HIPAA industry experts, the CAQH CORE template organizes information into several sections including, general information (sections 1 through 9) and

transaction-specific information (section 10), as well as appendices that provide helpful information, such as an information checklist, descriptions of typical business scenarios, transmission examples, FAQs, and a summary of the changes between companion guides. The CAQH CORE recognizes that different health plans may have different requirements, so the CORE v5010 Master Companion Guide Template gives health plans the flexibility to tailor companion guides to meet each of their own particular needs.

The Phase I CORE 153: Eligibility and Benefits Connectivity Rule (updated for Version 5010) addresses usage patterns for both batch and real time transactions, the exchange of security identifiers, and communications-level errors and acknowledgements. It does not define the specific content of the message.

Currently, multiple connectivity methods, some based on open standards, others on proprietary approaches, are in use for administrative electronic transactions in the health care industry. Health care providers and health plans support multiple connectivity methods to connect to different health plans, clearinghouses, provider organizations and others, which add costs for health plans and providers. This rule is designed to provide a ''safe harbor'' that providers and health plans can be assured will be supported by any trading partner, including providers. Safe harbors are essentially connectivity requirements. When trading partners including providers, agree to follow the same connectivity requirements, connectivity is better enabled. This rule is not intended to require trading partners, including providers, to remove existing connections that do not match the rule, nor is it intended to require that all trading partners, including providers, must use this method for all new connections. It is expected that some trading partners, including providers, may agree to use different communication mechanism(s) and/or security requirements than that described by this rule. The rule simply provides a secure connection for those entities that do not currently have one.

The Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule (updated for Version 5010) provides more robust and consistent information prior to or at the point of care. It specifies the minimum requirements for using the ASC X12 005010X279A1 Eligibility Benefit Request and Response (270/271) to inquire about health plan insurance coverage and to respond to such an inquiry using the ASC X12 005010X279A1 Eligibility Benefit Request and Response (270/271). The requirements address certain situational elements and codes and are in addition to requirements contained in the Version 5010 270/271 implementation guides. This rule provides for not only determination of an individual's eligibility but also his financial responsibility information for co-pay, deductible, and coinsurance prior to or at the point of care. This rule covers, for example, the following content in the Version 5010 271:

- The dates of eligibility under the health plan (contract) level for past and future dates and the dates of eligibility at the benefit level if different from the contract level.
- The patient financial responsibility for each specified benefit at the base contract amounts for both in-network and out-of-network.
- The name of the health plan when it exists in the health plan's system.

Compliance with the requirements of this operating rule will ultimately reduce the time it takes providers to track down such information after the service has been rendered, and decrease the provider's accounts receivable.

The Phase I CORE 155 and 156: Eligibility and Benefits Batch Response and Real Time Response Rules (updated for Version 5010) streamline and improve the flow of transactions by imposing timeframe requirements for when a response is to be submitted for an eligibility for a health plan inquiry.

For a Version 5010 270 batch mode response to a provider's inquiry submitted by 9:00 pm Eastern time of a business day, the response must be returned by 7:00 am Eastern time the following business day. The maximum response time when processing in real time mode must be 20 seconds or less.

The Phase I CORE 157: Eligibility and Benefits System Availability Rule (updated for Version 5010) also streamlines and improves the flow of transactions. It recognizes that many institutional providers need to be able to conduct health plan eligibility activities at any time. It also recognizes that health plans have a business need to take their eligibility and other systems offline periodically in order to perform system maintenance, which means that some systems will not be available for eligibility inquiries and responses on certain nights and weekends. The rule requires that systems be available to process eligibility inquiries no less than 86 percent of the time per calendar week for real and batch modes, and requires health plans to publish regularly scheduled downtime. It ensures that systems are up and running in a consistent manner and that trading partners, including providers, are aware of any downtime so they can plan accordingly.

The Phase II CORE 250: Claim Status Rule (updated for Version 5010) encourages and increases the use of the health care claim status transaction by providing for batch and real-time response times, system availability, the use of a companion guide template, and support for the CORE ''safe harbor'' connectivity requirement. These elements included in the CORE 250 rule follow the same requirements as and build upon the same requirements as for the eligibility for a health plan transaction infrastructure rules included in Phase I CORE 152, Phase I CORE 155, Phase I CORE 156 and Phase I CORE 157 rules we are adopting in this interim final rule with comment period. This means that Phase II CORE 250 rule (updated for Version 5010) requires each health plan to: follow the companion guide format requirement as provided in CORE 152, which is the CORE Version 5010 Master Companion Guide Template; support the CORE ''safe harbor'' connectivity requirements; support a maximum response time of 20 seconds from the time of submission of a Version 5010 276 for real time and for batch mode response to a provider's inquiry submitted by 9 p.m. Eastern time of a business day, the response must be returned by 7 a.m. Eastern time the following business day; ensure system availability of no less than 86 percent per calendar week for both real time and batch modes; and follow the companion guide format requirement as provided in CORE 152, which is the CORE v5010 Master Companion Guide Template.

The CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule (updated for Version 5010). Health plans and health care providers must be able to uniquely identify patients in order to ascertain patient eligibility. Although the Version 5010 270/271 standards specify data elements and data element attributes that may be used to identify an individual, the standards do not address the use of punctuation and special characters. Therefore, the way health plans identify individuals does not always match the way providers identify individuals, which results in the rejection or denial of eligibility transactions. The CAQH CORE 258 rule addresses certain aspects of individual identification that enhance the real time processing of eligibility inquiries and responses.

The Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code

Reporting Rule (updated for Version 5010) provides consistent and specific patient identification information on reasons for patient identification errors on an eligibility for a health plan inquiry. This allows providers to know specifically why they did not receive a match in an eligibility for a health plan inquiry, instead of trying to determine for themselves the reasons for the error and what corrective action is needed. This rule improves the specificity and standardized use of the AAA codes that would give providers better feedback to understand what information is missing or incorrect in order to obtain a valid match. It defines a standard way for health plans to report errors in the eligibility response that cause a health plan not to be able to respond with a Version 5010 271 showing eligibility information for the requested patient or subscriber. The goal is to use a unique error code wherever possible for a given error condition so that the re-use of the same error code is minimized. Where this is not possible, the goal (when re-using an error code) is to return a unique combination of one or more AAA segments along with one or more of the submitted patient identifying data elements such that the provider will be able to determine as precisely as possible what data elements are in error and take the appropriate corrective action.

The Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule (updated for Version 5010) builds on and enhances the Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule (updated for Version 5010) by requiring the provision in the eligibility response of the remaining patient deductible amounts for certain service type codes. The use of this rule further reduces the time it takes to track down this information manually or eliminates the time completely after the service has been rendered and decreases the provider's accounts receivable.

The CAQH CORE determined that Phase I CORE rules should focus on improving electronic eligibility and benefits verification, as eligibility is the first transaction in the claims process. Thus, if eligibility and benefits are accurately known to health care providers, all the associated electronic transactions that follow will be more effective and efficient. The Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule (updated for Version 5010) primarily outlined a set of requirements for health plans to return base (not remaining or accumulated) patient financial responsibility related to the deductible, co-pay and co-insurance for a set of 12 services in the ASC X12 005010X279A1 Eligibility Benefit Request and Response (270/271), and for vendors, clearinghouses and providers to transmit and use that financial data. The Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule (updated for Version 5010) extends and enhances the CORE Phase I Version 5010 271 transaction by requiring the provision of remaining deductible amounts for both the Phase I required 12 service type codes and an additional set of 39 other service type codes.

The Phase II CORE 270: Connectivity Rule (updated for Version 5010), which applies to both the eligibility for a health plan and health care claim status transactions, builds on CORE 153: Eligibility and Benefits Connectivity Rule (updated for Version 5010) by requiring additional connectivity specifications which further facilitate interoperability. This rule addresses the message envelope metadata (that information which defines the context for interpretation of the rest of the data in the message, for example, response codes, request methods, *etc.*) and the message envelope, (a fixed number of fields that show source, destination, tag, and communicator) and the submitter authentication requirements for both batch and real time transactions, and communications-level errors.

This rule improves utilization of electronic transactions by enabling more entities to interoperate with other entities, including reducing the implementation barrier for small entities (for example, small providers). It also extends the Phase I CORE 153: Eligibility and Benefits Connectivity Rule (updated for Version 5010) and establishes a safe harbor by further specifying the connectivity that all covered entities must demonstrate and implement.

Tables 3 and 4 summarize each of the CAQH CORE Phase I and Phase II Version 5010 operating rules, which we are adopting in this interim final rule with comment period, as reflected in 45 CFR 162.920, 162.1203, and 162.1403.

TABLE 3—THE CAQH CORE PHASE I OPERATING RULES

[Updated for version 5010]

Rule	High level requirements
Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, Version 1.1.0, March 2011 and CORE Version 5010 Master Companion Guide Template, 005010, 1.2, March 2011.	*Goal:* Standardize template/common structure of companion guides for more efficient reference. *Requirements:* Standard template/structure for companion guides.
Phase I CORE 153: Eligibility and Benefits Connectivity Rule, Version 1.1.0, March 2011.	*Goal:* Provide a ''safe harbor'' that application vendors, providers, and health plans can be assured will be supported by any trading partner including providers, to facilitate connectivity standardization and interoperability across the exchange of health information. *Requirements:* Supports data exchange over the public Internet (HTTP/S).
Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, Version 1.1.0, March 2011.	*Goal:* Enable more robust and consistent exchange of eligibility information. *Requirements:* Specifies what is to be included in the 271 eligibility for a health plan response to a 270 eligibility for a health plan inquiry.
Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, Version 1.1.0, March 2011.	*Goal:* Streamline and improve flow of transactions. *Requirements:* Response time is 20 seconds or less for real time, next day for batch.
Phase I CORE 156: Eligibility and Benefits Real Time Response Time Rule, Version 1.1.0, March 2011.	
Phase I CORE 157: Eligibility and Benefits System Availability Rule, Version 1.1.0, March 2011.	*Goal:* Streamline and improve flow of transactions. *Requirements:* Systems must be available 86 percent per calendar week, and regular downtime must be published.

TABLE 4—THE CAQH CORE PHASE II VERSION 5010

Rule	High level requirements
Phase II CORE 250: Claim Status Rule, Version 2.1.0, March 2011	*Goal:* Promote increased availability and usage of the health care claim status transaction through rules for real-time and batch response times, system availability, and connectivity. *Requirements:* Application of real-time and batch response times, system availability, and connectivity rules for health care claim status transactions, which were derived from the eligibility Phase I infrastructure rules.
Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, Version 2.1.0, March 2011.	*Goal:* Improve patient matching. *Requirements:* Normalize the submitted and stored last name (*e.g.,* remove special characters, suffixes/prefixes) before trying to match.
Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, Version 2.1.0, March 2011.	*Goal:* Provide better information on why a match did not occur in an eligibility for a health plan request. *Requirements:* Return specified AAA codes for each error condition.
Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, Version 2.1.0 , March 2011.	*Goal:* Provide additional financial responsibility/patient liability information in response to an inquiry and support more high volume service type codes. *Requirements:* Includes remaining deductible amount (plus static copay and coinsurance information) in response to an eligibility for a health plan inquiry, along with 39 additional service type codes beyond the service type codes provided in Phase I.
Phase II CORE 270: Connectivity Rule, Version 2.2.0, March 2011	*Goal:* Provide more comprehensive connectivity specifications to further interoperability. *Requirements:* Includes requirements for two message envelope standards submitter authentication (*i.e.,* username/password, digital certificates) and metadata.

In 45 CFR 162.103, we provide that a standard transaction means ''a transaction that complies with an applicable standard adopted under this part.'' In this interim final rule with comment period we are adopting operating rules and requiring that covered entities comply with those operating rules when conducting a transaction for which we have adopted a standard. In order to reflect that requirement in regulation text, in part, we need to modify the definition of standard transaction to be clear that a standard transaction is one that complies with the adopted standard and the adopted associated operating rule. Therefore, we are amending the definition of standard transaction at 45 CFR 162.103. See the ''Additional Requirements'' section for discussion of this change.

In the following sections, we identify and discuss several specific CAQH CORE operating rule requirements that we believe require further explanation. These include acknowledgements, certification, and the use of the CAQH CORE companion guide template. We believe these topics require additional explanation because in this interim final rule with comment period, we are not adopting the operating rules that pertain to acknowledgements or the requirements within the adopted operating rules that pertain to acknowledgements, nor are we adopting the CAQH CORE certification policies. Additionally, we believe we need to be especially clear that we are adopting the CAQH CORE companion guide template to avoid any confusion as to whether the companion guide template is included as part of the companion guide rules under CAQH CORE Phase I and Phase II rules we are adopting.

a. Acknowledgements Operating Rules

Acknowledgements are responses transmitted by EDI that inform submitters whether or not their transaction has been received or if there are problems with the transaction. The use of acknowledgements adds a great deal of value to the underlying transactions for which they are sent by informing the sender that a transaction has been received or has been rejected. Without acknowledgements, it is difficult for the sender to know whether the intended recipient received the transmission, which often results in the sender repeatedly querying the intended receiver as to the status of the transmission.

In the February 2010 report to the NCVHS, the Designated Standards Maintenance Organization (DSMO), which receives and processes requests for adopting new standards or modifying adopted standards recommended that the NCVHS consider acknowledgements for adoption as HIPAA transactions, using the Version 5010 999, 271, 277, and TA1 standards. In the DSMO recommendation, it was noted that acknowledgements help the health care industry better reconcile the status of transmitted EDI transactions, especially when sending claims and remittance transactions. The transaction sender benefits from knowing that the receiving party has successfully received the transaction or has encountered errors that need to be reconciled.

We have received anecdotal reports of wide-spread industry use of acknowledgements on a voluntary basis, and we understand that provisions for acknowledgements are contained in many health plans' companion guides. It is our understanding also that the health care industry has long supported, and even anticipated, the adoption of an acknowledgement transaction standard under HIPAA. The CAQH CORE 150 and 151 rules (updated for Version 5010) specifically pertain to requiring the use of the Version 5010 999, 271, and 277 acknowledgements. Additionally, the use of acknowledgements is referenced throughout many of the other CAQH CORE rules adopted in this interim final rule with comment period, including the CORE v5010 Master Companion Guide Template.

Section 1173(a)(4)(A)(iii) of the Act, as added by section 1104(b) of the Affordable Care Act, provides that standards and associated operating rules shall ''provide for timely acknowledgement, response, and status reporting that supports a transparent claims and denial management process (including adjudication and appeals).'' This new provision is an indication of Congress' recognition of the important role acknowledgements play in EDI.

Although we are not requiring compliance with any of the CAQH CORE rule requirements regarding acknowledgements, we are addressing the important role acknowledgements play in EDI by strongly encouraging the industry to implement the acknowledgements requirements in the CAQH CORE rules we are adopting herein. We reflect the exclusion of the requirement to use acknowledgments in regulation text at § 162.1203 and § 162.1403.

Until such time as the Secretary adopts a standard for acknowledgments, we support the industry's ongoing voluntary use of acknowledgements and encourage even more widespread use. We welcome industry and stakeholder comments on this topic.

b. CAQH CORE Operating Rules Certification

Currently, the CAQH CORE administers a voluntary certification process, for a fee. Once the entity passes the certification requirements, the CAQH CORE assigns the status of ''CORE-certified Entity'' and requires those entities to adhere to the CAQH CORE policies. The CAQH CORE operating rules are free and available for voluntary use today, and any trading partner, including providers, can opt to use them, they would simply not be able to claim that they were ''CORE certified entities.''

Throughout the CAQH CORE rules we are adopting, there are also many references to CORE certification. For example, the rules reference CORE-certified entity, CORE-authorized testing vendor, CORE-certified participant, and the like. In many places, the rules describe what is required for the successful completion of the approved CORE test suite, CORE testing requirements, *etc.* In this interim final rule with comment period, we are not requiring covered entities to obtain the CAQH CORE certification or to adhere to the CAQH certification policies for Phase I and Phase II operating rules. We want to be clear that we are not requiring compliance with any aspect of CORE certification.

We note that section 1173(h)(1)(A) of the Act (as added by section 1104(b)(2) of the Affordable Care Act) requires that health plans certify to the Secretary no later than December 31, 2013 that they are in compliance with any applicable HIPAA standards and associated operating rules for the eligibility for a health plan, health care claim status, and health care payment and remittance advice transactions. Until we develop a certification process in accordance with section 1173(h) of the Act specifying health plan compliance requirements, health plans and all other covered entities are not required to certify compliance with the CAQH CORE Version 5010 operating rules we are adopting. We reflect the exclusion of CORE certification in regulation text at § 162.1203 and § 162.1403.

c. Use of the CAQH CORE Companion Guide Template

During the July 2010 NCVHS hearing, the NCVHS also heard testimony concerning the continued use of companion guides when operating rules are adopted. The NCVHS indicated that it does not wish to encourage the perpetual use of companion guides, which subvert the goals of administrative simplification; however, it acknowledged that companion guides may continue to be necessary for proprietary information, transmission instructions, and other limited business purposes, and will likely never be totally replaced by operating rules or updated versions of the standards.

The NCVHS recommended that the Secretary require that any companion guides deemed necessary by health plans not conflict with the HIPAA standards, implementation specifications and operating rules, and that they follow a standard format and content agreed upon by industry consensus across all sectors. The NCVHS stated that companion guides should be limited to providing basic trading partner, including providers, facts, such as contact information, Web sites, service phone numbers, and other necessary information for conducting business, *etc.*

With input from health plans, system vendors, provider representatives and healthcare/HIPAA industry experts, the CAQH CORE has developed a companion guide template as part of their Phase I and Phase II operating rules (updated for Version 5010) that organizes information into several simple sections and gives health plans the flexibility to tailor the document to meet their particular needs. The CORE 152: Eligibility and Benefit Real Time Companion Guide Rule states that the ASC X12 005010X279A1 Eligibility Benefit Request and Response (270/271) transactions must follow the format/flow as defined in the CORE v5010 Master Companion Guide Template. The CORE 250: Claim Status Rule (updated for Version 5010) includes a requirement that entities using the ASC X12N/005010X212 Health Care Claim Status Request and Response (276/277) transactions must follow the format/flow as defined in the Phase I CORE 152, which is the CORE v5010 Master Companion Guide Template. The CAQH CORE companion guide template can be found on the CAQH CORE Web site at *http://www.caqh.org/pdf/CLEAN5010/MasterCompGuidTemp-Version 5010.pdf.*

We are requiring that covered entities that use or plan to use companion guides comply with the CORE 152 and CORE 250 rules requirement to use the CORE v5010 Master Companion Guide Template for the eligibility for a health plan and health care claim status transactions.

d. Updates to Standards and Operating Rules

Section 1173(i) of the Act provides for the establishment of a review committee for the purposes of reviewing and amending the adopted standards and operating rules. It calls for a hearing of this review committee no later than April 2014 and not less than biennially thereafter as well as a report outlining recommendations for updating and improving the standards and operating rules. Per the statute, this review committee can include the NCVHS, or any appropriate committee as determined by the Secretary.

Additionally, section 1173(a)(5) of the Act provides for the solicitation of input from the NCVHS and the Health Information Technology Standards Committee, as well as the standards setting organizations and stakeholders as determined appropriate by the Secretary for the purposes of describing ''(i) whether there could be greater uniformity in financial and administrative activities and items, as determined appropriate by the Secretary; and (ii) whether such activities should be considered financial and administrative transactions * * * for which the adoption of standards and operating rules would improve the operation of the health care system and reduce administrative costs.''

Finally, we note that this interim final rule with comment period does not specify the timing or the process for updating operating rules. The timing and process for updating these, as well as future operating rules will be forthcoming.

e. Additional Information

The current definition of standard at 45 CFR 160.103 is written so broadly that it could include operating rules as we are defining that term at § 162.103. However, as we have determined that operating rules are separate and distinct from standards, and that standards do not encompass operating rules, we believe it is necessary to revise the definition of standard to specifically

exclude operating rules. Therefore, we have amended the definition of standard at § 160.103 to exclude operating rules.

Currently, 45 CFR 162.103 provides that a standard transaction means ''a transaction that complies with an applicable standard adopted under this part.'' In this interim final rule with comment period we are adopting operating rules and requiring covered entities to comply with those operating rules when conducting a transaction for which we have adopted a standard. We believe it is necessary to revise the definition of a standard transaction in order to be clear that a standard transaction is one that uses the adopted standard as well as the adopted operating rule for that transaction. Therefore, we are amending the definition of a standard transaction at 45 CFR 162.103 to mean ''a transaction that complies with an applicable standard and associated operating rules adopted under this part.''

Section 1173(a)(4)(A)(iv) of the Act provides that the standards and associated operating rules must ''describe all data elements (including reason and remark codes) in unambiguous terms, require that such data elements be required or conditioned upon set values in other fields, and prohibit additional conditions (except where necessary to implement State or Federal law, or to protect against fraud and abuse).'' We interpret this provision to mean that covered entities may not require additional data conditions of their trading partners, including providers, outside of those already included in the adopted standards and associated operating rules, except where it is necessary to implement State or Federal law, or to protect against fraud and abuse. Our regulations at 45 CFR 162.915 already place restrictions on covered entities with regard to what they may require of their trading partners including providers, concerning standards. Currently, under § 162.915(a), covered entities may not enter into a trading partner agreement that would change the definition, data condition, or use of a data element or segment in a standard. We do not need to do anything to incorporate the statutory requirement of section 1173(a)(4)(iv) of the Act into our regulations with regard to standards; however we believe it is appropriate to revise § 162.915(a) to expand the restriction to include operating rules. Therefore, we are amending § 162.915(a) to include operating rules. The law permits limited circumstances under which covered entities may require additional data conditions where necessary to implement State or Federal law, or to protect against fraud and abuse. Therefore, we are also amending § 162.915(a) to reflect that narrow exception.

f. Conclusion

Based on our analysis of the CAQH CORE operating rules and the recommendations of the NCVHS, and for the reasons provided in the previous discussions, we are adopting the CAQH CORE operating rules (updated for Version 5010), including the companion guide template, for the non-retail pharmacy eligibility for a health plan and health care claim status transactions, as reflected at 45 CFR 162.920, 162.1203, and 162.1403. We are not requiring compliance with any of the requirements of the operating rules that pertain to the use of acknowledgements and CAQH CORE certification.

2. NCPDP Telecommunication Standard Implementation Guide Version D.0 Operating Rules for Retail Pharmacy Transactions

In its testimony before the NCVHS, the NCPDP stated that the NCPDP Version D.0 standard represents retail pharmacy industry consensus on clarification of transactions, data elements, data values, and situations of usage. Additionally, the NCPDP testified at the July 2010 NCVHS hearing that it also publishes a free NCPDP Version D.0 Editorial document, which is updated quarterly, and contains frequently asked questions, examples, and further clarifications, as well as addresses Medicare Part D prescription drug program needs that the industry brings forward. As business requirements change, as clarifications are needed, and as questions are asked, the NCPDP has indicated that, where possible, the information in the NCPDP Version D.0 Editorial will be incorporated into future versions of the NCPDP Version D.0 standard to further support ongoing retail pharmacy business needs.

The NCPDP formally requested that the NCVHS recommend to the Secretary that the NCPDP Version D.0 standard be adopted as the operating rule for use with the retail pharmacy eligibility for a health plan transaction, and the NCVHS included this recommendation in its September 30, 2010 letter to the Secretary.

The pharmacy industry has long been utilizing NCPDP standards to conduct electronic transactions. These standards provide for real-time claims adjudication, eligibility and benefit verification, real-time ordering by the physician, and sharing of medication history. We believe that the NCPDP Version D.0 standard itself provides enough detail and clarity to operationalize the standards to the point where no gaps exist that operating rules would need to fill, so that no further infrastructure or data content rules need to be adopted at this time. Additionally, we believe that the NCPDP Version D.0 standard already fulfills the purposes and principles of sections 1173(a)(4)(A) and (B) of the Act so that the adoption of operating rules to supplement or enhance the standard is not appropriate at this time.

III. Effective and Compliance Dates

Section 1173(g)(4)(B)(i) of the Act states that ''[t]he set of operating rules for eligibility for a health plan and health claim status transactions shall be adopted not later than July 1, 2011, in a manner ensuring that such operating rules are effective not later than January 1, 2013.'' In each of our previous HIPAA rules, the date on which the rule was effective was the date on which the rule was considered to be established or adopted, or, in other words, the date on which adoption took effect and the CFR was accordingly amended. Typically, the effective date of a rule is 30 or 60 days after publication in the **Federal Register**. Under certain circumstances the delay in the effective date can be waived, in which case the effective date of the rule may be the date of filing for public inspection or the date of publication in the **Federal Register**.

The effective date of standards, implementation specifications, modifications, or operating rules that are adopted in a rule, however, is different than the effective date of the rule. The effective date of standards, implementation specifications, modifications, or operating rules is the date on which covered entities must be in compliance with the standards, implementation specifications, modifications, or operating rules. Here, the Act requires that the operating rules be effective not later than January 1, 2013. This means that covered entities must be in compliance with the operating rules by January 1, 2013. If we receive comments that compel us to change any of the policies we are finalizing in this interim final rule with comment period, we will seek to finalize any such changes by January 1, 2012, to allow sufficient time for industry preparation for compliance.

IV. Waiver of Proposed Rulemaking

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), we are required to publish a notice of proposed rulemaking in the **Federal**

Register. In addition, the APA mandates a 30-day delay in the effective date. Sections 553(b) and (d) of the APA provide for an exception from these APA requirements. Section 553(b)(B) of the APA authorizes an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest. Section 553(d)(3) of the APA allows the agency to avoid the 30-day delay in effective date where the agency finds good cause to do so and includes a statement of support.

Subsection (C) of section 1173(g)(4) of the Act is titled ''Expedited Rulemaking'' and provides that ''[t]he Secretary shall promulgate an interim final rule applying any standard or operating rule recommended by the [NCVHS] pursuant to paragraph (3). The Secretary shall accept and consider public comments on any interim final rule published under this subparagraph for 60 days after the date of such publication.'' It is clear to us the statute intends that the ordinary notice and comment rulemaking procedures of the APA do not apply here. We are statutorily *required* to proceed with an interim final rule with comment period, which means we are compelled by the statute to dispense with normal APA notice and comment procedures. In light of the statutory requirement for us to publish an IFC for the adoption of these operating rules, we conclude that it is unnecessary for us to undertake ordinary notice and comment procedures and therefore, for good cause, we waive them. In accordance with the requirements of section 1173(g)(4)(C) of the Act, we are providing a 60-day public comment period.

We also find good cause for waiving the 30-day delay in the effective date of this interim final rule with comment period. The 30-day delay is intended to give affected parties time to adjust their behavior and make preparations before a final rule takes effect. Sometimes a waiver of the 30-day delay in the effective date of a rule directly impacts the entities required to comply with the rule by minimizing or even eliminating the time during which they can prepare to comply with the rule. That is not the case here. In this case, covered entities are not required to comply with the adopted operating rules until January 1, 2013, nearly one-and-one-half years after the publication of this interim final rule with comment period; a waiver of the 30-day delay in the effective date of the rule does not change that fact. A waiver is in fact inconsequential here to covered entities—their statutorily-prescribed date of compliance remains January 1, 2013. Because we believe the 30-day delay is unnecessary, we find good cause to waive it.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information 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.

We are soliciting public comment on each of these issues for the following section of this document that contains information collection requirements (ICRs): Specifications: Companion Guides Template.

In current practice, companion guides are developed by individual health plans and require providers to adhere to different transaction implementation rules for each health plan. Health plans have created these companion guides to describe the specifics of how they implement the HIPAA transactions and how they will work with their trading partners. Health plans' companion guides vary not only in format and structure, but also in size, being anywhere from a few to 60 pages or more. Such variances can be confusing to trading partners and providers who must implement them along with the standard implementation guides, and who must refer to different companion guides for different health plans. As previously stated, there are currently more than 1,200 such companion guides in use today.

Use of the CORE 152: Eligibility and Benefit Real Time Companion Guide Rule and the CORE 250: Claim Status Rule, two of the operating rules adopted in this interim final rule with comment period provide a standard template/common structure that health plans must use that is more efficient for providers to reference, given the multiple industry companion guides they must consult today.

The increasing use of health care EDI standards and transactions has raised the issue of the applicability of the PRA. The OMB has determined that this regulatory requirement (which mandates that the private sector disclose information and do so in a particular format) constitutes an agency-sponsored third-party disclosure as defined under the PRA.

The burden associated with the requirements of this interim final rule with comment period, which is subject to the PRA, is the initial onetime burden on health plans to use a standardized template for companion guides. The burden associated with the routine or ongoing maintenance of the information reported in the standard template format for companion guides is exempt from the PRA as defined in 5 CFR 1320.3(b)(2).

Based on the assumption that the burden associated with systems modifications that need to be made to implement the standard template for companion guides may overlap with the systems modifications needed to implement other HIPAA standards, and the fact that the standard template for companion guides will replace the use of multiple companion guides, resulting in an overall reduction of burden for providers, commenters should take into consideration when drafting comments that: (1) One or more of these current companion guides may not be used; (2) companion guide modifications may be performed in an aggregate manner during the course of routine business; and/or (3) systems modifications may be made by contractors such as practice management vendors, in a single effort for a multitude of affected entities.

Health plans that issue companion guides do so, in part, to direct providers on how to implement the ASC X12 and, in the case of the NCPDP standards, they issue payer sheets specific to their requirements and often times provide other plan-specific information, such as contact information, address, *etc.* It is expected that even with the advent of operating rules, companion guides will never be completely eliminated, but the companion guides themselves may be greatly reduced in size and complexity as a result of the use of operating rules. The companion guide templates serve the purpose of providing a uniform structure for health plans to use when preparing companion guides. The use of these templates by health plans currently issuing companion guides is considered to be a one-time action and is considered a permanent standard

template for a health plan companion guide.

The information collection burden associated with this interim final rule with comment period is for the costs for adapting a health plan companion guide(s) to the CORE v5010 Master Companion Guide Template, 005010, 1.2, March 2011 as required by the CAQH CORE operating rules for the eligibility for a health plan and health care claim status standard transactions. This is a one-time burden on health plans that will commence no later than January 1, 2013, the date by which HIPAA covered entities must be using the adopted operating rules for eligibility for a health plan and health care claim status transactions.

Common practice in the industry is for companion guides to be published as electronic documents and updated periodically in the routine course of business. Companion guides are posted to and made available on health plan Web sites trading partners, including providers, to access; therefore, printing and shipping costs are not considered. As the transition to the template is a one-time requirement, we do not estimate any ongoing labor costs associated with the use of this template beyond the initial first year conversion. We have estimated the one-time conversion to the template will cost industry $3,028,000. Our calculations were determined as follows:

The current length of health plan companion guides related to the eligibility for a health plan and health care claim status transactions, is anecdotally estimated at anywhere from just a few, to 60 or more pages. We estimate it will take a health plan staff person, most likely a technical writer, from 1 to 4 hours per page to reformat companion guides into the standard template for companion guides. This burden would involve re-entering of information, reconfiguration of the sequence in which information appears, addition of information, and other word processing and related tasks. It also would require specific technical knowledge, such as expertise in the Version 5010 standard transactions. We estimate that a technical writer, at an estimated hourly salary rate of $31.55, would make these revisions. Using the high estimate obtained in testimony to the NCHVS by the American Medical Association of 1,200 companion guides currently in use, we calculate an estimated average of 40 pages, (48,000 responses) at an average rate of 2 hours per page (1,200 guides × 40 pages × 2 hours per page × hourly rate of $31.55), for a one-time burden of $3,028,800 across the industry for health plans that issue companion guides to adopt the standard template for health plan companion guides. As existing word processing capabilities would be used for this task, we do not anticipate any software, hardware or other specialized equipment to be purchased and/or maintained for this specific purpose.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this interim final rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–0032–IFC; Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov.*

VI. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this interim final rule with comment as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354) (as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. 104–121), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

We have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of this interim final rule with comment period. 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. Executive Order 13563 also directs agencies to not only engage public comment on all regulations, but also calls for greater communication across all agencies to eliminate redundancy, inconsistency and overlapping, as well as outlines processes for improving regulation and regulatory review.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million in 1995 dollars or more in any 1 year). This rule has been designated an ''economically'' significant regulatory action, under section 3(f)(1) of Executive Order 12866 as it will have an impact of over $100 million on the economy in any 1 year. Accordingly, the rule has been reviewed by the Office of Management and Budget. We anticipate that the adoption of these operating rules would result in benefits that outweigh the costs to providers and health plans.

Our Regulatory Impact Analysis also meets the various requirements of the Unfunded Mandates Reform Act of 1995 (URMA). Section 202 of the URMA requires that agencies assess the anticipated costs and benefits before issuing any rule whose mandate requires spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation in any 1 year by State, local, or Tribal governments, in the aggregate, or by the private sector. That threshold level is currently approximately $136 million. Based on our analysis, we anticipate that the private sector would incur costs exceeding $136 million per year in the first 2 years following publication of the rule.

In addition, under section 205 of the UMRA (2 U.S.C. 1535), having considered at least three alternatives that are referenced in the RIA section of this rule, HHS has concluded that the provisions in this rule are the most cost-effective alternative for implementing HHS' statutory obligation of administrative simplification.

B. Current State, Need for Mandated Operating Rules and General Impact of Implementation

Based on the current environment, there is a need for operating rules. When a patient calls to set up an appointment with a provider, or comes into the office or hospital for an appointment, a staff member will often verify the patient's eligibility, coverage, and cost-sharing requirements. However, not all

providers will verify the eligibility of their patients, and even for providers' offices that do, often just a subset of patients are verified. Some providers, however, do not conduct eligibility verification at all, and a claim is submitted to the health plan without an eligibility inquiry.

Eligibility verification is done in a variety of ways including the following:

- Accessing patient ''eligibility'' information via a health plan's secure Web site.
- Telephone.
- The ASC X12 270 eligibility for a health plan inquiry. This is an electronic data interchange (EDI).

After an actual claim has been submitted to a health plan, the need sometimes arises for a provider to follow-up on the claim regarding where it is in the payment process. This is called a claim status inquiry and, again, this inquiry is conducted via Web site, telephone, or through EDI.

Currently, many providers do not use EDI at all as a means to conduct these two transactions and, of those that do, do not necessarily conduct them through EDI for every patient. Rather, most providers that use EDI transactions to verify a patient's eligibility or claim status also use telephone or other means.

In a larger context, most providers use EDI, but only for some transactions. For instance, according to the Healthcare Efficiency Index and the Oregon Study, over 75 percent of health care claims are now submitted by providers through EDI.

Because of the infinite number of variations of a specific provider's use of EDI, it is very difficult to determine the following: (1) the number of providers who use the eligibility for a health plan or the claim status transactions (or any other specific transaction) via EDI; and (2) the percent of eligibility for a health plan or claim status transactions that the average provider makes through EDI. However, studies have estimated the total number of electronic transactions conducted by all providers, even at the level of a specific transaction, and we will use such estimates to arrive at our saving assumptions.

We assume that most providers have the technological capacity to perform EDI (or have hired a trading partner with that capacity). We base this assumption on— (1) the high percentage of claim submissions that are conducted through EDI; (2) responses to the Oregon study from providers indicating that 96 percent of hospitals and 93 percent of ambulatory clinics (that is, physicians offices) are ready or would be ready for EDI transactions within 2 years; and (3) the impact analysis in the Modifications proposed rule (73 FR 49757 through 49790) that, through industry interviews, stated ''we do not believe that the number of providers who have no electronic capability is very high.''

There are a number of studies that have illustrated the benefits and savings in conducting EDI in contrast to manual or paper-based transactions. We have noted a number of them in the Impact Analysis Resources section in this interim final rule with comment period. The basic idea is that systems can conduct these transactions faster, less expensive, and more accurate than human intervention. Specific to our purpose, it is faster, less expensive, and more accurate than human intervention for a provider's system to communicate with a health plan's system to verify the eligibility of a patient or check the status of a claim.

So, why do not the majority of providers who have EDI capacity: (1) Use EDI to conduct the eligibility for a health plan or the claim status transaction; or (2) verify all their patients' eligibility through EDI instead of just a few? In the Oregon Survey, the most robust study with regard to a provider environment, 87 percent of hospitals and 60 percent of physician clinics said that the barrier to using the electronic eligibility for a health plan transaction is that health plans ''do not provide enough information in response to this type of inquiry.'' This was the most frequently selected response among the providers surveyed. In addition, 16 percent of hospitals and 20 percent of physician clinics stated that the barrier was that health plans ''do not provide fast enough responses.''

The June 22, 2009 AMA document entitled ''Standardization of the Claims Process: Administrative Simplification White Paper'' (hereinafter referred to as the 2009 AMA White Paper) describes the importance of a robust response in the eligibility for a health plan transaction: ''Receiving an explicit answer can quickly assist in patient scheduling, billing the appropriate payer with financial responsibility for the service, communicating the patient's financial responsibility and reducing the number of denied claims which the physician practice must manually handle.'' (*http://www.ama-assn.org/ama1/pub/upload/mm/368/admin-simp-wp.pdf*)

The picture that emerges is that providers conduct the electronic eligibility for a health plan transaction only with health plans that return robust eligibility information and return the response quickly. If a provider's staff will get more and faster eligibility information out of a specific health plan by picking up the phone or looking up the patient online, then the manual transaction will be used instead of the electronic transaction.

In terms of the claim status inquiry, we know that the average providers' office telephones the health plan in order to check on claim status. The ''Health Care Administration Expense Analysis'', produced by the State of Washington Office of the Insurance Commissioner, found that 37 percent of the telephone calls from providers to the State's largest insurer were claim status inquiries (costing the plan $4 million a year on staffing costs to answer only claim status calls) (Health Care Administration Expense Analysis: Blue Ribbon Commission Recommendation #6, Final Report, 11–16–2007, *http://www.insurance.wa.gov/consumers/documents/BRC_Efficiencies_Report.pdf.*) Other studies indicate that less than 40 percent of all claim status inquires are conducted electronically. Although we do not have direct data that informs the reasons why providers use the telephone instead of EDI for claim status inquiries, we can assume that the same dynamic as the eligibility verification is at play: If the electronic transaction is slower and produces less information, than a manual process will be used instead.

Operating rules address this need for more and faster information. As noted in the provision section, this interim final rule with comment period is adopting specific operating rules with requirements regarding response times and robust responses about a patient's eligibility from health plans.

A number of extensive surveys, both private and governmental, have reinforced the causal link between requiring health plans to return fast, robust responses to the eligibility for a health plan electronic request and an increased use in the transaction itself. In its Blue Ribbon report, the state of Washington reported that less than 9 percent of eligibility verification requests are conducted electronically in the state, while the state of Utah reported closer to 50 percent usage. The report credited Utah's adoption rate with the State having an ''enhanced transaction'' in place for the eligibility verification in which providers are told exactly the benefits a particular patient has. The report concluded that ''improving the enhanced message [of the eligibility for a health plan response]* * * will greatly improve this area of administration.''

The Oregon Survey explicitly expressed the causal link between

''standardizing the standard'' and greater use of EDI by concluding from its research that ''the healthcare industry is unlikely to take major strides toward automated processes until there is greater standardization of the methods for conducting the transactions electronically.''

The 2009 AMA White Paper also speaks to providers' need for robust health plan responses to the eligibility for a health plan transactions and how such a response would affect providers: ''Such information would also be extraordinarily valuable to physicians to ensure accurate and timely payment, and this value would encourage wide-spread utilization of the standard transactions by physicians and increased physician automation. The AMA strongly supports the efforts of the Council on Affordable Quality Healthcare Committee on Operating Rules for Information Exchange [CAQH CORE] to not only expand the value of the eligibility standard transaction but also continue its efforts of adding value to electronic remittance advice and other standard transactions * * *''

The IBM study demonstrates that electronic eligibility for health plan transactions would increase with use of operating rules. The study illustrates that providers' use of the eligibility for a health plan transaction increases on two levels after operating rules are adopted. First, more patients as a whole are having their eligibility verified, either electronically or otherwise. Second, there is an increased use of the electronic transaction. The participating health care entities in the study reported increases in use of the eligibility for a health plan electronic transaction at the average rate of 33 percent in the first year after adopting CORE Phase I rules—a rate that participants of the study credited to operating rules. Additionally, the IBM study showed that providers saw on average 20 percent increase of patients verified prior to a visit, significantly reducing practice administrative and financial burden at the point of care.

On a more general level, in both the Transactions and Code Sets final rule and the update to the standards in the Modifications final rule, the savings analysis has been based on the increased use of electronic transactions due to the implementation of standards (in the Transactions and Code Sets final rule) and increased use of electronic transactions due to improved standards (in the Modifications final rule). The cost benefit of both these rules rested on the causal relationship between improved standards and the predicted increased use of EDI (and the cost savings that use of EDI brought with it). The impact analysis for this interim final rule with comment period rests on the same causality, except that we are more specific in how operating rules cause increased use of electronic transactions.

As an example, the need for more robust and faster response to the eligibility for a health plan transaction has been realized by states seeking to reduce the administrative costs of health care in general. In the ''Health Care Administration Expense Analysis,'' required by Colorado state law and developed under the state's Commissioner of Insurance, recommendations included requiring all health plans and providers to use CAQH CORE Phase I and II data content and infrastructure rules for the eligibility for a health plan and the claim status transactions ''as a means of streamlining and standardizing administrative interoperability between plans and providers.'' (Senate Bill 08–135 Work Group to Develop Standardized Electronic Identification System for Health Insurance: Final Report and Recommendations. September 3, 2009; *http://caqh.org/Host/CORE/SB135_COreport.pdf*)

As well, Minnesota has a set of companion guides for the HIPAA standard transactions. These companion guides are analogous to the operating rules developed by the CAQH CORE in that they are intended to standardize ''administrative processes when implementation of the processes will reduce administrative costs.'' We have already mentioned initiatives and reports by Oregon and Washington that seek to achieve similar savings. (*http://www.health.state.mn.us/auc/mn270271guide.pdf*).

It is evident that both state governments and private industry recognize the cost advantage to operating rules and similar ''enhanced transaction'' business rules to accompany the HIPAA standard transactions, in this case with regard to the eligibility for a health plan transaction. However, both state governments and private industry recognized the need for the adoption of operating rules on the Federal level because of the clear advantages to a faster adoption by all covered entities that a Federal mandate would engender. As illustrated by the numerous State and private initiatives, there is the danger that, without Federally mandated operating rules, different sets of ''operating rules'' will emerge, on a State by State or health plan by health plan basis. In such a case, both plans and providers would have to continue to customize their EDI transactions depending on the operating rules required under a particular state or contract.

As well, some health care entities may be slow to adopt and implement any ''operating rules'' voluntarily for fear that the Federal government, or a particular State government, will adopt ''operating rules'' that require a new set of implementation requirements with associated costs.

Finally, most providers now have to conduct transactions such as the eligibility for a health plan and the claim status transaction through two different processes, electronic and manual and paper-based, depending on the health plan that covers the patient or processes the claim. As long as some health plans continue to conduct standard transactions that are not fast or robust enough for providers' needs, providers may continue to conclude that manually processing all such transactions is easier and more economical.

C. Regulatory Flexibility Analysis: Impact on Small Entities

The Regulatory Flexibility Act (RFA) of 1980, Public Law 96–354, requires agencies to describe and analyze the impact of the rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. In the health care sector, a small entity is one with between $7 million to $34.5 million in annual revenues or is a nonprofit organization. For details, see the SBA's Web site at *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf* (refer to Sector 62—Health Care and Social Assistance). (Accessed 2–1–11).

For the purposes of this analysis (pursuant to the RFA), nonprofit organizations are considered small entities; however, individuals and States are not included in the definition of a small entity. We attempted to estimate the number of small entities and provided a general discussion of the effects of this interim final rule with comment period, and where we had difficulty, or were unable to find information, we solicited industry comment. We discuss the impact of the rule on small entities in section VII.K. of this interim final rule with comment period.

As well, section 1102(b) of the RFA requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the

RFA. For purposes of section 1102(b) of the RFA, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. (See the discussion at section VII.K. of this interim final rule with comment period for our discussion of the expected impact on small rural hospitals.)

D. Alternatives Considered

In deciding to adopt operating rules for the eligibility for a health plan and the health care claim status transactions, we considered a number of alternatives, on which we solicit public and industry comments.

1. Do Not Adopt Operating Rules for Non-Retail Pharmacy Industry

We considered this option, but determined that this would only be appropriate if operating rules for use in the health care industry were not available, or available and already in use on a voluntary basis. Per the aforementioned NVCHS hearings, public testimony and analysis, the NCVHS deemed that two authoring entities who came forward and applied to be candidates as authoring entities were qualified under the stipulations for the adoption of operating rules in the Affordable Care Act to act as authoring entities, namely the Council for Affordable Quality Healthcare's (CAQH) Committee on Operating Rules for Information Exchange (CORE) and the National Council for Prescription Drug Programs (NCPDP). The CAQH CORE offered operating rules that, with some exceptions, have been determined to be feasible for use with the eligibility for a health plan transaction, and the health care claim status transaction under HIPAA, as specified in the Affordable Care Act. The NCPDP also offered operating rules, which are already in use in all retail pharmacies by virtue of the pharmacies' use of the NCPDP Telecommunications standard Version 5.1, and which will be updated on January 1, 2012, when the update to this standard, NCPDP Telecommunications standard Version D.0, goes into effect. Additionally, not adopting any operating rules for the eligibility for a health plan transaction and health care claim status transaction, as required by the Affordable Care Act, would violate the Act's statutory requirements under section 1104(c) ''Promulgation of Rules'', which requires the Secretary to adopt operating rules for the two aforementioned electronic health care transactions by no later than July 1, 2011 with a compliance date of January 1, 2013.

2. Adopt Another Authoring Entity's Operating Rules

As previously discussed in section II.B. of this interim final rule with comment period, section 1104(b)(3) of the Affordable Care Act amends section 1173(g)(3)(a) of the Act by charging the NCVHS with advising the Secretary as to whether a nonprofit entity meets the statutory requirements for developing the operating rules to be adopted by the Secretary, and outlines the entity's specific qualification requirements. Of those organizations testifying at the NCVHS hearing, two organizations formally requested to be considered authoring entities for operating rules, namely the CAQH CORE and the NCPDP.

In its testimony before the NCVHS, the ASC X12, the standards development organization responsible for the development of the Version 5010 standards for electronic health care transactions, expressed its support for the NCPDP being named as an operating rule authoring entity not only for the pharmacy industry, but for the entire health care industry (transcript of the July 20, 2010 NCVHS Subcommittee on Standards hearing at *http://www.ncvhs.hhs.gov*). The ASC X12's support was based upon their belief that—

- The NCPDP's ANSI-approved organization status supports consensus building and open participation;
- The infrastructure for the NCPDP is able to handle the development of operating rules in the associated workgroup task group without any modifications to procedures or processes;
- The NCPDP members are frequent users of the ASC X12 standards and thus the NCPDP is familiar with them; and
- The pharmacy industry's growing experience with real-time eligibility, real-time claim status, and real-time submission of claims beyond pharmacy.

Based on the ASC X12 testimony, the NCPDP stated that it would consider playing a larger role if the NCVHS deemed that there should only be one authoring entity, and would take on the role of more than just the NCPDP standards, as appropriate.

However, with respect to the requirements for the operating rules themselves, neither the NCPDP nor the CAQH CORE met all of the requirements for operating rules for both health care segments. As noted earlier, the July 2010 NCVHS hearings were followed by a request from the NCVHS to each candidate to respond to a detailed questionnaire about the statutory requirements. The questionnaire solicited specific documentation to validate the testimony. Based on review of the CAQH CORE and the NCPDP submissions to this questionnaire the NCVHS determined, and we have concurred, that neither organization can unilaterally provide operating rules to support both retail pharmacy and non-retail pharmacy health care segments. The NCPDP naturally focuses on the NCPDP retail pharmacy standards, while the CAQH CORE has focused on the ASC X12 administrative health care transactions. While both entities have similar policies related to securing a consensus view of health care stakeholders and ensuring that rules are consistent with (and do not conflict with) other existing standards, neither organization has rules in place for both health care segments. While addressing the retail pharmacy industry's needs relative to operating rules, the NCPDP did not present to the NCVHS for their consideration any existing NCPDP operating rules to accommodate the ASC X12 standards. The CAQH CORE has phases of operating rules that accommodate the ASC X12 standard for electronic health care transactions, but are not specific to retail pharmacy transactions.

3. Wait for Resolution of All Outstanding Technical and Administrative Issues Before Adopting the Operating Rules Developed by the Authoring Entities

Both the CAQH CORE and the NCPDP demonstrated to the NCVHS that their operating rules were based upon broad public and stakeholder input. However, as previously discussed in section II. of this interim final rule with comment period, there are certain exceptions that exist with regard to our adoption of the CAQH CORE operating rules in their entirety. Upon analysis, we declined to adopt the CAQH CORE operating rules for the ASC X12 999 acknowledgement transaction, and the references to being ''CORE certified'' contained in the CAQH CORE Operating Rules as we have already described in section II.F. of this interim final rule with comment period. If we had opted to wait until the resolution of the administrative issues affecting the adoption of the entire CAQH CORE operating rules, it would seriously delay the health care industry's ability to begin to achieve the benefits of administrative simplification.

Additionally, as described in section III of this interim final rule with comment period, we have declined to adopt the NCPDP business rules and guidelines as embedded in its NCPDP

Telecommunication Standard Version D.0, as they do not qualify as operating rules as defined in section II.A. of this interim final rule with comment period. The NCPDP business rules and guidelines are embedded within the NCPDP Telecommunications Standard Version D.0, and while technically not operating rules as defined by this interim final rule with comment period, they function as such nonetheless in that they provide robust business rules and guidelines for use in retail pharmacy transactions. The pharmacy industry is already preparing to use the NCPDP Version D.0 standard in their day-to-day pharmacy transactions as required by the January 16, 2009 final rule (74 FR 3296) adopting the NCPDP Telecommunication Standard Version D.0 for use in retail pharmacy transactions, effective January 1, 2012. The NCPDP Telecommunications Standard Version D.0 already provides a full and robust array of tools for the retail pharmacy industry to realize the potential benefits of administrative simplification.

E. Impact Analysis Resources

We have considered a number of different cost benefit studies that have been conducted by industry and independent entities in recent years. The background and conclusions on these studies and surveys will illuminate how we calculated our assumptions and how we applied them to this impact analysis. In this section, we briefly describe these studies, as well as an explanation of all of the following:

- The depth and completeness of the analysis and supporting evidence for the conclusions.
- Data sources and a presentation of the data limitations.
- The perceived objectivity of the analysis as demonstrated by the discussion of data sources and the rigor of the analysis.
- Our ability to explain and justify the findings and conclusions presented in the study.

We then present assumptions and an impact analysis for each of the covered entity types, referencing the data and conclusions of the various studies. The following is a description of the studies and reports referenced for this impact analysis.

1. The Milliman Study

Electronic Transaction Savings Opportunities for Physician Practices, hereinafter referred to as the Milliman study, was published by Milliman in January 2006 (*http://transact.emdeon.com/documents/milliman_study.pdf*). Milliman is an international consulting and actuarial firm serving health care payers, service providers and consumer organizations. The Milliman study was commissioned by the Emdeon Corporation, a nationwide clearinghouse that provides a wide variety of information exchange services that connects payers, providers and patients in the U.S. health care system. The study's main objective focused on how much providers could save by implementing electronic transactions. The Milliman study's calculations are based on examining labor time and costs required to perform both manual and electronic transactions. These labor costs include employee benefits, payroll taxes, and general and administrative overhead. Notably, the study compensated for related fees for transactions and set-up costs for electronic transactions.

The Milliman study's methodology was basically mathematical, using factors established through payrolls and average administrative costs, as opposed to research based on surveys or interviews with providers. Milliman's calculations were based on a model of a provider's administrative processes developed with assumptions about the operating environment of the typical solo physician practice. Ultimately, Milliman tested its results ''by observing administrative procedures in actual physician practices and medical groups.''

The study reflected other industry research that found that, while manual processes are very similar among physicians, ''there is much greater variance among practices * * * in the use of technology and the associated costs for electronic transactions.'' In some cases, providers are fully automated. In the majority, however, there is a mix of electronic and manual processes, as well as processes that require a wide range of levels of human intervention.

Milliman found that a single-physician practice could save as much as $42,000 a year by moving processes from manual to electronic. This estimate is based on a physician office that moves from all manual transactions to fully electronic for six standard transactions. For our impact analysis, this savings could not be used as a factor to project savings for all physicians ($42,000 × the number of physicians), as other studies have demonstrated that most providers are already using some of the electronic transactions.

Milliman's approach was to look at provider costs and benefits, and we opine that it appears to be objective in its assumptions. The Milliman study will be useful in our impact analysis as it provides labor and administrative overhead costs.

The Milliman study was published in 2006. In its calculations, it accounted for inflation and other factors that may have changed since its source data were gathered and the study was finally published. However, its final conclusions are somewhat dated, and we will consider this in our assumptions.

2. The AHIP Survey (2006)

America's Health Insurance Plans' (AHIP) Center for Policy and Research conducted a survey of its members to examine the issue of claims processing and turnaround times for claim payments. The survey is summarized in the document entitled ''An Updated Survey of Health Care Claims Receipt and Processing Times, May 2006'' at *http://www.ahipresearch.org/pdfs/PromptPayFinalDraft.pdf*.

AHIP is a national association representing nearly 1,300 companies providing health insurance coverage to more than 200 million Americans. The study is a follow-up to a survey done in 2002. We took data from the AHIP study to develop assumptions about savings calculations for health plans.

3. The McKinsey Analysis

Overhauling the U.S. Healthcare Payment System conducted by McKinsey & Company, hereinafter referred to as the McKinsey analysis, was published in *The McKinsey Quarterly* on June 2007 (*http://www.mckinseyquarterly.com/Overhauling_the_US_health_care_payment_system_2012*). McKinsey & Company is an international management consulting firm advising companies on strategic, organizational, technology, and operational issues. The McKinsey analysis relies on a number of different resources in order to calculate the cost of non-electronic transactions compared with the cost of electronic transactions. As in the Milliman study, the McKinsey analysis makes the case for the move from paper to electronic transactions. Their analysis used sources including Faulkner & Gray Health Data Directory; Health Data Management; HIPAA Survey—Claims and Payment Practices; Milliman; National Health Expenditures, Centers for Medicare & Medicaid Services (CMS); U.S. Department of Health and Human Services (HHS); and McKinsey's own analysis. For its analysis' cost per transaction, it appears McKinsey relied mostly on the Milliman study.

As noted, the McKinsey analysis brings together secondary sources to make its assumptions, so it is not based on any primary research or surveys. However, the McKinsey analysis does summarize these secondary sources into quantitative ranges that are useful to our impact analysis. For instance, based on secondary sources, the McKinsey analysis gives a range of 1.4 to 3.5 billion total eligibility verifications annually, both electronic and non-electronic, across the health care industry. While this is a broad range, it is useful in estimating the low and high estimates for our calculations.

The McKinsey analysis suggests that making the flow of dollars in the health care industry more efficient through electronic means will trim the administrative costs that are spent on the payment system, which its analysis calculates as 15 percent of every healthcare dollar.

The McKinsey analysis was objective in its approach, especially with regard to its data on eligibility for a health plan transactions because it was focused on claim-centered transactions. Its emphasis was mostly on the deficiencies and possibilities regarding payment flow between payers and providers, with commentary on the involvement of financial institutions. Its recommendations did not include mention of operating rules or the eligibility for a health plan transaction, so we find its data neutral with regard to the purpose of this impact analysis. The McKinsey analysis, presented in June 2007, is used by other related industry studies, and, because we could not identify studies or analyses that argued against its conclusions, we presume that it reflects industry assumptions.

4. The Healthcare Efficiency Report

The National Progress Report on Healthcare Efficiency, hereinafter referred to as the Healthcare Efficiency Report, is the first annual report from the U.S. Healthcare Efficiency Index (USHEI), (*http://www.ushealthcareindex.com*). an industry forum for monitoring business efficiency in healthcare USHEI's advisory council consists of representatives from hospitals, clearinghouses, health care consultants, health plans and other entities (*http://www.ushealthcareindex.com/advisorycouncil.php*). The USHEI was launched in 2008 to raise awareness of the cost savings associated with the adoption of electronic transactions in health care. The USHEI National Progress Report takes the Milliman, McKinsey, and other studies and applies them to a tool that measures current status of electronic transaction usage (in percentages of transactions) and projects possible cost savings if those percentages are increased.

The Healthcare Efficiency Report analyzed the eligibility for a health plan transaction as a part of its Phase 1, which relied on the Milliman study and the McKinsey report for most of its data. Nevertheless, the Healthcare Efficiency Report consolidates the secondary sources in an original and illustrative manner, and appears to be an accepted yardstick for administrative simplification in the health care industry.

The Healthcare Efficiency Report repeats an important point presented by Milliman and which we considered in our analysis: Even among providers that use electronic means to conduct some of their transactions, there is a broad range of how much they utilize standard transactions, which standard electronic transactions they use, and which transactions are still conducted manually.

5. The Oregon Provider and Payer Survey

Like the Milliman, McKinsey, and the Healthcare Efficiency Report, the Oregon Provider and Payer Survey, hereinafter referred to as the Oregon Survey, (*http://www.oregon.gov/OHPPR/HEALTHREFORM/AdminSimplification/Docs/FinalReport_AdminSimp_6.3.10.pdf*) sought to estimate the possible cost savings that would be realized if there was a continual shift from nonelectronic to electronic transactions among healthcare entities in Oregon. The survey was conducted by the Oregon Health Authority, Office for Oregon Health Policy and Research, which conducts impartial, non-partisan policy analysis, research, and evaluation, and provides technical assistance to support health reform planning and implementation in Oregon. The Office serves in an advisory capacity to Oregon Health Policy Board, the Oregon Health Authority, the Governor, and the Legislature. The survey asked payers, providers, and clearinghouses a number of qualitative questions in terms of how administrative simplification can best be realized.

The study was comprehensive, and used both secondary sources and a survey in which responses were gathered from 55 percent of the State's hospitals and 225 of the State's ''ambulatory clinics.'' Of those 225 ambulatory clinics, 69 percent were clinics with less than 9 clinicians, and 23 percent were clinics with only 1 clinician. In our impact analysis on providers, the category of ''physicians'' corresponds to the Oregon Survey's category of ''ambulatory clinics.''

Of all the studies cited in this impact analysis, the Oregon Survey had the most recent and statistically valid data with regard to provider use of electronic transactions and gave the clearest picture of how providers verify eligibility. The study received quantitative and qualitative data from a large number and range of providers. Oregon itself is a mix or rural and urban communities. However, we recognize that there are regional differences in the health care industry and the fact that only Oregon health care entities were surveyed.

6. The IBM Study

In 2009, the CAQH CORE contracted with IBM's Global Business Services, the world's largest business and technology services provider with the aim towards helping companies manage their IT operations and resources, to conduct a study (hereinafter referred to as the IBM study) (*http://www.caqh.org/COREIBMstudy.php*) to assess the costs and benefits to health plans, provider groups, and vendors of adopting the CAQH CORE Phase I rules, which include the operating rules for the electronic eligibility for a health plan transaction, as adopted under this interim final rule with comment period. According to the IBM study, industry-wide adoption of the CAQH CORE Phase I rules could potentially yield $3 billion in savings in 3 years.

The IBM study consisted of interviews during which participants answered a set of questions geared towards assessing the costs and savings of adopting the CAQH CORE operating rules. Participants in the study included six national and regional health plans, five clearinghouses and vendors, and six providers. The health plans together represented 33 million commercial members, 1.2 million providers, 22 million eligibility verifications per month, and 30 million claims per month. The providers included hospitals, physician groups, and a surgery center.

The IBM study did not track the costs and benefits of adopting the operating rules for the health care claim status transactions. It did attempt to track the costs and benefits of the infrastructure elements of the operating rules (connectivity, response time, system availability, acknowledgements, and companion guides) but health plan study participants were not able to fully account for the costs related to implementation, citing that they may

have allocated some costs to IT overhead.,

Highlights of the IBM study closely parallel the three key objectives outlined above that necessitate the adoption of operating rules:

• Providers rapidly took advantage of the new capabilities that the operating rules provided; for example, real-time transactions (page 20 of IBM study report).

• The average return on investment (ROI) for health plans surveyed in the study was less than a year. Average initial and on-going cost of implementing the operating rules for an individual health plan was $592,000. The average savings, due mostly to moving away from telephone to electronic transaction over the same time period, was nearly $2.7 million for an individual health plan (page 23 of the IBM study report). The ratio of verifications to claims was up from .63 to .73 after the operating rules were adopted (page 20 of IBM study report).

7. The 2009 Health Affairs Survey

In 2009, Health Affairs published survey results in an article entitled ''What Does It Cost Physician Practices to Interact With Health Insurance Plans,'' authored by Lawrence P. Casalino, Sean Nicholson, David N. Gans, Terry Hammons, Dante Morra, Theodore Karrison, and Wendy Levinson (Health Affairs, 28, no. 4(2009):w533–w543, published online May 14, 2009; 10:1377hlthaff.28.4. 2533). The survey collected data from physicians from those identified as working in solo or two-physician practices, and physicians from those working in practices of three or more. Selection was stratified by specialty type—primary care (including family physicians, general internists, and general pediatricians), medical specialists, and surgical specialists, for a total of 895 physician practices. The survey asked about the physicians' offices' interactions with health plans by the physicians themselves and by staff at the administrative level, including the nursing staff, clerical staff, senior administrators, and lawyers and accountants.

The survey was able to calculate the mean time and cost that a physician's office spent interacting with health plans according to the size of the practice and according to the level at which the interaction took place, that is, whether the interaction was with the physicians themselves, the nursing staff, the administrative staff, or with the accountants, *etc.*

Among other conclusions, the study demonstrated that a single physician spent a mean average of 3 hours a week interacting with plans, while nursing and clerical staff spent much larger amounts of time.

We find the conclusions of the survey to be valid based on the large sampling of physicians' offices that were used. We will be applying some of the results of the survey to our calculation of savings for providers.

8. The Project SwipeIt (MGMA) Study

In 2009, the Medical Group Management Association (MGMA) launched an industry wide effort calling on health insurers, vendors, and healthcare providers to adopt standardized, machine-readable patient ID cards by Jan. 1, 2010. In support of the effort, the MGMA developed costs estimates of implementing a machine-readable patient ID card. Ultimately, the project's aim is for administrative simplification. The Project SwipeIt study demonstrated the quantifiable benefits to administrative simplification. Therefore, some of Project SwipeIt study's estimates, especially the base assumptions used in the savings calculations can be applied to our impact analysis of the implementation of operating rules.

Through their study, the MGMA estimated that it costs $25 to resubmit a denied claim. Additionally they found that 50 percent of the time claims are being denied because of incorrect patient information. We believe this could also be alleviated through the implementation of operating rules since eligibility information, including patient information, will be returned prior to or at the point of care.

The MGMA cites many resources that were used to gather their data for their analysis. We find that the data used in the MGMA study are relevant to our analysis and therefore we will use some of this data in our calculations of provider savings.

We invite public and industry stakeholder comments on our assumptions.

F. Impacted Entities

All HIPAA covered entities would be affected by this interim final rule with comment period, as well as software vendors and any other business associates providing transaction related services, such as billing support and third party administrators (TPAs). Covered entities include all health plans, health care clearinghouses, and health care providers that transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a standard. We note that health care providers may choose not to conduct transactions electronically. Therefore, they would be required to use these operating rules only for HIPAA transactions that they conduct electronically. However, one of the objectives of operating rules is to not only decrease manual transactions by entities that currently conduct some health care transactions electronically, but to make electronic transactions, specifically the eligibility for a health plan and health care claim status transactions attractive to those entities that do not currently use the HIPAA standards in EDI transactions to verify eligibility or claim status. (See the Transactions and Code Sets rule (65 FR 50361) for a more detailed discussion of affected entities under the HIPAA.)

As mentioned previously in this interim final rule with comment period, the barrier to adoption of the HIPAA standards is due to their flexibility and ''situationality'' that allows health plans to implement them in very different ways. It allows plans to send back information that is inconsistent from plan to plan. By making these optional or situational elements mandatory, more entities, especially providers, will have more consistent data across health plans, making it easier to determine what information they will be receiving in a transaction, thus increasing the use of electronic transactions.

We recognize that a few health plans have already embraced the use of the CAQH CORE operating rules and have, in a published report on the utility of operating rules in the health care industry, noted substantive return on investment (ROI) derived from reduced costs associated with avoidance of manual (both paper and staff time) response to provider inquiries. This raises the question of why all health plans would not voluntarily adopt the use of operating rules (or standards, for that matter) given the benefits. We opine that there are a number of barriers, including a tendency by providers to simply accept the status quo, for example, whatever information currently is provided to them by a health plan; a health plan's lack of experience with, and knowledge of, the role that operating rules play in making a standard work more efficiently, given that the use of operating rules is not yet widespread throughout the health care industry; and the expense to a health plan of systems and other business transitions without a regulatory mandate for adoption. Despite projected savings, health plan system managers would be hard pressed to obtain from their managements the upfront funds, staff and/or contractors, and corporate commitment needed for such a

transition without a regulatory requirement. Absent specifications as codified in regulation, health plans could be confused as to which operating rule version to use, and/or any exceptions to the use of operating rules that may or may not be effective, which would adversely affect enforcement of the HIPAA transaction and code sets. In our impact analysis, we analyze the impact of moving from non-electronic to electronic transactions among all entities, whether they currently use some electronic transactions or not. We assume that most providers and health plans use some electronic transactions and very few if any use none. Through the use of operating rules, we assume that all entities will increase their use of electronic transactions. The total savings and return on investment for each category of covered entity will not include the costs associated with setting up the basic infrastructure to send and receive standard health care transactions. Those costs are accounted for in the May 7, 1998 (63 FR 25300) proposed rule entitled, ''Health Care Reform: Standards for Electronic Transactions''. The costs included in this impact analysis include only those that are necessary to implement the operating rules as adopted for the two HIPAA transactions stipulated in this interim final rule with comment period.

Based on industry surveys and research referenced herein, we do not believe there are many entities that are not capable of conducting electronic transactions. As stated previously, according to the Oregon Survey, 96 percent of hospitals and 93 percent of ambulatory clinics (physicians) in that state indicated that they were ready, or could be ready within 2 years, to implement a system for electronic information exchange. Although the study only reflects Oregon providers, we believe the study's findings demonstrate that there will be very few covered entities that will not have the ability to conduct electronic health care transactions by the time the operating rules are required to be implemented.

The segments of the health care industry that will be affected by the implementation of operating rules include the following:

- Providers: Physicians and Hospitals
- Health Plans
- Clearinghouses and Vendors

Please note that we have not included an impact to pharmacies because this interim final rule with comment period adopts only operating rules for the eligibility for a health plan (270/271) and the health care claim status (276/277) transactions which are not used by the retail pharmacy industry for drugs and medications. Therefore, we assume no impact to pharmacies of this interim final rule with comment period.

Table 5 outlines the number of entities in the health care industry that we use in our analysis along with the sources of those numbers. We have not apportioned the data to reflect any particular sub-segment of the industry, other than ''physicians'' and ''hospitals'' in general terms. In this impact analysis, the number of providers impacted is not a factor in our calculation of the benefits of the adoption of these operating rules. (The number if providers are a factor in our calculation of providers costs.) Rather, benefits for providers are based on the total number of all health care claims throughout the health care system, including non-hospital institutions. We invite public comment on our assumptions and estimates, particularly as they related to non-hospital institutions.

TABLE 5—TYPE AND NUMBER OF AFFECTED ENTITIES

Type	Number	Source
Providers—Offices of Physician Offices (includes offices of mental health specialists).	234,222	Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule, *http://edocket.access.gpo.gov/2008/pdf/E8-19296.pdf,* (based on the AMA statistics).
Providers—Hospitals	5,764	Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards; Proposed Rule, *http://edocket.access.gpo.gov/2008/pdf/E8-19296.pdf.*
Providers—All	239,986	Physicians Offices + Hospitals.
Health Plans—Commercial	4,523	The # of health plans was obtained from the 2007 Economic Census Data—Finance and Insurance (sector 52)—NAICS code 5241114 (Direct health and medical insurance carriers). (n=4,523) *http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=EC0752A1&-geo_id=01000US&-dataitem=*.*
Health Plans—Government	54	Represents the 51 state Medicaid programs, Medicare, the Veteran's Administration (VA), and Indian Health Service (IHS).
Health Plans—All	4577	Census Data for commercial plans (n=4,523) + Medicaid agencies (N=51) + Medicare, VA and IHS = 4,577 total health plans.
Clearinghouses	51	EC EDI Vantage Point Healthcare Directory—6th Edition (n=51) *http://www.ec-edi.biz/content/en/dir-guest-login.asp.*
Vendors	51	EC EDI Vantage Point Healthcare Directory—6th Edition (n=51) *http://www.ec-edi.biz/content/en/dir-guest-login.asphttp://www.ec-edi.biz/content/en/dir-guest-login.asp.*

Also, although we acknowledge the impact to ERISA (Employee Retirement Income Security Act) plans, we did not include them in our analysis due to the complexity involved with describing downstream costs to these plans, as well as members/beneficiaries of health plans, tax payers, *etc.* While it is understood that the approximately 2.5 million ERISA plans (and, ultimately, their members) may be charged by their third party administrators (TPAs) and health insurance companies to comply with any Federal regulation, ultimately we assume that the 4,577 plans that do business as health plans, or their business associates, are the entities conducting the transactions and that is where the costs will be incurred. We assume that few, if any, of the ERISA plans do their own transactions. Additionally, because not all ERISA plans are required to report, it is difficult to determine the exact number of ERISA plans.

G. Impact Analysis Approach

This impact analysis is framed by the two key objectives that operating rules will achieve by augmenting the eligibility for a health plan and health care claim status transactions:

- Decrease covered entities' use of more costly manual activities, including telephone and paper-based transactions,

by addressing ambiguous requirements of the standards and clarifying when to use or not use certain elements or code values. We assume that the cost and benefits of these operating rules will be directed toward covered entities that currently perform some or no eligibility for a health plan and claim status transactions. For those who currently perform these two standard transactions, we assume that their volumes of electronic transactions will increase due to operating rules.

- Decrease the clerical burdens that are associated with the inconsistent use of these two standard transactions; for example, the instances of denied claims and pended claims that burdens patients, providers, and health plans in terms of time and money.

Our overall calculation for this analysis is as follows:

(X * Y) + C–Z = Annual Return on investment of operating rules implementation

Where—

X = annual increase in number of electronic eligibility for a health plan and health care claim status transactions due to operating rules implementation

Y = savings per transaction conducted electronically

C = savings through decrease in claim denials for providers and pended claims for health plans

Z = cost of operating rules implementation

In order to make this calculation, we need to describe baseline assumptions, transaction increase assumptions, and cost assumptions that correspond to the X, Y, C, and Z factors in the calculation before arriving at costs and benefits.

In section VII.H. of this interim final rule with comment period, we describe the baseline assumptions for each of the two transactions. The baseline assumptions include, first, an estimate on the number of electronic and non-electronic eligibility for a health plan transactions and health care claim status transactions, respectively, that physicians, providers, and health plans will be conducting in 2012, the year before the operating rules take effect. Second, from those estimates, we will estimate the number of eligibility for a health plan transactions and health care claim status transactions that are conducted *electronically* starting in 2012. For the baseline assumption on the number of electronic transactions in 2012, we have developed a range of high and low estimates derived from data gathered from a number of studies. This range of high and low reflects different estimates that are presented by industry studies that have attempted to arrive at a similar baseline. The final baseline assumption is an estimate on the rate of increased use of each of the two transactions due to operating rules adopted herein for 10 years after implementation of the operating rules (X factor in the calculation).

The transaction increase estimate (X factor in the calculation) assumes an annual percentage increase in the use of the eligibility for a health plan and health care claims status electronic transactions due to the implementation of operating rules. In this specific baseline assumption, we will be giving a range of high and low estimates. Although these estimates on the increase in usage due to operating rules are informed by industry studies, specifically the IBM study, they also illustrate the uncertainty inherent in such a predictive estimate. As we have described, there is a causal link between operating rules and increased use of EDI. However, the rate of increased use of the two transactions is dependent on many factors above and beyond operating rules. For instance, visits to physicians' offices and hospital emergency and outpatient departments are experiencing a steady rise, translating into an accompanying rise in health care transactions in general. (The CDC reports that health care visits increased 25 percent from 1997 to 2007: *http://www.cdc.gov/nchs/data/series/sr_13/sr13_169.pdf accessed on June 21*). The range of estimates on the increased use of the two electronic transactions included in our baseline assumptions should be viewed as a reflection of the uncertainties involved.

For our cost assumptions, Z in the calculation is the total cost of implementing the operating rules for both the eligibility for a health plan transaction and the health care claim status transaction. The costs will be analyzed according to each impacted category of health care entity. Many of our estimates in terms of cost are derived from the cost estimates in the Modifications final rule because industry studies we surveyed focused on savings rather than costs. These costs will be presented in a range of high and low estimates to reflect the broad range in readiness for operating rule implementation among covered entities in terms of infrastructure, software, and business process. In section VII.I. of this interim final rule with comment period, we describe our cost assumptions.

For our savings assumptions, Y and C in the calculation, Y is the dollar savings per eligibility of a health plan and health care claim status transaction that is saved when the transactions are conducted electronically as opposed to non-electronically, and C is the dollar saved, or cost avoided, of a decrease in claim denials for providers and a decrease in pended claims for health plans. For the C estimate, we will again provide a high and low range of estimates. Industry studies indicate that more robust eligibility for a health plan transactions will result in a decrease in pended and denied claims (which, in turn, will result in savings). However, we are less certain of the percent of decrease that operating rules will effect, so we have reflected this uncertainty with a range. In section VII.J. of this interim final rule with comment period, we describe our savings assumptions.

Our analysis begins with a description of the baseline and transaction increase assumptions; that is, how we arrived at the numbers of eligibility for a health plan transactions and health care claim status conducted electronically as of 2012, and our assumptions on what percentage of annual increase in the transactions are due to the implementation of operating rules. We will subsequently describe our cost assumptions, savings assumptions, and finally summarize the costs and savings. The costs and savings will also be presented in a range of high and low estimates.

In general, the high and low range approach used in this impact analysis illustrates both the range of probable outcomes, based on state and industry studies, as well as the uncertainty germane to a mandated application of business rules on an industry with highly complex business needs and processes. Within those ranges, however, the summary demonstrates that there is considerable return on investment resulting from the implementation of operating rules. We solicit comments on these assumptions as well as the direct costs of implementing these operating rules adopted under this interim final rule with comment period.

H. Baseline Assumptions

1. Baseline Assumption A

Total number of electronic and nonelectronic eligibility for a health plan and health care claim status transactions conducted by providers.

We estimate that the total number of claims submitted, both electronically and manually, for the year 2012 is 5.6 billion. This estimate is the average of the high and low estimates given in the January 2009 Modifications final rule, *http://edocket.access.gpo.gov/2009/pdf/E9-740.pdf.*

In order to arrive at the number of eligibility verifications conducted in 2012, both electronic and non-electronic, we applied the per claim

ratio as concluded by the Oregon Survey. The Oregon Survey concluded that, for every claim submitted, the low estimate was 0.68 eligibility verifications per claim; the high estimate was 1.12 eligibility verifications per claim submitted. We use the average of these two estimates, 0.9 eligibility verifications per claim submitted. We then assume that of the 5.6 billion claims submitted, 0.9 of those were preceded by an eligibility inquiry to come up with approximately 5 billion eligibility verifications.

In order to arrive at the number of claim status inquiries conducted in 2012, both electronic and non-electronic, we again applied the per claim submitted ratio as concluded by the Oregon Survey. The Oregon Survey concluded that, for every claim submitted, they estimated that 0.14 claim status inquiries were submitted. We looked at other studies that included various numbers for claim status transactions, but we believe the Oregon Survey to be the most valid picture of providers' use of these transactions based on the interviews conducted. Based on our previous assumptions, we estimate that there will be 784 million claim status inquiries conducted in 2012.

To find the total number of eligibility for a health plan transactions and health care claim status transactions that physicians and hospitals conducted individually, we divided the total number of eligibility for a health plan transactions and health care claim status transactions between physicians and hospitals by a factor of 9 to 1; that is, approximately 90 percent of all eligibility for a health plan and health care claim status inquiries, electronic and non-electronic, are conducted by physicians, while 10 percent are conducted by hospitals. We have taken this physician to hospital ratio from the Oregon Survey due to its reliance on direct provider input. The survey indicated that physicians are responsible for 91 percent of all eligibility for a health plan transactions and 89 to 90 percent of health care claim status transactions.

TABLE 6—ESTIMATES ON TOTAL NUMBER OF ELIGIBILITY AND HEALTH CARE CLAIM STATUS INQUIRIES, ELECTRONIC AND NON–ELECTRONIC CONDUCTED ANNUALLY

	Total number of transactions, electronic and non-electronic, conducted per year (in millions)	Number conducted by physicians (90%)	Number conducted by hospitals (10%)
Claim submissions	5,600	N/A	N/A
Eligibility inquiries	5,040	4,536	504
Claim status inquiries	784	705.6	78.4

For the health plan eligibility transaction, we determined that the total number of eligibility for a health plan inquiries conducted electronically by physicians to be between 453.6 million, and 201.6 million for hospitals. The Oregon Survey found that approximately 10 percent of all eligibility for a health plan transactions conducted by physicians are electronic. Other studies appear to contradict Oregon's findings by a considerable margin. For instance, the Healthcare Efficiency Index reports that 40 percent of all eligibility for a health plan transactions are conducted electronically and the McKinsey report estimates 40 to 50 percent. We weighed the Oregon Survey more heavily, and estimated that 10 percent, or 453.6 million, of all eligibility for a health plan transactions conducted by physicians are electronic. (Table 7). For the percentage of hospitals' use of the electronic eligibility for a health plan transaction, we relied on the Oregon Survey's finding that 40 percent, or 201.6 million, of all eligibility for a health plan inquiries conducted by hospitals are electronic. This Oregon estimate appears to be more in line with other industry studies on the use of these transactions. (Table 7).

For the health care claim status electronic transaction, the Oregon Survey found that none of the physicians or hospitals it surveyed uses the health care claim status electronic transaction. Instead, physicians and hospitals use the telephone and, to a lesser extent, a secure Internet Web site provided by the health plan or contractor to check the status of health care claims.

Although, as we have stated before, the Oregon Survey appears to have the most valid methodology, the McKinsey study's conclusion implies that many providers do conduct the health care claim status transaction electronically (30 to 50 percent). The two studies are basically incompatible with respect to conclusions about usage of the electronic health care claim status transaction. As noted, a percentage of the health care claim status checks are conducted through the Internet. It is possible that the numbers of the McKinsey analysis are affected by considering Web-based health care claim status transactions as ''electronic.'' Only the Oregon Survey is clear in its methodology to make a distinction between electronic data interchange of HIPAA transactions and electronic Web-based transactions. Still, the McKinsey analysis has been used by others, for example, the Healthcare Efficiency Report, to demonstrate the frequency of use of HIPAA standard transactions.

We assume that there are some physicians who use the electronic health care claim status and response transaction, but believe that the McKinsey study's high estimate of 30 to 50 percent of health care claim status transactions being electronic is too high given the Oregon Survey finding. We estimate that 10 percent of all health care claim status inquiries, 70.56 million for physicians and 7.84 million for hospitals, will be made electronically in 2012. Again, we weigh the Oregon Survey more heavily. (See Table 7).

In order to determine the number of eligibility for a health plan and health care claim status transactions that health plans respond to electronically, we use the number of eligibility for a health plan inquiries for physicians and hospitals added to the number of health claim status inquiries for physicians and hospitals, based on our assumption that for all inquiries submitted by physicians and hospitals, health plans will submit the same number of responses. We assume that health plans will conduct 655.2 million electronic eligibility responses and 78.4 million claim status responses.

TABLE 7—ESTIMATES ON NUMBER OF ELECTRONIC ELIGIBILITY FOR A HEALTH PLAN AND HEALTH CARE CLAIM STATUS TRANSACTIONS CONDUCTED BY PROVIDERS AND HEALTH PLANS

For 2012	Number of total eligibility for a health plan and health care claim status inquiries (non-electronic and electronic) conducted (in millions)	Percentage of inquiries that are electronic	Total number of electronic eligibility for a health plan and health care claim status as of 2012 (in millions)
Physicians:			
Eligibility for a Health Plan	4,536	10	453.6
Health Care Claim Status	705.6	10	70.56
Hospitals:			
Eligibility for a Health Plan	504	40	201.6
Health Care Claim Status	78.4	10	7.84
Health Plans:			
Eligibility for a Health Plan	N/A	N/A	655.2
Health Care Claim Status	N/A	N/A	78.4

2. Baseline Assumption B

Transaction Increase Assumptions: Annual increase in use of electronic eligibility for a health plan and health care claims status transactions due to implementation of operating rules.

a. Providers

As stated, there is a direct causal link between the implementation of operating rules and an increase in the use of eligibility for a health plan and health care claim status transactions industry-wide.

In its conclusions, the IBM study estimated the baseline growth of total health care eligibility for a health plan transaction transactions (electronic and non-electronic) to be 10 percent without operating rules over a period of 3 years. It then estimated a 25 percent increase in the use of electronic eligibility for a health plan transaction across the entire industry if operating rules are implemented. For our analysis, we have assumed a more conservative growth rate in the use of the electronic eligibility for a health plan transactions than that of the IBM study both *in general* (that is, not attributed to any particular factor) and *as a result of* the implementation of operating rules.

We have estimated a 15 percent annual growth rate *in general* from 2013 through 2017, and then an 8 percent annual growth for 5 years thereafter. This general growth rate is reflected in Table 8. *In general,* eligibility for a health plan inquiries, electronic and non-electronic, for both physicians and hospitals, are expected to increase annually due to a number of market forces. For one, it is anticipated that population trends will increase the total overall number of patient visits and claims in the United States, especially in regards to baby-boomers who will require more care in the coming years. (*http://www.cdc.gov/nchs/data/databriefs/db41.htm*). It is probable that this increase alone will account for our 15 percent estimated annual growth rate of the use of the eligibility for a health plan transaction. As well, it is probable that providers will adopt EDI out of necessity from the sheer number of health care visits and claims that will experienced. In summary, we have chosen this estimate as our *general* predicted increase because it is a probable increase, even without the mandated implementation of operating rules.

With the implementation of operating rules, the estimate on the increased use of transactions by providers moves from probable to practical. The estimate on the percentage increase due to operating rules is the primary savings driver in our per transaction benefit analysis. Again, we assume a more conservative growth rate *due to operating rules* than the IBM study. In this regard, our analysis of the IBM study follows: Although the IBM study did not control for other factors that may have contributed to an increased use of the eligibility for a health plan transaction, the study was based on interviews which directed respondents to isolate the costs and benefits of operating rules in particular. While it is probable that other factors contributed to the extreme increase in the use of the transaction among the study's participants, the participants themselves believed that both the costs and benefits were a consequence of the operating rules and CAQH CORE certification.

However, because the IBM study analyzed a comparably small number of entities that have adopted operating rules, we are hesitant to accept the study's conclusions as the normative result of implementing operating rules for the eligibility for a health plan transaction. There may be entities that have implemented (or will implement) the operating rules that did not experience the same success as those that were surveyed in the study.

With this in mind, we have given a high and low range of probable increase usage rates due to operating rules. Our low and high estimate of 10 to 12 percent annual for the first 5 years falls far below the IBM study's average rate (25 percent annual increase). We believe these estimates are conservative, but do not believe that we are justified in estimating a more aggressive growth.

We also assume that 5 years after implementation of the operating rules the 10 to 12 percent annual growth *due to operating rules* will decrease to 5 percent a year. We assume this will be due to the fact that by this time the health care industry will have implemented the operating rules thus making the use of the electronic transactions more widespread, resulting in market stabilization and less of an increase in the number of electronic transactions.

We then estimate the annual increase in the number of electronic eligibility for a health plan inquiries from physicians and hospitals respectively due to operating rules. It is calculated by multiplying the range of total number of electronic eligibility for a health plan inquiries by the range of total percent increase in electronic transactions due to operating rules per year.

TABLE 8—ANNUAL INCREASE IN NUMBER OF ELECTRONIC ELIGIBILITY FOR A HEALTH PLAN TRANSACTIONS FOR PHYSICIANS DUE TO IMPLEMENTATION OF OPERATING RULES

I	II	III	IV	V	VI	VII
Year	Number of electronic eligibility for health plan transactions (in millions). Assumes 15% increases first 5 yrs/8% increase second 5 yrs	Number increase in electronic eligibility for health plan transactions from previous year (in millions) (high = low)	Total percentage increase in electronic eligibility for health plan transactions from previous year due to operating rules (low) (percent)	Total percentage increase in electronic eligibility for health plan transactions from previous year due to operating rules (high)	Number increase in electronic eligibility for health plan transactions from previous year due to operating rules (in millions) (low)	Number increase in electronic eligibility for health plan transactions from previous year due to operating rules (in millions) (high)
2012	453.6	0.0	0	0	0.0	0.0
2013	521.6	68.0	10	12	45.4	54.4
2014	599.9	78.2	10	12	52.2	62.6
2015	689.9	90.0	10	12	60.0	72.0
2016	793.3	103.5	10	12	69.0	82.8
2017	912.4	119.0	10	12	79.3	95.2
2018	985.3	73.0	5	5	45.6	45.6
2019	1064.2	78.8	5	5	49.3	49.3
2020	1149.3	85.1	5	5	53.2	53.2
2021	1241.2	91.9	5	5	57.5	57.5
2022	1340.5	99.3	5	5	62.1	62.1
Totals					573.5	634.6

TABLE 9—ANNUAL INCREASE IN NUMBER OF ELECTRONIC ELIGIBILITY FOR A HEALTH PLAN TRANSACTIONS FOR HOSPITALS DUE TO IMPLEMENTATION OF OPERATING RULES

I	II	III	IV	V	VI	VII
Year	Number of electronic eligibility for health plan transactions (in millions). Assumes 15% increases first 5 yrs/8% increase second 5 yrs	Number increase in electronic eligibility for health plan transactions from previous year (in millions) (low = high)	Total percentage increase in electronic eligibility for health plan transactions from previous year due to operating rules (low)	Total percentage increase in electronic eligibility for health plan transactions from previous year due to operating rules (high)	Number increase in electronic eligibility for health plan transactions from previous year due to operating rules (in millions) (low)	Number increase in electronic eligibility for health plan transactions from previous year due to operating rules (in millions) (high)
2012	201.6	0.0	0			0.0
2013	231.8	30.2	10	12	20.2	24.2
2014	266.6	34.8	10	12	23.2	27.8
2015	306.6	40.0	10	12	26.7	32.0
2016	352.6	46.0	10	12	30.7	36.8
2017	405.5	52.9	10	12	35.3	42.3
2018	437.9	32.4	5	5	20.3	20.3
2019	473.0	35.0	5	5	21.9	21.9
2020	510.8	37.8	5	5	23.6	23.6
2021	551.7	40.9	5	5	25.5	25.5
2022	595.8	44.1	5	5	27.6	27.6
Totals					254.9	282.1

We assume that health care claim status inquiries will increase annually for all providers *in general* at a rate of 20 percent a year for the first 5 years, for many of the same reasons as our estimates on the usage rate of the eligibility for a health plan transaction. We also assume that this rate of increase will slow after 5 years to about 10 percent a year. This general growth rate is reflected in Tables 10 and 11. We expect health care claim status transactions to be adopted at a higher rate than the eligibility for a health plan transaction because there is significantly less use of the transaction now (and so there is more room for growth).

We again have given a range of high and low estimates for the rate of increase that can be attributed to the implementation of operating rules. We have estimated a 12 to 15 percent annual growth in usage attributable to operating rules from 2013 through 2017, and then a 7 percent annual growth in usage for 5 years thereafter.

TABLE 10—ANNUAL INCREASE IN NUMBER OF HEALTH CARE CLAIM STATUS TRANSACTIONS FOR PHYSICIANS DUE TO IMPLEMENTATION OF OPERATING RULES

I	II	III	IV	V	VI	VII
Year	Minimum number of electronic health care claim status transactions (in millions). Assumes 20% increases first 5 yrs/10% increase second 5 yrs	Number increase in electronic health care claim status transactions from previous year (in millions) (high = low)	Total percentage increase in electronic health care claim status transactions from previous year due to operating rules (low)	Total percentage increase in electronic health care claim status transactions from previous year due to operating rules (high)	Number increase in electronic health care claim status transactions from previous year due to operating rules (in millions) (low)	Number increase in electronic health care claim status transactions from previous year due to operating rules (in millions) (high)
2012	70.6	0.0	0	0	0.0	0.0
2013	84.7	14.1	12	15	8.5	10.6
2014	101.6	16.9	12	15	10.2	12.7
2015	121.9	20.3	12	15	12.2	15.2
2016	146.3	24.4	12	15	14.6	18.3
2017	175.6	29.3	12	15	17.6	21.9
2018	193.1	17.6	7	7	12.3	12.3
2019	212.4	19.3	7	7	13.5	13.5
2020	233.7	21.2	7	7	14.9	14.9
2021	257.1	23.4	7	7	16.4	16.4
2022	282.8	25.7	7	7	18.0	18.0
Totals					138.0	153.8

TABLE 11—ANNUAL INCREASE IN NUMBER OF HEALTH CARE CLAIM STATUS TRANSACTIONS FOR HOSPITALS DUE TO IMPLEMENTATION OF OPERATING RULES

I	II	III	IV	V	VI	VII
Year	Minimum number of electronic health care claim status transactions (in millions). Assumes 20% increases first 5 yrs/10% increase second 5 yrs	Number increase in electronic health care claim status transactions from previous year (in millions) (high = low)	Total percentage increase in electronic health care claim status transactions from previous year due to operating rules (low)	Total percentage increase in electronic health care claim status transactions from previous year due to operating rules (high)	Number increase in electronic health care claim status transactions from previous year due to operating rules (in millions) (low)	Number increase in electronic health care claim status transactions from previous year due to operating rules (in millions) (high)
2012	7.8	0.0	0	0	0.0	0.0
2013	9.4	1.6	12	15	0.9	1.2
2014	11.3	1.9	12	15	1.1	1.4
2015	13.5	2.3	12	15	1.4	1.7
2016	16.3	2.7	12	15	1.6	2.0
2017	19.5	3.3	12	15	2.0	2.4
2018	21.5	2.0	7	7	1.4	1.4
2019	23.6	2.1	7	7	1.5	1.5
2020	26.0	2.4	7	7	1.7	1.7
2021	28.6	2.6	7	7	1.8	1.8
2022	31.4	2.9	7	7	2.0	2.0
Totals					15.3	17.1

b. Health Plans

To find the increase in electronic eligibility for a health plan and health care claims status transactions annually for health plans, we add the total annual increase usage of the two transactions by providers. The sum again gives us a low to high range of increased usage of the two transactions due to operating rules.

We solicit comments on these baseline assumptions.

TABLE 12—ANNUAL INCREASE IN NUMBER OF ELIGIBILITY FOR A HEALTH PLAN TRANSACTIONS DUE TO IMPLEMENTATION OF OPERATING RULES

I	II	III	IV	V	VI	VII
Year	Physician number increase in electronic eligibility for a health plan transactions from previous year due to operating rules in millions		Hospital number increase in electronic eligibility for a health plan transactions from previous year due to operating rules in millions		Plan number increase in electronic eligibility for a health plan transactions from previous year due to operating rules in millions	
	Low	High	Low	High	Low	High
2012	0.0	0.0	0.0	0.0	0.0	0.0
2013	45.4	54.4	20.2	24.2	65.5	78.6
2014	52.2	62.6	23.2	27.8	75.3	90.4
2015	60.0	72.0	26.7	32.0	86.7	104.0
2016	69.0	82.8	30.7	36.8	99.6	119.6
2017	79.3	95.2	35.3	42.3	114.6	137.5
2018	45.6	45.6	20.3	20.3	65.9	65.9
2019	49.3	49.3	21.9	21.9	71.2	71.2
2020	53.2	53.2	23.6	23.6	76.9	76.9
2021	57.5	57.5	25.5	25.5	83.0	83.0
2022	62.1	62.1	27.6	27.6	89.6	89.6
Totals	573.5	634.6	254.9	282.1	828.3	916.7

TABLE 13—ANNUAL INCREASE IN NUMBER OF HEALTH CARE CLAIM STATUS TRANSACTIONS FOR HEALTH PLANS DUE TO IMPLEMENTATION OF OPERATING RULES

I	II	III	IV	V	VI	VII
Year	Physician number increase in electronic health care claim status transactions from previous year due to operating rules in millions		Hospital number increase in electronic health care claim status transactions from previous year due to operating rules in millions		Plan number increase in health care claim status transactions from previous year due to operating rules in millions	
	Low	High	Low	High	Low	High
2012	0.0	0.0	0.0	0.0	0.0	0.0
2013	8.5	10.6	0.9	1.2	9.4	11.8
2014	10.2	12.7	1.1	1.4	11.3	14.1
2015	12.2	15.2	1.4	1.7	13.5	16.9
2016	14.6	18.3	1.6	2.0	16.3	20.3
2017	17.6	21.9	2.0	2.4	19.5	24.4
2018	12.3	12.3	1.4	1.4	13.7	13.7
2019	13.5	13.5	1.5	1.5	15.0	15.0
2020	14.9	14.9	1.7	1.7	16.5	16.5
2021	16.4	16.4	1.8	1.8	18.2	18.2
2022	18.0	18.0	2.0	2.0	20.0	20.0
Totals	138.0	153.8	15.3	17.1	153.4	170.9

I. Cost Assumptions

1. Providers

We assume that physicians and hospitals will incur some start-up costs for implementing operating rules. These include training of staff and changes to internal business processes. Unlike the costs to health plans, we assume that the costs are less likely to be expensive infrastructure updates, because we assume most providers will already have the necessary infrastructure in place to accommodate the operating rules adopted under this interim final rule with comment period. We base this assumption on industry studies that demonstrates that EDI is utilized in over 75 percent of claim submissions. This means that the majority of providers or their business partners are capable of transmitting EDI.

While we assume that there may remain some providers who do not conduct any EDI, the operating rules adopted herein do not apply to providers who prefer paper-based or manual transactions. If such a provider were to move to EDI after learning of the advantages of operating rules, the provider's costs for initial EDI infrastructure can be found in the Transaction and Code Sets final rule, and impacts of the operating rules per se can be found in this interim final rule with comment period. In summary, costs regarding initial EDI infrastructure to transmit HIPAA transactions are not a factor in our estimates. We solicit comments on these assumptions.

We assume the costs of implementing operating rules will mostly be borne by health plans. However, we expect that some costs will be borne by providers in the form of increased fees from vendors and clearinghouses, such as upgraded software costs and an increase in per-claim transaction fees based on the increase in volume of transactions. These fees are variable depending on existing infrastructure, number of providers in a practice, geographic areas, *etc.* To account for possible costs to providers, we have assumed that the costs attributed to implementing the Modifications final rule are applicable here. We estimate the cost for providers

to implement operating rules will be 25 percent of the total unadjusted costs estimated by the Modifications rule. We use this estimate based on the fact that most of the costs of implementing operating rules will be realized by health plans due to the more robust information they will be required to send in these transactions. As well, any software updates that providers will need may only apply to the eligibility for a health plan and health care claim status transactions, unlike the Modifications rule, which required software updates that applied to up to seven transactions. (See Table 14.)

We base our estimates on provider costs solely on the Modifications final rule because the types of costs included in that impact analysis are similar to those that would be borne by implementing operating rules: software upgrades; training; and testing of transaction improvements.

We believe that these costs are high considering the fact that the Modifications rule applies to seven different transactions, while the operating rules adopted in this interim final rule with comment period only applies to two. However, we have no evidence or justification for supporting a lower cost.

TABLE 14—PROVIDER COSTS

	Unadjusted total physicians' cost from modifications final rule	Physicians' cost to implement operating rules for eligibility for a health plan and health care claim status transactions (25% of modifications final rule estimates)	Unadjusted total hospital's cost from modifications final rule	Hospitals' cost to implement operating rules for eligibility for a health plan and health care claim status transactions (25% of modifications final rule estimates)	Total cost to providers
5010 Implementation Costs—Low	$370	$93	$792	$198	$291
5010 Implementation Costs—High	740	185	1,584	396	581
5010 Transition Costs—Low	174	44	373	93	137
5010 Transition Costs—High	348	87	746	187	274
Total Costs—Low	544	136	1,165	291	427
Total Costs—High	1,088	272	2,330	583	855

2. Health Plans

As stated earlier, we assume that health plans will bear the majority of costs of adopting operating rules. All of the studies that were considered for this impact analysis provided qualitative descriptions of the possible costs of adoption; however, the IBM study was the only one to attribute specific costs of operating rule adoption for health plans. The IBM study gave a range of costs: $8,000 to $1.7 million total cost of adoption including IT staff services such as programming, software, and hardware across a number of systems; and annual ongoing costs of $0 to $79,000 for IT staff services such as programming, and minor hardware and software upgrades to annually update operating rules.

In contrast, total implementation costs to implement the updated Version 5010 of the HIPAA standards ranged from an average of $1.14 to $2.28 million per health plan, excluding government health plans. We assume that implementing Version 5010 may be comparable to implementing the operating rules adopted herein. However the Modifications rule broadly amends or alters seven HIPAA standard transactions. This interim final rule with comment period adopts operating rules for only two transactions.

To calculate the range of costs for health plans we start with the low and high costs to health plans estimated in the Modifications rule. We increased these costs by 14 percent to account for the 14 percent increase in the number of health plans from the Modifications rule. We estimate the cost for health plans to implement operating rules will be 50 percent of the total costs estimated by the Modifications rule. We estimated a low cost of $2.6 billion and a high $5.1 billion for health plans. We reduced the estimate of health plans costs based upon the Modifications final rule because, unlike the Modifications final rule, operating rules adopted herein only apply to the eligibility for a health plan and health care claim status transactions.

We will assume that the ongoing cost to maintaining operating rules for eligibility for a health plan and health care claim status will continue 2 years after implementation. However, since we do not know what updates will be needed at this time, we cannot determine costs for those updates. Afterwards, we will assume that ongoing costs will decrease to zero. We base this assumption on the IBM study finding that the majority of the ongoing cost was due to IT staff services for programming, and after 2 years we assume that this programming will no longer be necessary.

Note that by using 4,577 as the total number of health plans, we have not adjusted for the number of health plans that have already updated their infrastructure and communications, and have already implemented the operating rules. This includes not only those health plans that have been certified by the CAQH CORE as having implemented portions of Phase I and, perhaps, Phase II, but also health plans that have done so without going through the CAQH CORE certification process. As we have noted, a number of states have statutes that are similar, to the CAQH CORE operating rules with which all health care entities operating in the same state must comply. Therefore, we believe our costs may be overstated. We invite public and interested stakeholder comments on our cost assumptions.

TABLE 15—COST TO HEALTH PLANS OF OPERATING RULE ADOPTION FOR ELIGIBILITY FOR A HEALTH PLAN AND HEALTH CARE CLAIM STATUS TRANSACTIONS

	Total health plans' cost from modifications final rule (+14% to account for increase in number of plans)	Health plans' cost to implement operating rules for eligibility for a health plan and claim status transactions (50% of adjusted modifications final rule estimates)
5010 Implementation Costs—Low	$3,483	$1,742
5010 Implementation Costs—High	6,968	3,484
5010 Transition Costs—Low	1,640	820
5010 Transition Costs—High	3,279	1,639
Total Costs—Low	5,123	2,562
Total Costs—High	10,246	5,123

3. Vendors and Clearinghouses

None of the studies considered for this impact analysis were able to quantify the costs and savings, or the return on investment of adopting operating rules for vendors or clearinghouses. As previously mentioned, we expect that some costs will be borne by providers in the form of increased fees from vendors and clearinghouses, such as upgraded software costs and an increase in per-claim transaction fees based on the increase in volume of transactions.

Because of this we believe that costs to vendors will be the same as the costs expected by providers since vendors pass along their costs to their provider clients in the form of increased fees, which are included as the costs to providers of implementing these operating rules. Additionally, we believe that costs to clearinghouses for routing of additional electronic transactions, which we assume will be due to implementation of the operating rules, are included in the costs expected by health plans. We invite interested stakeholder comments regarding these costs and assumptions for vendors and clearinghouses.

J. Savings Assumptions

1. Providers

We have analyzed two areas in which providers will find savings or avoid costs upon implementation of the operating rules for eligibility for a health plan and health care claim status transactions. The first area that provides considerable cost savings is the avoidance of claim denials that implementation of the eligibility for a health plan operating rules is estimated to provide. The second area of savings for providers will be the per transaction savings of moving eligibility for a health plan and health care claim status transactions from non-electronic to EDI.

It is difficult, if not impossible, to estimate the number of eligibility for a health plan and claim status transactions conducted per provider, even as an average. Given the added difficulty of the range of technological capabilities of providers, it would be difficult, if not impossible, to make any assumptions on the cost or benefit on a per provider basis, or to project an estimate of increased EDI use for any one provider.

This impact analysis will not base its cost or benefit to providers on the number of providers or on a per-provider or average provider basis. It would be specious to presume that such numbers reflect any real situation in a provider's office. Rather, we will look at the total number of eligibility for a health plan and claim status transactions that we estimate all providers conduct through a given year, and estimate an increase based on the implementation of operating rules. In the same vein, we will calculate a savings based on an estimate of the total number of denied claims, instead of attempting to calculate an average of denied claims per provider.

In the area of claims denials, we assume that there will be a low to high range of $$560 million to $700 million annual cost savings in the reduction of denied claims once the eligibility for a health plan transaction operating rules are implemented. We base this assumption on a number of studies. We use the total annual number of claims submitted from the Modifications final rule as mentioned above, 5.6 billion, and divide it between physicians and hospitals according to the Oregon Survey's 9 to 1 ratio of physician to hospital transactions. We then take the 5 billion annual claims for physicians and 560 million for hospitals and apply the 5 percent of denied claims as outlined in the MGMA Project Swipe IT study. With this number, we consider the IBM study data that found that the implementation of eligibility for a health plan operating rules resulted in a 10 percent to 12 percent decrease in denied claims. We have consistently created low to high ranges in this impact analysis that uses the results of the IBM study as the ''best case'' or high estimates, and we will do so here as well. We have provided a range of 8 to 10 percent decrease in denied claims due to operating rules.

This results in a total of 22.4 million to 28 million denied claims for providers that could be avoided through eligibility for a health plan operating rules. We then take these numbers and apply them to the cost to providers of processing denied claims, which is $25 per denied claim according to a December 2000 study sponsored by the Medical Group Management Association, *http://www.acpinternist.org/archives/2000/12/claimsdenied.htm*). This results in $560 million to $700 million in annual savings for providers due to implementation of operating rules for the eligibility for a health plan transaction.

X * Y * Z * A = Total annual savings to providers by avoiding denied claims

Where:

X = Total number of claims (Column II)
Y = Percent of claims that are denied (Column III)
Z = Percent of denied claims that will be avoided by implementing eligibility for a health plan operating rules (Column V)
A = Cost for providers to resubmit a single denied claim (Column VII)

TABLE 16—ANNUAL SAVINGS TO PROVIDERS FOR AVOIDING CLAIMS DENIALS AFTER IMPLEMENTATION OF OPERATING RULES FOR ELIGIBILITY FOR A HEALTH PLAN

I	II	III	IV	V	VI	VII	VIII	IX	X	XI
	Total number of claims (in millions)	Percent of claims denied (MGMA 2007) (percent)	Number of claims denied in millions = *(Col II)* × *(Col III)*	Percent of denied claims that will be avoided through eligibility for a health plan operating rules (IBM: 10%–12%) (percent)		Number of denied claims that will be avoided through eligibility for a health plan operating rules in millions = *(Col IV)* × *(Col V/VI)*		Cost to resubmit a denied claim (Larch 2000, ACP–ASIM Observer)	Total annual savings of eligibility for a health plan operating rules through reduction in claims denial in millions (Col VII/VIII) × (Col IX)	
				LOW	HIGH	LOW	HIGH		LOW	HIGH
Physician	5,040	5	252	8	10	20.16	25.2	$25	504	630
Hospital	560	5	28	8	10	2.24	2.8	25	56	70
Totals						22.4	28		560	700

In the area of per transaction savings, we assume that the move from non-electronic to electronic transmission of the eligibility for a health plan transaction will save providers, physicians and hospitals, $2.10 per transaction. This number reflects the difference in labor time and costs required to conduct the electronic transaction compared to the manual transaction. It includes the difference in the cost of labor—employee salary, benefits, and payroll taxes—as well as the difference in general overhead.

We arrived at $2.10 savings per transaction after analyzing a number of the studies already mentioned, including the Health Efficiency Report, the Milliman study, and the IBM study. We decided that the IBM study's estimate of a savings of $2.10 per eligibility for a health plan transaction that moves from non-electronic to electronic was the best starting estimate because, unlike the other studies, the IBM study surveyed entities that actually realized costs savings as a result of the use of operating rules for the electronic eligibility for a health plan transactions. As well, the IBM study gives us the most conservative estimate, as can be seen by comparing it with other studies' conclusions.

We assume that the move from non-electronic to EDI transmission of the health care claim status transaction will save physicians and hospitals $3.33 per transaction. The benefits to physicians in streamlining the health care claim status transaction through operating rules are potentially significant if, as we assume, it leads to less dependence on more time consuming and costly manual means, and increased use of the EDI transaction.

Unlike the eligibility for a health plan transaction analysis, we did not base our savings per health care claim status transaction for providers on the IBM study, as the IBM study did not measure the impact of the operating rules for the health care claim status transaction. Instead, we took our assumptive savings of $3.33 per transaction from the number that is used in all studies we analyzed and which was first illustrated in the Milliman study. We will use this assumption as this is the number on which industry studies appear to agree. However, we note that, as the health care claim status transaction is very seldom used, there is very little data on which to base actual savings.

Note that the low to high estimates on the estimated increase in the transactions based on operating rules are carried through this calculation. We arrived at this range in our calculations described in the baseline assumptions.

TABLE 17—SAVINGS FOR PROVIDERS PER ELIGIBILITY FOR A HEALTH PLAN AND HEALTH CARE CLAIMS STATUS TRANSACTION THAT MOVES FROM NONELECTRONIC TO ELECTRONIC FOR PROVIDERS

Source	Savings for every eligibility for a health plan transaction that moves from non-electronic to electronic	Savings for every health care claim status transaction that moves from non-electronic to electronic
Health Efficiency Report	$2.95	$3.33
Oregon Survey (low estimate)	2.46	3.33
Milliman study	2.44	3.33
IBM study	2.10	NA
Our assumption	2.10	3.33

TABLE 18—PROVIDER (PHYSICIAN AND HOSPITALS) SAVINGS FOR ELIGIBILITY

I	II	III	IV	V	VI
Year	Low number increase in eligibility for a health plan transactions from previous year due to operating rules in millions (from table 12)	High number increase in eligibility for a health plan transactions from previous year due to operating rules in millions (from table 12)	Savings per transaction	Low annual savings in millions	High annual savings in millions
2012	0.0	0.0	$0.0	$0.0	$0.0
2013	65.5	78.6	2.10	137.6	165.1
2014	75.3	90.4	2.10	158.2	189.9
2015	86.7	104.0	2.10	182.0	218.4
2016	99.6	119.6	2.10	209.3	251.1
2017	114.6	137.5	2.10	240.6	288.8
2018	65.9	65.9	2.10	138.4	138.4
2019	71.2	71.2	2.10	149.4	149.4
2020	76.9	76.9	2.10	161.4	161.4
2021	83.0	83.0	2.10	174.3	174.3
2022	89.6	89.6	2.10	188.3	188.3
Total				1,739.5	1,925.0

TABLE 19—PROVIDER (PHYSICIAN AND HOSPITALS) SAVINGS FOR CLAIM STATUS

I	II	III	IV	V	VI
Year	Low number increase in health care claim status transactions from previous year due to operating rules in millions (from table 13)	High number increase in health care claim status transactions from previous year due to operating rules in millions (from table 13)	Savings per transaction	Low annual savings in millions	High annual savings in millions
2012	0.0	0.0	$0.0	$0.0	$0.0
2013	9.4	11.8	3.33	31.3	39.2
2014	11.3	14.1	3.33	37.6	47.0
2015	13.5	16.9	3.33	45.1	56.4
2016	16.3	20.3	3.33	54.1	67.7
2017	19.5	24.4	3.33	65.0	81.2
2018	13.7	13.7	3.33	45.5	45.5
2019	15.0	15.0	3.33	50.0	50.0
2020	16.5	16.5	3.33	55.0	55.0
2021	18.2	18.2	3.33	60.5	60.5
2022	20.0	20.0	3.33	66.6	66.6
Total				510.8	569.0

TABLE 20—PROVIDER SAVINGS SUMMARIZED

Year	Low savings			High savings		
	Annual provider savings due to increased use of electronic transactions	Annual provider savings due to decrease in claim denials	Total annual savings to providers (in millions)	Annual provider savings due to increased use of electronic transactions	Annual provider savings due to decrease in claim denials	Total annual savings to providers (in millions)
2013	$168.92	$560	$729	$204.27	$700	$904
2014	195.83	560	756	236.87	700	937
2015	227.08	560	787	274.75	700	975
2016	263.40	560	823	318.78	700	1,019
2017	305.61	560	866	369.98	700	1,070
2018	183.85	560	744	183.85	700	884
2019	199.46	560	759	199.46	700	899
2020	216.42	560	776	216.42	700	916
2021	234.84	560	795	234.84	700	935
2022	254.83	560	815	254.83	700	955

TABLE 20—PROVIDER SAVINGS SUMMARIZED—Continued

Year	Low savings			High savings		
	Annual provider savings due to increased use of electronic transactions	Annual provider savings due to decrease in claim denials	Total annual savings to providers (in millions)	Annual provider savings due to increased use of electronic transactions	Annual provider savings due to decrease in claim denials	Total annual savings to providers (in millions)
Cumulative Totals	.....	.....	7,850	.....	.....	9,494

2. Health Plans

We have analyzed two areas in which health plans will find savings or avoid costs upon implementation of the operating rules for eligibility for a health plan and health care claim status transactions. The first area that provides considerable cost savings is a decrease in the number of pended claims that implementation of the eligibility for a health plan operating rules is estimated to provide. Pended claims are claims that necessitate a manual review by the health plan. The second area of savings for health plans will be the per transaction savings of moving eligibility for a health plan and health care claim status transactions from non-electronic to EDI transmittal.

In the area of pended claims, we base this assumption on a study by the America's Health Insurance Plans in 2006 (AHIP Center for Policy and Research, An Updated Survey of Health Care Claims Receipt and Processing Times (May 2006) at *http://www.ahipresearch.org/pdfs/PromptPayFinalDraft.pdf*).

We start our calculation with the total annual number of claims submitted based on the Modifications final rule as mentioned previously, 5.6 billion. AHIP reported that 14 percent of all claims were pended by health plans, which calculates to 784 million pended claims. The AHIP study broke down the reasons why claims were pended. Four of those categories, including lack of necessary information, no coverage based on date of service, non-covered/non-network benefit or service, and coverage determination, we believe can be avoided by implementing operating rules for the eligibility for a health plan transaction and the increased use of the eligibility for a health plan transactions. These categories comprise 31 percent of all pended claims. We also assume that many pended claims can be avoided with increased use of the claim status transaction and its operating rules. However, we were unable to establish a correlation between use of claim status operating rules and a decrease in pended claims, and have not included any savings attributable to the claim status operating rules.

To reflect the uncertainty of this effect of operating rules on a ''downstream'' process, we estimate that 20 to 25 percent of pended claims could be avoided through use of operating rules. (See Table 21.)

AHIP estimated that $0.85 was the cost to reply electronically to a ''clean'' claim submission, while $2.05 was the cost to claims that ''necessitate manual or other review cost,'' according to the study. The difference is $1.20, which is the per pended claim factor we use for our cost savings analysis. (See Table 21.)

This results in $188 million to $235 million for health plans in annual savings of eligibility for a health plan operating rules through reduction in pended claims.

X * Y * Z * A = Total annual savings to providers by avoiding denied claims

Where:

X = Total number of claims (Column I)

Y = Percent of claims that are pended (Column II)

Z = Percent of pended claims that will be avoided by implementing eligibility for a health plan operating rules (Column IV)

A = Cost for health plans to manually review a pended claim (Column VI)

TABLE 21—ANNUAL SAVINGS TO PLANS FOR AVOIDING PENDED CLAIMS AFTER IMPLEMENTATION OF OPERATING RULES FOR ELIGIBILITY FOR A HEALTH PLAN

I	II	III	IV	V	VI	VII	VIII	IX	X
Total number of claims in millions	Percent of claims pended (AHIP 2006)	Number of claims pended claims in millions = *(Col I)* × *(Col II)*	Percent of pended claims that will be avoided through eligibility for a health plan operating rules (AHIP 2006) Low	Percent of pended claims that will be avoided through eligibility for a health plan operating rules (AHIP 2006) High	Number of pended claims that will be avoided through eligibility for a health plan operating rules in millions = *(Col III* × *(Col IV)* Low	Number of pended claims that will be avoided through eligibility for a health plan operating rules in millions = *(Col III)* × *(Col V)* High	Cost to review a pended claim (AHIP, 2006)	Total annual savings of eligibility for a health plan operating rules through reduction in pended claims in millions *(Col VI)* × *(Col VIII)* Low	Total annual savings of eligibility for a health plan operating rules through reduction in pended claims in millions *(Col VII)* × *(Col VIII)* High
5,600	14%	784	20%	25%	156.8	196	$1.20	$188	$235

The second area of savings for health plans is the per transaction savings of moving eligibility for a health plan and health care claim status transactions from non-electronic to electronic transmittal. We assume that the average savings for health plans in adopting operating rules for eligibility for a health plan is approximately $3.13 per transaction that moves from non-electronic to electronic, and $3.75 for health care claim status transactions that move from non-electronic to electronic.

To determine these savings, we assumed that the IBM study and the Oregon Survey were the most recent and the most valid with regard to eligibility for a health plan savings, as they are based on detailed surveys with health plans. To arrive at our savings

assumption, therefore, we averaged the two studies. (See Table 22)

For health care claim status transactions, we relied solely on the Oregon Survey, again based on the validity of its results. (See Table 22)

TABLE 22—SAVINGS PER ELIGIBILITY FOR A HEALTH PLAN AND HEALTH CARE CLAIM STATUS TRANSACTION THAT MOVES FROM NON–ELECTRONIC TO ELECTRONIC FOR HEALTH PLANS

Source	Savings for every eligibility for a health plan transaction that moves from non-electronic to electronic	Savings for every health care claims status transaction that moves from non-electronic to electronic
Oregon Survey	$3.75	$3.75
IBM study	$2.50	NA
Our assumption	$3.13	$3.75

Note that the low to high estimates on the estimated increase in the transactions based on operating rules are carried through this calculation (in Tables 23 and 24). We arrived at this range in our calculations described in the baseline assumptions.

TABLE 23—SAVINGS FOR ELIGIBILITY FOR A HEALTH PLAN OPERATING RULES FOR HEALTH PLANS

I	II	III	IV	V	VI
Year	Number increase in electronic eligibility for a health plan transactions from previous year due to operating rules (in millions) low	Number increase in electronic eligibility for a health plan transactions from previous year due to operating rules (in millions) high	Savings per transaction	Annual savings (in millions) low	Annual savings (in millions) high
2012	0.0	0.0	$0.0	$0.0	$0.0
2013	65.5	78.6	3.13	205.1	246.1
2014	75.3	90.4	3.13	235.8	283.0
2015	86.7	104.0	3.13	271.2	325.5
2016	99.6	119.6	3.13	311.9	374.3
2017	114.6	137.5	3.13	358.7	430.4
2018	65.9	65.9	3.13	206.2	206.2
2019	71.2	71.2	3.13	222.7	222.7
2020	76.9	76.9	3.13	240.6	240.6
2021	83.0	83.0	3.13	259.8	259.8
2022	89.6	89.6	3.13	280.6	280.6
Total				2,592.7	2,869.2

TABLE 24—SAVINGS FOR HEALTH CARE CLAIM STATUS OPERATING RULES FOR HEALTH PLANS

I	II	III	IV	V	VI
Year	Number increase in health care claim status transactions from previous year due to operating rules (in millions) low	Number increase in claim status health care transactions from previous year due to operating rules (in millions) high	Savings per transaction	Annual savings (in millions) low	Annual savings (in millions) high
2012	0.0	0.0	$0.0	$0.0	$0.0
2013	9.4	11.8	3.75	35.3	44.1
2014	11.3	14.1	3.75	42.3	52.9
2015	13.5	16.9	3.75	50.8	63.5
2016	16.3	20.3	3.75	61.0	76.2
2017	19.5	24.4	3.75	73.2	91.4
2018	13.7	13.7	3.75	51.2	51.2
2019	15.0	15.0	3.75	56.3	56.3
2020	16.5	16.5	3.75	62.0	62.0
2021	18.2	18.2	3.75	68.2	68.2
2022	20.0	20.0	3.75	75.0	75.0

TABLE 24—SAVINGS FOR HEALTH CARE CLAIM STATUS OPERATING RULES FOR HEALTH PLANS—Continued

I	II	III	IV	V	VI
Year	Number increase in health care claim status transactions from previous year due to operating rules (in millions) low	Number increase in claim status health care transactions from previous year due to operating rules (in millions) high	Savings per transaction	Annual savings (in millions) low	Annual savings (in millions) high
Total				575.2	640.8

TABLE 25—HEALTH PLAN SAVINGS SUMMARIZED

	Low savings			High savings		
	Annual health plan savings due to increased use of electronic transactions	Annual health plan savings due to decrease in claim denials	Total annual savings to health plans (in millions)	Annual health plan savings due to increased use of electronic transactions	Annual health plan savings due to decrease in claim denials	Total annual savings to health plans (in millions)
2013	$240.4	$188	$429	$290.19	$235	$525
2014	278.2	188	466	335.93	235	571
2015	322.0	188	510	388.96	235	624
2016	372.9	188	561	450.48	235	686
2017	431.8	188	620	521.86	235	757
2018	257.5	188	446	257.45	235	493
2019	279.1	188	467	279.07	235	514
2020	302.5	188	491	302.52	235	538
2021	328.0	188	516	327.97	235	563
2022	355.6	188	544	355.57	235	591
Totals			5,049			5,862

3. Vendors and Clearinghouses

None of the studies considered for this analysis were able to quantify the costs and savings, or the return on investment of adopting operating rules for the eligibility for a health plan and health care claim status inquiry and response transactions for vendors and clearinghouses. As noted previously, we expect that some costs will be borne by providers in the form of increased fees from vendors and clearinghouses such as upgraded software costs.

We would anticipate that the savings, as well as the costs, to vendors of upgrading provider software will be passed along to their provider clients. Therefore, we assume that the costs and benefits for vendors in implementing the operating rules will be the same as those for providers.

Additionally, since clearinghouses work on behalf of health plans and act as intermediaries between providers and health plan in regards to electronic transactions, we believe that the savings, as well as the costs, to clearinghouses for routing of additional electronic transactions will be the same savings and costs as those expected by health plans. We invite public and interested stakeholder comments on our assumptions.

K. Summary

1. Providers

As previously noted, providers will assume the least cost and see the greatest benefit from the implementation of operating rules as required by this interim final rule with comment period. Within 10 years of implementation of the operating rules for eligibility for a health plan and health care claim status transactions, we estimate that there will be $7.9 billion to $9.5 billion in savings for providers at a cost of up to $855 million.

TABLE 26—SUMMARY OF PROVIDER SAVINGS AND COSTS OVER 10 YEARS

[In millions]

	Low	High
Provider Savings	$7,850	$9,494
Total Provider Costs	427	855

2. Health Plans

We estimate that health plans will see a savings of $5 billion to $5.8 billion within 10 years of the implementation of operating rules (both for eligibility for a health plan and health care claim status transactions). We believe that this is a conservative estimate. The IBM study found an average return on investment of over $2 million per health plan within 1 year of implementation. If multiplied by the number of health plans, this results in over $9 billion savings after the first year. We estimate that costs to health plans will range from $2.6 billion to $5.1 billion over 10 years.

In March 2010, the Congressional Budget Office (CBO) (*http://www.cbo.gov/ftpdocs/113xx/doc11379/AmendReconProp.pdf*) estimated that the administrative simplification requirements in the Affordable Care Act would produce savings to the Federal budget. In contrast to the CBO analysis, government health plans are not considered separately in our impact analysis and summary estimate, and were instead included along with private health plans. When considering the impact on the Federal government of this interim final rule with comment period, note that the operating rules adopted herein are only one part of the broader administrative simplification mandates outlined in section 1104 of the Affordable Care Act, from which a

greater return on investment (ROI) in total is anticipated. Also, because we are addressing requirements that will impact the entire health care industry, we again reiterate that we choose to make conservative estimates based on the variation within the studies on which to base such estimates.

TABLE 27—SUMMARY OF HEALTH PLAN SAVINGS AND COSTS OVER 10 YEARS

[In millions]

	Low	High
Health Plan Savings	$5,049	$5,862
Health Plan Costs	2,562	5,123

TABLE 28—SUMMARY OF PROVIDER AND HEALTH PLAN SAVINGS AND COSTS OVER 10 YEARS

[In millions]

	Low	High
Provider and Health Plan Savings	$12,899	$15,356
Total Provider and Health Plan Costs	2,989	5,978

L. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) of 1980, Public Law 96–354, requires agencies to describe and analyze the impact of the interim final rule with comment on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. In the healthcare sector, the Small Business Administration (SBA) size standards define a small entity as one with between revenues of $7 million to $34.5 million in any 1 year. For details, see the SBA's Web site at *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf* (refer to Sector 62—Health Care and Social Assistance). (Accessed 2–1–11).

For the purposes of this analysis (pursuant to the RFA), nonprofit organizations are considered small entities; however, individuals and States are not included in the definition of a small entity. We have attempted to estimate the number of small entities and provide a general discussion of the effects of this interim final rule with comment period, and where we had difficulty, or were unable to find information, we solicit industry comment. Because most medical providers are either nonprofit or meet the SBA's size standard for small business, we treat all medical providers as small entities.

1. Number of Small Entities

The following sections discuss which entities across the health care industry, that are impacted by this interim final rule with comment period, are considered small entities as part of this Regulatory Flexibility Analysis.

- Providers—All health care providers are assumed to be small entities. The number of providers utilized in this analysis is taken from the August 21, 2008 HIPAA Electronic Transaction Standards proposed rule, as well as the U.S. Census Bureau, Detailed Statistics, 2007 Economic Census, August 31, 2010. The determination to include all health care providers as small entities is modeled after many previous HHS rules which utilized the same assumption.
- Clearinghouses—All clearinghouses were assumed to not be small entities. Three national association Web sites were consulted (EHNAC, HIMSS and the Cooperative Exchange). Additionally, the Health Data Dictionary by Faulkner and Gray which was last published in 2000 determined that the number of clearinghouses that would be considered small entities was negligible. The top 51 clearinghouse entities were listed, and the range of monthly transactions was 2,500 to 4 million, with transaction fees of $0.25 per transaction to $2.50 per transaction. It was determined that even based on this data, few of the entities would fall into the small entity category, and as such, we did not count them in this RFA analysis.
- Health Plans—All health plans are assumed to not be small entities. Based on the available public data, the number of plans that meet the SBA size standard of $7 million in annual receipts was unable to be determined; therefore we did not include an analysis of the impact on health plans.
- Software Vendors—Vendors are not considered covered entities under HIPAA; however we assume that all vendors are small entities based on their relation to providers. Based on our analysis in the regulatory impact analysis, we assume that the costs and benefits for software vendors would be the same as those for providers.

We solicit industry comment on our above assumptions.

In total, we estimate that there are approximately 300,000 health care organizations that may be considered small entities either because of their nonprofit status or because of their revenues. On the provider side, practices of doctors of osteopathy, podiatry, chiropractors, mental health independent practitioners with annual receipts of less than $7 million are considered to be small entities. Solo and group physicians' offices with annual receipts of less than $9 million (97 percent of all physician practices) are also considered small entities, as are clinics. Approximately 92 percent of medical laboratories, 100 percent of dental laboratories and 90 percent of durable medical equipment suppliers are assumed to be small entities as well. The American Medical Billing Association (AMBA) (*http://www.ambanet.net/AMBA.htm*) lists 97 billing companies on its Web site. It notes that these are only ones with Web sites.

The Business Census data shows that there are 4,526 (plus Medicare, VA, and IHS) firms considered as health plans and/or payers responsible for conducting transactions with health care providers (not including State Medicaid Agencies). For purposes of the RFA, we did not identify a subset of small plans, and instead solicit industry comment as to the percentage of plans that would be considered small entities. State Medicaid agencies were also excluded from the analysis as well because States are not considered small entities in any Regulatory Flexibility Analysis. We solicit industry comment on this assumption.

We identified the top 51 clearinghouses/vendors in the Faulkner and Gray health data directory from 2000, the last year this document was produced. Health care clearinghouses provide transaction processing and translation services to both providers and health plans.

The following table outlines the estimated number of small entities utilized in the preparation of the initial regulatory flexibility analysis.

TABLE 29—NUMBER OF IMPACTED SMALL ENTITIES

[In Whole Numbers]

Type	Number	Source
Hospitals (NAICS 622)	6,505	U.S. Census Bureau, Detailed Statistics, 2007 Economic Census, August 31, 2010.

TABLE 29—NUMBER OF IMPACTED SMALL ENTITIES—Continued

[In Whole Numbers]

Type	Number	Source
Ambulatory health care services (NAICS code 6211).	547,561	U.S. Census Bureau, Detailed Statistics, 2007 Economic Census, August 31, 2010.
Clearinghouses	0	Survey of EHNAC, HIMSS, the Cooperative Exchange, and the Maryland Commission for Healthcare) Assume, all clearinghouse are not small entities.
Health Plans (including Government Health Plans such as Medicare, VA and IHS).	0	Assume all health plans are *not* small entities.
Vendors (NAICS code 5415—Computer design and related services).	51	EC EDI Vantage Point Healthcare Directory—6th Edition (n=51) *http://www.ec-edi.biz/content/en/dir-guest-login.asp*.
Health Plans—Medicaid	0	State Medicaid agencies were excluded from the analysis because States are not considered small entities in any Regulatory Flexibility Analysis.

2. Cost for Small Entities

To determine the impact on health care providers we used Business Census data on the number of establishments for hospitals and firms for the classes of providers and revenue data reported in the Survey of Annual Services for each NAICS code. Because each hospital maintains its own financial records and reports separately to payment plans, we decided to report the number of establishments rather than firms. For other providers, we assumed that the costs to implement the operating rules for eligibility for a health plan and health care claim status transactions would be accounted for at the level of firms rather than at the individual establishments. Therefore, we reported the number of firms for all other providers.

In the following tables, we take the information from the impact analysis and break out the costs for both physicians and hospitals. As stated earlier in the impact analysis, we assume that vendor costs will be the same as those for providers because of our assumption that vendors will pass along their costs in the form of increased fees to their provider clients.

As we are treating all health care providers as small entities for the purpose of the regulatory flexibility analysis, we allocated 100 percent of the implementation costs reported in the impact analysis for physicians and hospitals. Accordingly we treat all software vendors as small entities based on their relationship to providers and allocate the same costs. Table 30 shows the impact of the implementation costs of operating rules as a percent of the provider revenues. Data on the number of entities for these tables were gathered from the 2007 census (*http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-_skip=0&-ds_name=EC0762SSSZ1&-_lang=en*). We used the NAICS code 5415 computer system design and related services for software vendors.

TABLE 30—ANALYSIS OF THE BURDEN OF IMPLEMENTATION OF OPERATING RULES ON SMALL COVERED ENTITIES

NAICS No.	Entities	Total number of entities	Number of small entities	Revenues or receipts ($ in millions)	Small entity receipts of total receipts (percent)	Op rules costs annual ($ in millions)	Implementation cost revenue receipts (percent)
6211	Ambulatory health care services.	547,561	547,561	668,453	100	136–272	0.0002–0.004
622	Hospitals	6,505	6,505	702,960	100	291–583	0.0004–0.0008
5415	Computer system design and related services.	105,710	105,710	297,200	100	136–272	0.0005–0.0009

In Column I we display the NAICS code for class of entity. Column II shows the number of entities that are reported in the Business Census for 2002 and Column III shows the number of small entities that were computed based on the Business Census and Survey of Annual Service. As mentioned previously, we assume that all health care providers are small. Column IV shows revenues that were reported for 2008 in the Survey of Annual Services (*http://www.census.gov/services/sas_data.html*). Column V shows the percent of small entity revenues. Column VI shows the costs to providers for implementation of eligibility for a health plan and health care claim status operating rules. Column VII shows the costs allocated to the small entities based on the percent of small entity revenues to total revenues.

Column VIII presents the percent of the small entity share of implementation costs as a percent of the small entity revenues. We have established a baseline threshold of 3 percent of revenues that would be considered a significant economic impact on affected entities. None of the entities exceeded or came close to this threshold.

We note that the impact in our scenarios is consistently under the estimated impact of 3 percent for all of the entities previously listed, which is below the threshold we consider as a significant economic impact. As expressed in the guidance on conducting regulatory flexibility analyses, the threshold for an economic impact to be considered significant is 3 percent to 5 percent of either receipts or costs. As is clear from the analysis, the impact does not come close to the threshold. Thus, based on the foregoing analysis, we conclude that some small health care providers may encounter some burdens in the course of implementing the eligibility for a health plan and health care claim status operating rules. However, we are of the opinion that, for most small providers, the costs will not be significant, and for providers who are not HIPAA covered entities and do not conduct electronic health care transactions, there is no cost.

We did not include an analysis of the impact on small health plans here, because we were not able to determine the number of plans that meet the SBA size standard of $7 million in annual receipts.

In evaluating whether there were any clearinghouses that could be considered small entities, we consulted with three national associations (EHNAC, HIMSS, and the Cooperative Exchange), as well as the Maryland Commission for Health Care, and determined that the number of clearinghouses that would be considered small entities was negligible.

Revenues cited on the Cooperative Exchange Web site (*http://www.cooperativeexchange.org/faq.html*) divided clearinghouses into three revenue categories—small ($10 million); medium ($10 million to $50 million) and large ($50 million or greater). We identified the top 51 clearinghouses, and determined that they are typically part of large electronic health networks, such as Siemens, RxHub, Availity, GE Healthcare *etc.,* none of which fit into the category of small entity. As referenced earlier, in a report by Faulkner and Gray in 2000, the top 51 entities were listed, and the range of monthly transactions was 2,500 to 4 million, with transaction fees of $0.25 per transaction to $2.50 per transaction. We determined that even based on this data, few of the entities would fall into the small entity category, and we do not count them in this analysis.

Based on the results of this analysis, we are reasonably confident that the rule will not have a significant impact on a substantial number of small entities. Nevertheless, we are specifically requesting comments on our analysis and asking for any data that will help us determine the number and sizes of firms implementing the operating rules adopted in this interim final rule with comment period.

We solicit industry comment on our above assumptions.

3. Alternatives Considered

As stated in section VII.D. of this interim final rule with comment period, we considered various policy alternatives to adopting operating rules, including not adopting operating rules, adopting another authoring entity's operating rules, or waiting for resolution of all outstanding technical and administrative issues before adopting the operating rules developed by the authoring entities. For reasons cited in section VII.D. of this interim final rule with comment period we have determined that none of these options were viable. Please see section VII.D. of this interim final rule with comment period for a discussion of these options and why we determined they were not viable.

4. Conclusion

As stated in the HHS guidance cited earlier in this section, HHS uses a baseline threshold of 3 percent of revenues to determine if a rule would have a significant economic impact on affected small entities. None of the entities exceeded or came close to this threshold. Based on the foregoing analysis, we could certify that this interim final rule with comment would not have a significant economic impact on a substantial number of small entities.

However, because of the relative uncertainty in the data, the lack of consistent industry data, and our general assumptions, we invite public comments on the analysis and request any additional data that would help us determine more accurately the impact on the various categories of small entities affected by this interim final rule with comment period. In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule would have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 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. Based on the analysis above, including that the overall costs to small hospitals is under the $136 million threshold, we do not believe this rule would have a significant impact on small rural hospitals, for the reasons stated above in reference to small entities. Therefore, the Secretary has determined that this interim final rule with comment period would not have a significant impact on the operations of a substantial number of small rural hospitals.

M. Accounting Statement

TABLE 31—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2011 TO FY 2023

[in millions]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, *etc.*
BENEFITS				
Annualized Monetized benefits				
7% Discount	Not estimated	$1,124	$1,347	RIA.
3% Discount	Not estimated	1,153	1,376	RIA.
Qualitative (un-quantified) benefits.	Wider adoption of standards due to consistent use of standards and responses robust in data; increased productivity due to decrease in manual intervention requirements; avoidance of pended claims, claim denials, and other obstacles to expedited billing.			
Benefits generated from plans to providers, and providers to plans.				
COSTS				
Annualized Monetized costs				
7% Discount	Not estimated	$373	$745	RIA.
3% Discount	Not estimated	314	627	RIA.
Qualitative (un-quantified) costs	None	None	None	

TABLE 31—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM FY 2011 TO FY 2023—Continued

[in millions]

Category	Primary estimate (millions)	Minimum estimate (millions)	Maximum estimate (millions)	Source citation (RIA, preamble, *etc.*
Providers will pay costs to vendors and clearinghouses. Health plans will pay costs to software vendors, programming and IT staff/contractors, and clearinghouses. Clearinghouses will pay costs to programming and IT staff/contractors and software developers. Government will pay costs to vendors and staff.				
TRANSFERS				
Annualized monetized transfers: "on budget".	N/A	N/A	N/A	
From whom to whom?	N/A	N/A	N/A	
Annualized monetized transfers: "off-budget".	N/A	N/A	N/A	

List of Subjects

45 CFR Part 160

Administrative practice and procedure, Computer technology, Health care, Health facilities, Health insurance, Health records, Hospitals, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 162

Administrative practice and procedures, Electronic transactions, Health facilities, Health insurance, Hospitals, Incorporation by reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in this preamble, the Department of Health and Human Services amends 45 CFR parts 160 and 162 to read as follows:

PART 160—ADMINISTRATIVE DATA STANDARDS AND RELATED REQUIREMENTS

■ 1. The authority citation for part 160 is revised to read as follows:

Authority: 42 U.S.C. 1302(a), 42 U.S.C. 1320d–1320d–8, sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)), 5 U.S.C. 552; secs. 13400 and 13402, Pub. L. 111–5, 123 Stat. 258–263, and sec. 1104 of Pub. L. 111–148, 124 Stat. 146–154.

Subpart A—General Provisions

§ 160.101 [Amended]

■ 2. Amend § 160.101 by removing the phrase "and section 13410(d) of Public Law 111–5." and adding in its place the phrase "section 13410(d) of Public Law 111–5, and section 1104 of Public Law 111–148."

■ 3. Amend § 160.103 by adding a paragraph (3) to the definition of "standard" to read as follows:

§ 160.103 Definitions.

* * * * *

Standard * * *

(3) With the exception of operating rules as defined at § 162.103.

* * * * *

PART 162—ADMINISTRATIVE REQUIREMENTS

■ 4. The authority citation for part 162 is revised to read as follows:

Authority: Secs. 1171 through 1180 of the Social Security Act (42 U.S.C. 1320d–1320d–9), as added by sec. 262 of Pub. L. 104–191, 110 Stat. 2021–2031, sec. 105 of Pub. L. 110–233, 122 Stat. 881–922, and sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2(note), and secs. 1104 and 10109 of Pub. L. 111–148, 124 Stat. 146–154 and 915–917.

Subpart A—General Provisions

■ 5. Amend § 162.103 as follows:

■ A. Adding the definition of "operating rules".

■ B. Revising the definition of "standard transaction".

The revision and addition read as follows:

§ 162.103 Definitions.

* * * * *

Operating rules means the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.

* * * * *

Standard transaction means a transaction that complies with an applicable standard and associated operating rules adopted under this part.

Subpart I—General Provisions for Transactions

■ 6. Amend § 162.915 by revising paragraph (a) to read as follows:

§ 162.915 Trading partner agreements.

* * * * *

(a) Change the definition, data condition, or use of a data element or segment in a standard or operating rule, except where necessary to implement State or Federal law, or to protect against fraud and abuse.

* * * * *

■ 7. Amend § 162.920 as follows:

■ A. Revising the section heading and introductory text.

■ C. Adding paragraph (c).

The revisions and addition read as follows:

§ 162.920 Availability of implementation specifications and operating rules.

Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 714–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* The materials are also available for inspection by the public at the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244.

For more information on the availability on the materials at CMS, call (410) 786–6597. The materials are also available from the sources listed below.

* * * * *

(c) Council for Affordable Quality Healthcare's (CAQH) Committee on Operating Rules for Information Exchange (CORE), 601 Pennsylvania Avenue, NW. South Building, Suite 500 Washington, DC 20004; Telephone (202) 861–1492; Fax (202) 861- 1454; E-mail *info@CAQH.org*; and Internet at *http://www.caqh.org/benefits.php*.

(1) CAQH, Committee on Operating Rules for Information Exchange, CORE Phase I Policies and Operating Rules, Approved April 2006, v5010 Update March 2011.

(i) Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(ii) Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(iii) Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(iv) Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(v) Phase I CORE 156: Eligibility and Benefits Real Time Response Time Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(vi) Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(2) ACME Health Plan, HIPAA Transaction Standard Companion Guide, Refers to the Implementation Guides Based on ASC X12 version 005010, CORE v5010 Master Companion Guide Template, 005010, 1.2, (CORE v 5010 Master Companion Guide Template, 005010, 1.2), March 2011, as referenced in §§ 162.1203 and 162.1403.

(3) CAQH, Committee on Operating Rules for Information Exchange, CORE Phase II Policies and Operating Rules, Approved July 2008, v5010 Update March 2011.

(i) Phase II CORE 250: Claim Status Rule, version 2.1.0, March 2011, as referenced in § 162.1403.

(ii) Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(iii) Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(iv) Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(v) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011, as referenced in § 162.1203 and § 162.1403.

Subpart L—Eligibility for a Health Plan

■ 8. Adding a new § 162.1203 to read as follows:

§ 162.1203 Operating rules for eligibility for a health plan transaction.

On and after January 1, 2013, the Secretary adopts the following:

(a) Except as specified in paragraph (b) of this section, the following CAQH CORE Phase I and Phase II operating rules (updated for Version 5010) for the eligibility for a health plan transaction:

(1) Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, and CORE v5010 Master Companion Guide Template. (Incorporated by reference in § 162.920).

(2) Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(3) Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(4) Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(5) Phase I CORE 156: Eligibility and Benefits Real Time Response Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(6) Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(7) Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011. (Incorporated by reference in § 162.920).

(8) Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0. (Incorporated by reference in § 162.920).

(9) Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011. (Incorporated by reference in § 162.920).

(10) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011. (Incorporated by reference in § 162.920).

(b) Excluding where the CAQH CORE rules reference and pertain to acknowledgements and CORE certification.

Subpart N—Health Care Claim Status

■ 9. Add § 162.1403 to read as follows:

§ 162.1403 Operating rules for health care claim status transaction.

On and after January 1, 2013, the Secretary adopts the following:

(a) Except as specified in paragraph (b) of this section, the following CAQH CORE Phase II operating rules (updated for Version 5010) for the health care claim status transaction:

(1) Phase II CORE 250: Claim Status Rule, version 2.1.0, March 2011, and CORE v5010 Master Companion Guide, 00510, 1.2, March 2011. (Incorporated by reference in § 162.920).

(2) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011. (Incorporated by reference in § 162.920).

(b) Excluding where the CAQH CORE rules reference and pertain to acknowledgements and CORE certification.

Dated: May 26, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 29, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–16834 Filed 6–30–11; 2:00 pm]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014; Ambulance Fee Schedule; and Durable Medical Equipment; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

[CMS–1577–P]

RIN 0938–AQ27

Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014; Ambulance Fee Schedule; and Durable Medical Equipment

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and make certain revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2012. This proposed rule would also set forth proposed requirements for the ESRD quality incentive program (QIP) for payment years (PYs) 2013 and 2014. In addition, this proposed rule would revise the ambulance fee schedule regulations to conform with statutory changes. Finally, this proposed rule would revise the definition of durable medical equipment (DME) by adding a 3-year minimum lifetime criterion that must be met by an item or device in order to be considered durable for the purpose of classifying the item under the Medicare benefit category for DME. (See the Table of Contents for a listing of the specific issues addressed in this proposed rule.)

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 30, 2011.

ADDRESSES: In commenting, please refer to file code CMS–1577–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1577–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1577–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Lisa Hubbard (410) 786–4533, for issues related to ESRD.

Roechel Kujawa, (410) 786–9111, for issues related to ambulance services.

Heidi Oumarou, (410) 786–7942, for issues related to the ESRD market basket.

Shannon Kerr, (410) 786–3039, for issues related to the quality incentive program.

Sandhya Gilkerson, (410) 786–4085, for issues related to the definition of durable medical equipment (DME).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys),* a service of the U.S. Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/*

Addenda Are Only Available Through the Internet on the CMS Web Site

In the past, a majority of the Addenda referred to throughout the preamble of our proposed and final rules appeared in the **Federal Register**. However, beginning with this CY 2012 proposed rule, the Addenda of the annual proposed and final rules will no longer appear in the **Federal Register**. Instead, these Addenda to the annual proposed and final rules will be available only through the Internet on the CMS Web site. The Addenda to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) rules are available at: *http://www.cms.gov/ESRDPayment/PAY/list.asp.* Readers who experience any problems accessing any of the Addenda to the proposed and final rules that are posted on the CMS Web site identified above should contact Lisa Hubbard at 410–786–4533.

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).

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Acronyms

In addition, because of the many terms to which we refer by acronym in this proposed 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
CBSA Core Based Statistical Area
CDC Centers for Disease Control and Prevention
CLABSI Central Line Access Bloodstream Infections
CFR Code of Federal Regulations
CIP Core Indicators Project
CMS Centers for Medicare & Medicaid Services
CPM Clinical Performance Measure
CPT Current Procedural Terminology
CROWNWeb Consolidated Renal Operations in a Web-Enabled Network
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
FY Fiscal Year
GDP Gross Domestic Product
HAI Healthcare-associated Infections
HCPCS Healthcare Common Procedure Coding System
HD Hemodialysis
HHD Home Hemodialysis
ICD–9–CM International Classification of Diseases, 9th
ICH CAHPS In-Center Hemodialysis Consumer Assessment of Healthcare Advisors
IGI IHS Global Insight
IPPS Inpatient Prospetive 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
PY Payment Year
QIP Quality incentive program
REMIS Renal management information system
RFA Regulatory Flexibility Act
RUL Reasonable Useful Lifetime
SBA Small Business Administration
SIMS Standard information management system
SHR Standardized Hospitalization Ratio
SSA Social Security Administration
the Act Social Security Act
the Affordable Care Act The Patient Protections and Affordable Care Act
URR Urea reduction ratio
VBP Value Based Purchasing

I. Calendar Year (CY) 2011 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background for the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2012

On August 12, 2010, we published in the **Federal Register**, a final rule (75 FR 49030 through 49214), entitled, ''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 patients beginning January 1, 2011, 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). The ESRD PPS replaced the prior basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD services.

Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of Public Law 111–148, the Affordable Care Act, for 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 the CY 2011 ESRD PPS final rule (75 FR 49030), the Centers for Medicare & Medicaid Services (CMS) finalized the following:

- A base rate of $229.63 per treatment for renal dialysis services (but postponed payment for oral-only renal dialysis drugs under the ESRD PPS until January 1, 2014) that applies to both adult and pediatric dialysis patients prior to the application of any case-mix adjustments. This amount included the 2 percent reduction for budget-neutrality required by MIPPA, a one percent reduction for estimated outlier payments, and a reduction to account for estimated payments for case-mix and the low-volume payment adjustments.
- A 4-year transition (for those ESRD facilities that elected to receive blended payments during the transition) period during which ESRD facilities receive a blend of payments under the prior basic case-mix adjusted composite payment system and the new ESRD PPS. Although the statute uses the term ''phase-in'', we are using the term ''transition'' to be consistent with other Medicare payment systems.
- A −3.1 percent transition budget-neutrality adjustment to ensure that overall spending under the ESRD PPS did not increase as a result of the provision that permits ESRD facilities to be excluded from the 4-year transition.
- A payment adjustments for dialysis treatments furnished to adults for patient age, body surface area (BSA), low body mass index (BMI), onset of dialysis, and six specified co-morbidities.
- A home or self-care dialysis training payment adjustment of $33.44 per treatment which is wage adjusted and applies to claims for patients trained by ESRD facilities certified to provide home dialysis training.
- Payment adjustments for dialysis treatments furnished to pediatric patients for patient age and dialysis modality.
- A low-volume payment adjustment for adult patients of 18.9 percent that applies to the otherwise applicable case-mix adjusted payment rate for facilities that qualifies as low-volume ESRD facilities.
- An outlier payment policy that provides an additional payment to ESRD facilities treating high cost, resource-intensive patients.
- The wage index adjustment that is applied when calculating the ESRD PPS payment rates in order to account for geographic differences in area wage levels.
- An ESRDB market basket index used to project prices in the costs of goods and services used to furnish outpatient maintenance dialysis.

In addition, on April 6, 2011, we published an interim final rule with comment period in the **Federal Register** (76 FR 18930), entitled ''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.

B. Routine Updates and Proposed Policy Changes for CY 2012 ESRD PPS

In this proposed rule, we propose to (1) Make a number of routine updates for CY 2012, (2) implement the second year of the transition, and (3) make several policy changes under the ESRD PPS, as well as technical changes to the CY 2011 ESRD PPS final rule.

1. Proposals Related to the Composite Rate Portion of the ESRD PPS Blended Payment

This proposed rule would implement the second year of the transition period for those ESRD facilities that elected to go through the transition rather than electing to receive payment based on 100 percent of the payment amount under the ESRD PPS. Specifically, we would implement in CY 2012 the second year of the transition where 50 percent of payment is based on the basic case-mix adjusted composite payment system and the remaining 50 percent of payment is based on the payment amount under the ESRD PPS.

As a result of the transition period under the ESRD PPS, we must continue to update the composite rate portion of the blended payment, which would include updates to the drug add-on adjustment required by section 1881(b)(12(F) of the Act, as well as the wage index values (which include a budget-neutrality factor) used to adjust the labor component of the composite rate. The proposed updates to the drug add-on adjustment under the composite rate portion of the blended rate can be found in section I.C.6.d of this proposed rule and the wage index is discussed in section I.C.d.7 of this proposed rule.

Also, the ESRD bundled (ESRDB) market basket increase factor (which is further reduced, beginning in 2012, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act) is used to update the composite rate portion of the blended payment in accordance with section 1881(b)(14)(F)(ii) of the Act. A discussion of the proposed market basket increase factor for CY 2012 can be found in section I.C.2 of this proposed rule. A discussion of the proposed productivity adjustment can be found in section I.C.2.c of this proposed rule. We are also proposing to update the second part of the transition budget-neutrality adjustment for CY 2012 that is applied to both the blended payments under the transition and payments under the ESRD PPS. The discussion regarding the proposed transition budget-neutrality adjustment can be found in section I.C.4 of this proposed rule.

In this proposed rule, we also are proposing to add the $.49 for the Part D drugs to the composite rate portion of the blended payment during the transition, which represents the first part of the transition budget-neutrality adjustment, and update it using the ESRDB market basket minus productivity adjustment. We discuss this proposal in the update to the composite rate and the proposed CY 2012 transition budget-neutrality adjustment in I.C.1.a and I.B.4, respectively, of this proposed rule.

Finally, we are proposing to revise the national average used in calculating the BSA adjustment under the basic case-mix adjusted composite payment system. This change is discussed in detail in section I.C.9 of this proposed rule.

2. Proposals Related to the ESRD PPS

As discussed above in section I.A, 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, requires the ESRD bundled payment amounts 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. Therefore, in CY 2012, an ESRD market basket increase factor that is reduced by a productivity adjustment would be applied to the ESRD PPS payment rate portion of the blended payment under the transition and under the full ESRD PPS. A discussion of the proposed market basket increase factor for CY 2012 can be found in section I.C.2 of this proposed rule. A discussion of the proposed productivity adjustment can be found in section I.C.2.c of this proposed rule.

We are also proposing to update the transition budget-neutrality adjustment for CY 2012 which is applied to both the blended payments under the transition and payments under the full ESRD PPS. The discussion regarding the proposed transition budget-neutrality adjustment can be found in section I.C.4 of this proposed rule.

This proposed rule would also update the wage index which is applied to both the ESRD PPS portion of the blended payments under the transition and payments under the full ESRD PPS. We are proposing to apply a wage index budget-neutrality adjustment factor to the ESRD PPS base rate. The discussion regarding the wage index can be found in section I.C.7 of this proposed rule.

Also, for CY 2012, we are proposing the following revisions to the ESRD PPS outlier policy: (1) Eliminate the drug-specific list of eligible outlier services; (2) make modifications to the computation of the separately billable Medicare Allowable Payment (MAP) amounts to exclude access management drugs that are composite rate drugs and include certain anemia management drugs; and (3) stop using the 50 percent rule and eliminate the Automated Multi-Channel Chemistry (AMCC) laboratory tests from the definition of outlier services. In addition, we are proposing to consider anti-infective drugs when used at home by a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis as non-composite rate ESRD-related drugs, and reiterating that under the current regulation, all non-composite rate ESRD-related drugs are considered outlier services. That is, all non-composite rate ESRD-related drugs are considered outlier services for purposes of determining outlier payments. The discussion regarding the proposed changes to the outlier policy can be found in section I.C.10 of this proposed rule.

3. Clarifications and Proposals Regarding the Low-Volume Adjustment Policy Under the ESRD PPS

In this proposed rule, we are clarifying that the term ''payment year'' is the period of time that we use for determining payment to ESRD facilities, which is a calendar year. We propose to establish a process for CY 2012 and each year thereafter that facilities would need to follow, when submitting its attestation to notify its FI/MAC that it is eligible for the low-volume adjustment. We are clarifying the term ''year'' that is used for purposes of establishing the treatment threshold for low-volume eligibility. A discussion of the low-volume payment adjustment can be found in section I.c.5 of this proposed rule.

4. Technical Corrections to the CY 2011 ESRD PPS Final Rule

In the CY 2011 ESRD PPS final rule, we inadvertently made two technical errors: (1) The training add-on amount was listed incorrectly as $33.38 instead of $33.44; and (2) the composite rate laboratory test, ''Assay of protein by other source,'' which is identified by the Current Procedural Terminology code 84157, was inadvertently omitted from the list of ESRD-related laboratory tests. For more information regarding these technical corrections please see section I.B.4 of this proposed rule.

5. Clarifications Regarding the ESRD PPS

In this proposed rule, we are clarifying the method for updating ICD–9–CM codes in accordance with ICD–9–CM annual updates and clarifying whether certain renal dialysis service furnished in an emergency room or department are considered renal dialysis services covered under the ESRD PPS.

C. Provisions of the Proposed Regulations for the ESRD PPS

1. Proposed Updates to the Composite Rate and ESRD PPS Base Rate

a. Proposed Composite Rate

Under section 1881(b)(14)(E)(i) of the Act, we are required to provide a 4-year transition under the new ESRD PPS. For CY 2012, under 42 CFR § 413.239(a)(2), facilities that go through the transition will receive a blended rate equal to the sum of 50 percent of the full ESRD PPS amount and 50 percent of the basic case-mix adjusted payment amount. Accordingly, we continue to need to update the composite rate portion of the blended payment during the 4-year transition (that is, CYs 2011 through 2013). For a historical perspective of the basic case-mix adjusted composite payment system for ESRD facilities, including the CY 2011 update to the composite rate portion of the ESRD PPS blended rate, please see the CY 2011 Physician Fee Schedule (PFS) final rule (75 FR 40164) and the CY 2011 PFS proposed rule (75 FR 40164 through 40168). In addition, we discuss the proposed CY 2012 drug add-on and the updated wage index values for the composite rate portion of the blended payment in sections I.C.6 and I.C.7, respectively.

As discussed in section i.B.2 of this proposed rule, 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, provides that, for years during which the transition applies, the composite rate portion of the blend shall be annually increased by the ESRDB market basket for CY 2012 and each subsequent year shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. In sections I.C.2.b and I.C.2.c of this proposed rule, we describe the basis for the proposed CY 2012 ESRDB market basket increase of 3.0 percent, and the productivity offset of 1.2 percent, yielding a proposed forecasted rate of increase in the base rate of 1.8 percent. In addition, as discussed in the transition budget-neutrality adjustment in section I.C.a of this proposed rule, we are proposing to add the CY 2011 Part D per treatment amount (that is, $0.49) to the CY 2011 composite rate in order to update the Part D amount for CY 2012 using the ESRDB market basket minus the productivity adjustment. The basis for the first part of the transition budget-neutrality adjustment (that is, the calculation of the $0.49 Part D add-on) was set forth in the CY 2011 ESRD PPS final rule at 75 FR 49082.

Consequently, for CY 2012, the composite rate portion of the ESRD PPS blended payment would be $141.52. The $141.52 reflects the addition of the CY 2011 Part D per treatment amount ($0.49) to the CY 2011 composite rate of $138.53, and application of the ESRD market basket minus productivity ($138.53 + 0.49 = $139.02; $139.02 × 1.018 = $141.52).

b. ESRD PPS Base Rate

We described the development of the ESRD PPS per-treatment base rate in the CY 2011 ESRD PPS final rule (75 FR 49071) under Medicare regulations at 42 CFR §§ 413.220 and 413.230. The CY 2011 ESRD PPS final rule has a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of reduction 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 (75 FR 49071 through 49082). 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. In addition, in accordance with § 413.230, the per treatment base rate is adjusted for the patient-specific case-mix adjustments, any applicable facility adjustments, wages to reflect ESRD facility differences in area wage levels using an area wage index, as well as any outlier payment or training add-on. For CY 2011, the ESRD PPS base rate was $229.63 (75 FR 49082).

As discussed previously, section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the rate of increase in the ESRD market basket, reduced by the productivity adjustment. Accordingly, we applied the 1.8 percent increase to the CY 2011 ESRD PPS base rate of $229.63, which results in a CY 2012 ESRD PPS base rate of $233.76 ($229.63 × 1.018 = $233.76). The proposed CY 2012 ESRD PPS Base Rate applies to the ESRD PPS portion of the blend.

In addition, as discussed in section I.C.7.c of this proposed rule, we are proposing to apply the wage index budget-neutrality adjustment factor of 1.001126 to the CY 2012 ESRD PPS base rate (that is, $233.76), yielding a proposed CY 2012 ESRD PPS wage-index budget-neutrality adjusted base rate of $234.02 ($233.76 × 1.001126 = $234.02).

2. ESRD Bundled Market Basket

a. Overview and Background

Under 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 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 ESRD bundled (ESRDB) rate market basket increase factor will also be used to update the composite rate portion of ESRD payments during the ESRD PPS transition period from 2011 through 2013; though beginning in 2012, such market basket increase factor will be reduced by the productivity adjustment. As a result of amendments by section 3401(h) of the Affordable Care Act, 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. Proposed Market Basket Update Increase Factor and Labor-Related Share for ESRD Facilities for CY 2012

As required under section 1881(b)(14)(F) of the Act, effective beginning CY 2012 (and for purposes of the transition, effective beginning CY 2011), 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.

For this proposed rule, we have used the same methodology described in the CY 2011 ESRD PPS final rule (75 FR 49151 through 49162) to compute the CY 2012 ESRDB market basket increase factor and labor-related share. Using this method and the IHS Global Insight, Inc. (IGI) forecast for the first quarter of 2011 of the CY 2008-based ESRDB market basket, the proposed CY 2012 ESRDB market basket increase factor is 3.0 percent. IGI is an economic and financial forecasting firm that contracts with CMS to forecast the components of providers' market baskets.

The labor-related share of a market basket is determined by identifying the national average proportion of its operating costs that are related to, influenced by, or vary with the local labor market. In the CY 2011 ESRD PPS final rule, we finalized a labor-related share for CY 2011 of 41.737 percent using the base year cost weights for the CY 2008-based ESRDB market basket (75 FR 49161 through 49162). Table 1 below contains the calculation of the labor-related share. This labor-related share represented the sum of Wages and Salaries, Benefits, Housekeeping and Operations, All Other Labor-related Services, 87 percent of the cost weight for Professional Fees, and 46 percent of the cost weight for Capital-related Building and Equipment expenses. The 87 percent of Professional fees was determined based on a survey that CMS conducted of ESRD facilities. Based on the survey results, we determined that, on average, 87 percent of professional services are purchased from local firms and 13 percent are purchased from businesses located outside of the ESRD's local labor market. The 46 percent of Capital-related Building and Equipment expenses is based on regressions run for the inpatient hospital capital PPS (56 FR 43375). We use a similar methodology to calculate capital-related expenses for the labor-related shares for rehabilitation facilities (70 FR 30233), psychiatric facilities, long-term care facilities, and skilled nursing facilities (66 FR 39585).

TABLE 1—ESRDB MARKET BASKET LABOR-RELATED SHARE

Cost category	2008-based ESRDB labor-related share (percent)
Wages and Salaries	26.755
Benefits	6.754
Housekeeping and Operations	2.029
All Other Labor-related Services	1.219
Professional Fees, Labor-related	1.549
Capital, Labor-related	3.431
Total	41.737

In this proposed rule, we are not proposing to make any further changes to the labor-related share since we have not proposed to update the cost weights of the ESRDB market basket. Therefore, we are proposing to continue to use a labor-related share of 41.737 percent for CY 2012 for the ESRDB PPS.

If an ESRD facility elected to transition to the bundled PPS system, then the CY 2012 payment to these providers will be based on a 50/50 blended payment of the composite rate and the ESRD PPS bundled rate. The labor-related share under the composite portion of the blended payment is 53.711 percent. This labor-related share was developed from the labor-related components of the 1997 ESRD composite rate market basket that was finalized in the 2005 PFS final rule (70 FR 70168). We propose to continue to use the labor-related share of 53.711 for the ESRD composite rate portion of the ESRD payment for all years of the transition. This labor-related share is consistent with the mix of labor-related services paid under the composite rate and is consistent with the method finalized in the CY 2011 ESRD PPS final rule (75 FR 49116).

c. Proposed Productivity Adjustment

Section 3401(h) of the Affordable Care Act requires that, in CY 2012 (and in subsequent calendar years), the market basket percentage under the ESRD prospective payment system as described in section 1881(b)(14)(F) of the Act be annually adjusted by changes in economy-wide productivity. Specifically, section 3401(h) of the Affordable Care Act amends section 1881(b)(14)(F)(i) of the Act to add clause (II) which sets forth the application of this productivity adjustment, which is defined 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 proposed 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, an economic forecasting firm. In order to generate a forecast of MFP, IGI replicated the MFP measure calculated by the BLS using a series of proxy variables derived from IGI's U.S. macroeconomic models. These models take into account a very broad range of factors that influence the total U.S. economy. IGI forecasts the underlying proxy components such as gross domestic product (GDP), capital, and labor inputs required to estimate MFP and then combines those projections according to the BLS methodology. In Table 2 below, we identify each of the major MFP component series employed by the BLS to measure MFP. We also provide the corresponding concepts forecasted by IGI and determined to be the best available proxies for the BLS series.

TABLE 2—MULTIFACTOR PRODUCTIVITY COMPONENT SERIES EMPLOYED BY THE BUREAU OF LABOR STATISTICS AND IHS GLOBAL INSIGHT

BLS series	IGI series
Real value-added output, constant 2005 dollars	Non-housing non-government non-farm real GDP, Billions of chained 2005 dollars—annual rate.
Private non-farm business sector labor input; 2005 = 100.00	Hours of all persons in private nonfarm establishments, 2005 = 100.00, adjusted for labor composition effects.

TABLE 2—MULTIFACTOR PRODUCTIVITY COMPONENT SERIES EMPLOYED BY THE BUREAU OF LABOR STATISTICS AND IHS GLOBAL INSIGHT—Continued

BLS series	IGI series
Aggregate capital inputs; 2005 = 100.00	Real effective capital stock used for full employment GDP, Billions of chained 2005 dollars.

IGI found that the historical growth rates of the BLS components used to calculate MFP and the IGI components identified are consistent across all series and therefore suitable proxies for calculating MFP. We have included below a more detailed description of the methodology used by IGI to construct a forecast of MFP, which is aligned closely with the methodology employed by the BLS. For more information regarding the BLS method for estimating productivity, please see the following link: *http://www.bls.gov/mfp/mprtech.pdf*.

During the development of this proposed rule, the BLS published a historical time series of private nonfarm business MFP for 1987 through 2009, with 2009 being a preliminary value. Using this historical MFP series and the IGI forecasted series, IGI has developed a forecast of MFP for 2010 through 2021, as described below.

To create a forecast of BLS' MFP index, the forecasted annual growth rates of the ''non-housing, nongovernment, non-farm, real GDP,'' ''hours of all persons in private nonfarm establishments adjusted for labor composition,'' and ''real effective capital stock'' series (ranging from 2010 to 2021) are used to ''grow'' the levels of the ''real value-added output,'' ''private non-farm business sector labor input,'' and ''aggregate capital input'' series published by the BLS. Projections of the ''hours of all persons'' measure are calculated using the difference between the projected growth rates of real output per hour and real GDP. This difference is then adjusted to account for changes in labor composition in the forecast interval. Using these three key concepts, MFP is derived by subtracting the contribution of labor and capital inputs from output growth. However, in order to estimate MFP, we need to understand the relative contributions of labor and capital to total output growth. Therefore, two additional measures are needed to operationalize the estimation of the IGI MFP projection: Labor compensation and capital income. The sum of labor compensation and capital income represents total income. The BLS calculates labor compensation and capital income (in current dollar terms) to derive the nominal values of labor and capital inputs. IGI uses the ''nongovernment total compensation'' and ''flow of capital services from the total private non-residential capital stock'' series as proxies for the BLS' income measures. These two proxy measures for income are divided by total income to obtain the shares of labor compensation and capital income to total income. In order to estimate labor's contribution and capital's contribution to the growth in total output, the growth rates of the proxy variables for labor and capital inputs are multiplied by their respective shares of total income. These contributions of labor and capital to output growth is subtracted from total output growth to calculate the ''change in the growth rates of multifactor productivity:''

MFP = Total output growth − ((labor input growth * labor compensation share) + (capital input growth * capital income share))

The change in the growth rates (also referred to as the compound growth rates) of the IGI MFP are multiplied by 100 in order to calculate the percent change in growth rates (the percent change in growth rates are published by the BLS for its historical MFP measure). Finally, the growth rates of the IGI MFP are converted to index levels based to 2005 to be consistent with the BLS' methodology. For benchmarking purposes, the historical growth rates of IGI's proxy variables were used to estimate a historical measure of MFP, which was compared to the historical MFP estimate published by the BLS. The comparison revealed that the growth rates of the components were consistent across all series, and therefore validated the use of the proxy variables in generating the IGI MFP projections. The resulting MFP index was then interpolated to a quarterly frequency using the Bassie method for temporal disaggregation. The Bassie technique utilizes an indicator (pattern) series for its calculations. IGI uses the index of output per hour (published by the BLS) as an indicator when interpolating the MFP index.

d. Multifactor Productivity-Adjusted Market Basket Update

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, the Secretary ''shall annually increase payment amounts established under this paragraph by an ESRD market basket percentage increase factor for a bundled payment system for renal dialysis services that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services''. Also, under section 1881(b)(14)(F)(ii)(II), as amended by section 3401(h) of the Affordable Care Act, for years in which the transition of the payment system is applicable, the Affordable Care Act states that the Secretary ''shall annually increase such composite rate by the ESRD market basket percentage increase factor described in clause (i)(I)'' subject to this factor being reduced by a productivity adjustment beginning in 2012.

As described in section I.C.2.b of this proposed rule, we are proposing to estimate the ESRDB market basket percentage for CY 2012 based on the CY 2008-based ESRDB market basket. Section 3401(h) of the Affordable Care Act amends section 1881(b)(14)(F)(i) of the Act by adding a new clause (II), which requires that after establishing the percentage for a calendar year 2012 (and each subsequent year), ''the Secretary shall reduce such percentage by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II)'' (which we refer to as the multifactor productivity adjustment or MFP adjustment).

In order to calculate the MFP-adjusted update for the ESRDB market basket during the transition period, we propose that the MFP percentage adjustment be subtracted from the CY 2012 market basket update calculated using the CY 2008-based ESRDB market basket. We propose that the end of the 10-year moving average of changes in the MFP should coincide with the end of the appropriate CY update period. Since the market basket update is reduced by the MFP adjustment to determine the annual update for the ESRDB PPS and the ESRD composite rate during the transition, we believe it is appropriate for the numbers associated with both components of the calculation (the market basket and the productivity adjustment) to coincide so that changes in market conditions are aligned.

Therefore, for the CY 2012 update, we propose that the MFP adjustment be calculated as the 10-year moving average of changes in MFP for the period ending December 31, 2012. We propose to round the final annual adjustment to the one-tenth of one percentage point level up or down as applicable according to conventional rounding rules (that is, if the number we are rounding is followed by 5, 6, 7, 8, or 9, we will round the number up; if the number we are rounding is followed by 1, 2, 3, or 4, we will round the number down).

The market basket percentage we are proposing for CY 2012 for the ESRDB market basket is based on the 1st quarter 2011 forecast of the CY 2008-based ESRDB market basket update, which is estimated to be 3.0 percent. This market basket percentage would then be reduced by the MFP adjustment (the 10-year moving average of MFP for the period ending CY 2012) of 1.2 percent, which is calculated as described above and based on IGI's 1st quarter 2011 forecast. The resulting MFP-adjusted ESRDB market basket update is equal to 1.8 percent, or 3.0 percent less 1.2 percent. We propose that if more recent data are subsequently available (for example, a more recent estimate of the market basket and MFP adjustment), we would use such data, if appropriate, to determine the CY 2012 market basket update and MFP adjustment in the CY 2012 ESRD PPS final rule.

3. Transition Budget-Neutrality Adjustment for CY 2011

Section 1881(b)(14)(E)(iii) of the Act requires that an adjustment to payments be made for renal dialysis services provided by ESRD facilities during the transition so that the estimated total payments under the ESRD PPS, including payments under the transition, equal the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition. In the CY 2011 ESRD PPS final rule, we explained that because we would not know the actual number of ESRD facilities that would elect to opt out of the transition prior to publishing the final rule, we would simulate payments under the existing basic case-mix adjusted composite payment system and under the ESRD PPS to determine the number of ESRD facilities that we believed would elect to receive payment under 100 percent ESRD PPS. We explained that based on our simulations using 2007 data, we estimated that 43 percent of ESRD facilities would financially benefit from receiving full payment under the ESRD PPS. We also indicated that based on the simulation of estimated payments, a 3.1 percent reduction would be applied to all payment made to ESRD facilities for renal dialysis services furnished on January 1, 2011 through December 31, 2011 (75 FR 49082 through 49083).

On April 6, 2011, we published an interim final rule with comment period in the **Federal Register** (76 FR 18930), entitled ''Changes to the End-Stage Renal Disease Prospective Payment System Transition Budget-Neutrality Adjustment'', which revised the ESRD transition budget-neutrality adjustment finalized for CY 2011. In the interim final rule, we indicated that based on the election data submitted by ESRD facilities, 87 percent of ESRD facilities elected to opt out of the transition. When we applied the actual number of ESRD facilities electing to receive payment under the ESRD PPS, the transition budget-neutrality adjustment was determined to be zero rather than a 3.1 reduction in payments. 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. We will respond to comments submitted on the interim final rule in the CY 2012 ESRD PPS final rule.

4. Proposed Transition Budget-Neutrality Adjustment for CY 2012

As we discussed in the background section of this proposed rule, section 1881(b)(14)(E)(i) of the Act requires the Secretary to provide ''a four 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.'' Also, we indicated that instead of using the term ''phase-in'', we are using the term ''transition'' to be consistent with other Medicare payment systems.

Section 1881(b)(14)(E)(ii) of the Act permits 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 would receive payment for renal dialysis services provided 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 rate under the basic case-mix adjusted composite payment system and in part on the payment rate under the ESRD PPS.

Section 1881(b)(14)(E)(iii) of the Act also requires that we make an adjustment to payments for renal dialysis services provided by ESRD facilities 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.

As described in the CY 2011 ESRD PPS final rule (75 FR 49082), the transition budget-neutrality adjustment is comprised of two parts. For the first part, we created a payment adjustment under the basic case-mix adjusted composite payment system portion of the blended rate during the transition to account for the per treatment costs of drugs that are currently paid under Part D. For the second part, we computed a factor that would make the estimated total amount of payments under the ESRD PPS, including payments under the transition, equal the estimated total amount of payments that would otherwise occur without such a transition. In this proposed rule, we are addressing both parts of the transition budget-neutrality adjustment.

For the first part of the transition budget-neutrality adjustment, for CY 2012, we propose to add the $0.49, which represents the CY 2011 Part D payment amount, to the composite rate portion of the ESRD PPS blended payment. We then propose to apply the ESRDB market basket minus productivity adjustment to the updated composite rate (which includes the $0.49). Since the composite rate is updated by the ESRDB market basket minus productivity and we are proposing to add the $0.49 to the composite rate, it would be consistent to use the same update. We believe that this approach is preferable to applying a growth factor to the $0.49 that is based on the rates for overall prescription drug prices that were used in the National Health Expenditure Projections, as we did for the establishment of the CY 2011 ESRD PPS base rate, because it is consistent with the update applied to the ESRD PPS base rate, which includes a per treatment amount for former Part D drugs (that is, $0.49). We discuss the addition of the $0.49 to the composite portion of the ESRD PPS payment in section I.c.1.a of this proposed rule. For the first part of the transition budget-neutrality adjustment, we are seeking comment on our proposal to add the CY 2011 Part D payment amount (that is, $0.49) to the composite rate portion of the blended payment and update it using the ESRDB market basket minus productivity adjustment.

For the second part, as described in the CY 2011 ESRD PPS proposed rule (74 FR 49946), to calculate the transition budget-neutrality adjustment, we first determined the estimated increases in payments under the transition and then determined an offset factor, based on estimates of which facilities would choose to opt out of the transition. We estimated the number of facilities that would choose to opt out of the transition by comparing payment under the transition to payment under the PPS and choosing the option that was financially beneficial to each facility. Using that approach, we estimated that 43 percent of facilities would choose to opt out of the transition and determined the transition budget-neutrality adjustment to be a reduction of 3.1 percent. In the April 6, 2011 interim final rule with comment (76 FR 18930 through 18934) published in the **Federal Register**, however, we revised the number of facilities that chose to opt out of the transition to 87 percent, based on actual election data that we received, and recalculated a transition budget-neutrality adjustment of 0 percent.

Given that the transition budget-neutrality adjustment required under section 1881(b)(14)(A)(ii) of the Act applies in each year of the transition, we must update the transition budget-neutrality adjustment for CY 2012, the second year of the transition. As discussed in detail below, and in accordance with section 1881(b)(14)(E)(iii) of the Act, that requires an adjustment to be made to payments so that total payments under the transition equal total payment amounts without such a transition, that results in the reduction of all payments to ESRD facilities in CY 2012 by a factor that is equal to 1 minus the ratio of estimated payments under the ESRD PPS if there were no transition to the total estimated payments under the transition. In this proposed rule, we are not proposing for CY 2012 to change the methodology used to calculate the second part of the budget-neutrality adjustment. We are, however, proposing to use more updated data.

For CY 2012, we started with 2009 utilization data from claims, as 2009 is the latest complete year of claims data available. We updated the CY 2009 utilization data to CY 2011 and CY 2012 payments by using the price growth factors for CY 2011 and CY 2012, as discussed in the impact analysis in section VII of this proposed rule. We then took the estimated payments under the full CY 2012 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 2012 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 if there were no transition to the total estimated payments under the transition, which results in 0 percent. Therefore, for CY 2012, we are proposing a 0 percent reduction to all payments made to ESRD facilities (that is, the 0 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, 2012 through December 31, 2012. We solicit comments on the proposed second part of CY 2012 transition budget-neutrality adjustment.

5. Proposed Low-Volume Facility Provisions

In the CY 2011 ESRD PPS final rule, we established a low-volume payment adjustment as required by section 1881(b)(14)(D)(iii) of the Act, that ''reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent'' (75 FR 49117).

We explained in the CY 2011 ESRD PPS final rule (75 FR 49120) that we analyzed the effect of facility size on cost by analyzing the total treatment counts from ESRD facility cost reports for 2006, 2007, and 2008. We used all treatments including non-Medicare treatments from the cost reports because we believe that inclusion of all treatments regardless of payer type represents the true volume of treatments that an ESRD facility furnishes (75 FR 49122). Because the analysis included data that spanned a 3-year period, we defined a low-volume ESRD facility as a facility that is able to maintain its low-volume status each year of the 3-year period because we believed that this timeframe provided us with a sufficient span of time to view consistency in business operations through the data (75 FR 49123).

Our analysis showed that when compared to larger facilities, facilities that would be eligible for the low-volume adjustment are more likely to be located in a rural area, less likely to be part of a large dialysis organization (LDO), more likely to be hospital-based, likely to have a somewhat higher percentage of Medicare patients, more likely to be a pediatric facility, more likely to have previously received an isolated essential facility composite rate payment exception, and more likely to concentrate on home dialysis (75 FR 49120).

Under 42 CFR § 413.232(b), a low-volume facility is as an ESRD facility that: (1) Furnished less than 4,000 dialysis treatments in each of the 3 years preceding the payment year and (2) has not opened, closed, or received a new provider number due to a change in ownership during the 3 years preceding the payment year. Under § 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments shall be equal to the aggregate number of treatments furnished by the other ESRD facilities that are both under common ownership, and 25 road miles or less from the ESRD facility in question. This geographic proximity criterion is only applicable to ESRD facilities that are Medicare certified on or after January 1, 2011. Section 413.232(f) requires an ESRD facility to provide an attestation statement to their respective fiscal intermediary medicare administrative contractor (FI/MAC) that the facility has met all the criteria in order to receive the low-volume adjustment. We note that furnishing 4,000 treatments in a year equates to approximately 25 patients per year receiving three dialysis treatments a week (or hemo-equivalent treatments). The regulation at § 413.232 provides the criteria that an ESRD facility must meet to be eligible for the low-volume adjustment and uses the term ''payment year.'' Although we believe the meaning of this term is clear, in response to questions that we received subsequent to the publication of the CY 2011 ESRD PPS final rule demonstrating confusion between the payment year and eligibility year, we are clarifying that the term ''payment year'' is the period of time that we use for determining payment to ESRD facilities, which is a calendar year. We are also clarifying that the eligibility years means the 3 years preceding the payment year and that the eligibility years are based on cost reporting years. We are making this clarification to ensure that ESRD facilities and their respective FI/MACs understand the distinction between eligibility (which is based on cost reporting years) and the payment year (when ESRD facilities can begin to receive the low-volume payment adjustment).

In this proposed rule, we also are proposing to establish the process, for CY 2012 and each year thereafter that an

ESRD facility would be required to follow when submitting its attestation to notify its FI/MAC that it is eligible for the low-volume payment adjustment. The attestation is required because: (1) The ESRD facility's cost reporting periods vary and may not be based on the calendar year; and (2) the cost reports are due 5 months after the close of the cost reporting period (that is, there is a lag in the cost reporting submission). Thus, the FI/MACS may not have the cost report for the third year to determine eligibility and will need to rely on the attestation for that year. If an ESRD facility believes that it is eligible for the low-volume adjustment, we are proposing that the ESRD facility would be required to submit an attestation to its respective FI/MAC no later than November 1st of each year. This timeframe provides 60 days for a FI/MAC to verify the cost report information and update the systems. For example, for payment year 2012 (January 1, 2012 through December 31, 2012), ESRD facilities that believe they are eligible for the low-volume adjustment must submit an attestation to their respective FI/MAC no later than November 1, 2011 (with regard to its low-volume status based on services furnished in its cost reporting period ending in 2009, 2010, and 2011).

ESRD facilities that are receiving the low-volume adjustment for the CY 2011 payment year should submit another attestation to their respective FI/MAC no later than November 1, 2011, to qualify for the low-volume adjustment for the CY 2012 payment year. Thus, for an attestation applicable to the 2012 payment year, the ESRD facility would attest that it meets the low-volume facility requirements based on its cost reporting periods ending in 2009, 2010, and 2011. The ESRD facility would continue to attest that it is a low-volume facility for each subsequent payment year it believes it is eligible for the low-volume facility adjustment.

As we indicated above, we propose that attestations be submitted to the FI/MAC no later than November 1 preceding each payment year to allow the FI/MACs time to review the attestation and ensure that accurate payment is made for renal dialysis services provided on or after January 1. We suggest that ESRD facilities submitting a low-volume attestation verify that the attestation has been received by the appropriate FI/MAC prior to the November 1 deadline. In the event that a dialysis organization submits the low-volume attestation on behalf of its ESRD facilities, the dialysis organization will be required to identify each ESRD facility by name and provider number and submit them by the November 1 deadline.

If the FI/MAC does not receive an ESRD facility's attestation stating that the ESRD facility is eligible for the low-volume adjustment on or before November 1 prior to the payment year, the ESRD facility would not receive the low-volume adjustment for that payment year.

In this proposed rule, with regard to the deadline for attestation submission, we are proposing to amend the regulation text at § 413.232(f) to require an ESRD facility to submit its attestation no later than November 1. This requirement would provide FI/MACs time to review and verify ESRD facilities low-volume eligibility. We are soliciting comment on the proposed regulation text changes at § 413.232(f).

Under § 413.232(b)(1) and (b)(2), a low-volume facility is defined as an ESRD facility that ''furnished less than 4,000 treatments in each of the 3 *years* preceding the payment year'' and ''has not opened, closed, or had a change in ownership in the 3 *years* preceding the payment year'' (emphasis added). In response to comments we received subsequent to the CY 2011 ESRD PPS final rule, we are clarifying the meaning of the term ''years'' in this regulation, with regard to the treatment threshold that determines low-volume eligibility, and how it relates to the ''payment year.'' We are providing this additional clarification to emphasize because there are ESRD facilities that do not have cost reporting periods that fall on a calendar year period (January 1 through December 31), and there may be confusion about how the eligibility year relates to the payment year. Specifically, we emphasize again that for the purpose of low-volume eligibility, the term ''years'' refers to cost reporting periods because low-volume eligibility is determined based on the ESRD facility's cost report. For example, an ESRD facility's cost reporting period could span a fiscal year rather than a calendar year. However, the low-volume payment adjustment is paid according to the ESRD PPS payment year (that is, the calendar year). Accordingly, FI/MACs are reviewing the ESRD facility's cost reporting periods ending in the 3 years preceding the payment year for low-volume eligibility, and those cost reporting periods may not necessarily be calendar years (January 1 to December 31).

We believe that it is also important to reiterate that the ESRD facility's cost reports for the cost reporting periods ending in the 3 years immediately preceding the payment year, as discussed above, must report costs for 12-consecutive months. For example, an FI/MAC would not consider a short period cost report (that is, reporting costs for less than 12 months which may occur for new facilities or facilities under new ownership), for low-volume eligibility. Specifically, when an ESRD facility is assessing its eligibility for the low-volume adjustment and preparing its attestation, the ESRD facility would look at its 12-consecutive month cost reports for the cost reporting periods that end in the 3 years immediately preceding the payment year.

We acknowledge that the FI/MAC may not have a final-settled cost report for all 3 years needed to complete the ESRD facility's verification. For example, using a June 30th cost reporting period year end, for purposes of determining low-volume eligibility, the ESRD facility would need to have met the low-volume criteria for their cost reporting periods ending on June 30, 2009, June 30, 2010, and June 30, 2011, to begin to receive the low-volume adjustment January 1, 2012. The FI/MAC should have the ESRD facility's cost reports for 2009 and 2010 and both years should be either final-settled or as-filed (that is, submitted to and accepted by the FI/MAC) and such cost reports should be for 12-consecutive months in each of the 2 years. The facility would be required to submit an attestation for all 3 years, including the third eligibility year because the cost report for that year is not available and no cost report has been submitted.

Therefore, in this rule, we propose to amend the regulations text at § 413.232(b)(1) and (b)(2) to clarify the type of year that is used for determining low-volume eligibility. This change in the regulations text also provides clarification to the ESRD facilities and the FI/MACs that in the absence of an ESRD facility's final settled cost report, an FI/MAC can review the ESRD facility's as-filed cost report when determining if an ESRD facility meets the low-volume criteria. We believe that it is appropriate for the FI/MAC to determine eligibility based upon an as-filed cost report because the number of total treatments should not change between submission of the as-filed cost report and the final settled cost report. We are soliciting comment on the proposed changes at § 413.232(b)(1) and (b)(2).

Continuing with the example discussed above in which we address an ESRD facility with a cost reporting year that ends on June 30, the ESRD facility attests to its FI/MAC that it met the low-volume criteria for its cost reporting periods ending in 2009 and 2010 and that it expects to meet the low-volume

criteria for its cost reporting period ending in 2011. The ESRD facility's cost report for its cost reporting period ending in 2011 is the third year that is needed to meet the criteria specified at § 413.232 for purposes of the 2012 payment year. If the FI/MAC receives the ESRD facility's cost report for 2011 and finds that the ESRD facility did not meet the low-volume criteria in its cost reporting period ending on June 30, 2011 (that is, the third eligibility year), the FI/MAC will discontinue application of the low-volume adjustment to the facility's payments for CY 2012 because the facility was not eligible for the adjustment. If the ESRD facility does not remain low-volume for each of the 3 years (12-consecutive month cost reporting periods) immediately preceding the payment year, the ESRD facility will not be eligible for the low-volume adjustment until it can demonstrate again that for 3 years (12-consecutive month cost reporting periods) it met the low-volume criteria.

6. Proposed 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 four-year transition under the ESRD PPS. Under § 413.239, ESRD facilities were permitted to make a one-time election by November 1, 2011, to be excluded from the transition and receive full payment under the ESRD PPS. Under § 413.239, in CY 2012, ESRD facilities that elected to receive payment under the transition will be paid a blended amount that will consist of 50 percent of the basic case-mix adjusted composite payment system and 50 percent on the ESRD PPS payment. Thus, we must continue to update the composite rate portion of the blended payment amount during the ESRD PPS 4-year transition (CYs 2011 through 2013), which includes an update to the drug add-on, the application of the wage index, and an update to the composite rate portion of the ESRD PPS blended payment amount for the second year (CY 2012) of the ESRD PPS. The proposed wage index and composite rate portion of the ESRD PPS blended payment are discussed in sections I.C.7 and I.C.1.a of this proposed rule.

As required under section 1881(b)(12) of the Act, the basic case-mix adjusted composite payment system includes services comprising the composite rate and an add-on to the composite rate component to account for the difference between pre-MMA payments for separately billed drugs and the revised drug pricing specified in the statute. For the drug add-on for CY 2012, in this proposed rule, we are not proposing any changes to the methodology but are merely updating the data used in computing the drug add-on as described below.

a. Estimating Growth in Expenditures for Drugs and Biologicals in CY 2012

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.

In order to account for increases in drug prices and utilization, since we now have 5 years of drug expenditure data based on ASP pricing, for CY 2012, we continue estimating growth in drug expenditures based on the trends in available data. 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 2012, we looked at the average annual growth in total drug expenditures between 2006 and 2010. First, we estimated the total drug expenditures for all ESRD facilities in CY 2010. We used the final CY 2006 through CY 2009 ESRD claims data and the latest available CY 2010 ESRD facility claims, updated through December 31, 2010 (that is, claims with dates of service from January 1 through December 31, 2010, that were received, processed, paid, and passed to the National Claims History File as of December 31, 2010). For the CY 2012 PPS final rule, we intend to use additional updated CY 2010 claims with dates of service for the same timeframe. This updated CY 2010 data file will include claims received, processed, paid, and passed to the National Claims History File as of June 30, 2011. While the CY 2010 claims file used in this proposed rule is 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.

Next, for CY 2012, based on an analysis of the 2009 claims data, we inflated the CY 2010 drug expenditures to estimate the June 30, 2011 update of the 2010 claims file. We used the relationship between the December 2009 and the June 2010 versions of 2009 claims to estimate the more complete 2010 claims that will be available in June 2011 and applied that ratio to the 2010 claims data from the December 2010 claims file. The net adjustment to the CY 2010 claims data is an increase of 11.62 percent to the 2010 expenditure data. This adjustment allows us to more accurately compare the 2009 and 2010 drug expenditure data to estimate per patient growth.

Using the completed full-year 2010 drug expenditure figure, we calculated the average annual change in drug expenditures from 2006 through 2010. This average annual change showed an increase of 1.4 percent in drug expenditures from 2006 through 2010. We used this 1.4 percent increase to project drug expenditures for both 2011 and 2012.

b. Estimating Per Patient Growth

Once we had the projected growth in drug expenditures from 2011 to 2012, we calculated per patient growth between CYs 2011 and 2012 by removing the estimated growth in enrollment data between CY 2011 and CY 2012. We estimate a 4.2 percent estimated growth in enrollment between CY 2011 and CY 2012. To obtain the per-patient estimated growth in expenditures, we divided the total drug expenditure change between 2011 and 2012 (1.014) by enrollment growth of 4.2 percent (1.042) for the same timeframe. The result is a per-patient growth factor equal to 0.973 (1.014/1.042 = 0.973). Thus, we are projecting a 2.7 percent decrease (2.7% = .027 = 0.973 − 1) in per patient growth in drug expenditures between 2011 and 2012.

c. Applying the Proposed Growth Update to the Drug Add-On Adjustment

In the CY 2006 PFS final rule (71 FR 69683), we applied the projected growth update percentage to the total amount of drug add-on dollars established for CY 2005 to establish a dollar amount for the CY 2006 growth update. 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 growth in 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 an average drug add-on amount per treatment of $18.88 (or a 14.5 percent adjustment to the composite rate) for CY 2006.

In the CY 2007 PFS final rule with comment period (71 FR 69684), as a

result of public comments, 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 CY 2009, 2010 and 2011 PFS final rule with comment period (73 FR 69755 through 69757, 74 FR 61923, and 75 FR 73485, respectively), 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. As discussed in detail below, for CY 2012, we are again proposing no update to the per treatment drug add-on amount of $20.33 established in CY 2008.

d. Proposed Update to the Drug Add-On Adjustment for CY 2012

As discussed above, we estimate a 1.4 percent increase in drug expenditures between CY 2011 and CY 2012. Combining this increase with a 4.2 percent increase in enrollment, as described above, we are projecting a 2.7 percent decrease in per patient growth of drug expenditures between CY 2011 and CY 2012. Therefore, we are projecting that the combined growth in per patient utilization and pricing for CY 2012 would result in a decrease to the drug add-on equal to 0.4 percentage points. This figure is derived by applying the 2.7 percent decrease to the CY 2011 drug add-on of $20.33. This would result in a revised drug add-on of $19.78, which is 14.0 percent of the proposed CY 2012 base composite rate of $141.52. If we were to apply no decrease to the drug add-on of $20.33, this would result in 14.4 percent drug add-on. However, similar to last year and as indicated above, we are proposing 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. Our understanding of the statute contemplates ''annually increase'' to mean a positive or zero update to the drug add-on. Therefore, we propose to apply a zero update and maintain the $20.33 per treatment drug add-on amount for CY 2012. We are seeking comment on our proposed zero update to the drug add-on.

The current $20.33 per treatment drug add-on reflected a 14.7 percent drug add-on adjustment to the composite rate in effect for CY 2011. As discussed in section I.c.2.b of this 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 (forecast of 1.8 percent in 2012 effective January 1, 2012), resulting in a decrease to the CY 2012 drug add-on adjustment from 14.7 to 14.4 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 2012 composite rate is higher than the CY 2011 composite rate, and since the drug add-on remains at $20.33, the percentage decreases. Therefore, we are proposing a drug add-on adjustment to the composite rate for CY 2012 of 14.4 percent.

7. Updates to the Wage Index Values and Wage Index Floor for the Composite Portion of the ESRD PPS Blended Payment and Under 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 in the index referred to in section 1881(b)(12)(D), as the Secretary determines appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49117 through 49117) and CY 2011 PFS final rule (75 FR 73486), we finalized the wage index policy under the ESRD PPS. Specifically, under the ESRD PPS, we have adopted the same method and source of wage index values used previously for the basic case-mix adjusted composite payment system.

We use Office of Management and Budget's (OMB's) Core Based Statistical Area (CBSA)-based geographic area designations to define urban/rural areas and corresponding wage index values. In addition, the wage index values used under the ESRD PPS are the inpatient prospective payment system (IPPS) wage index values calculated without regard to geographic reclassifications authorized under sections 1881(d)(8) and (d)(10) of the Act, and utilize pre-floor hospital data that are unadjusted for occupational case mix. The CBSA-based geographic area designations are described in OMB Bulletin 03–04, originally issued June 6, 2003, and available online at *http://www.whitehouse.gov/omb/bulletins/b03-04.html*. In addition, OMB has published subsequent bulletins regarding CBSA changes, including changes in CBSA numbers and titles. We wish to point out that this and all subsequent ESRD rules and notices are considered to incorporate the CBSA changes published in the most recent OMB bulletin that applies to the hospital wage index used to determine the current ESRD wage index. The OMB bulletins may be accessed online at *http://www.whitehouse.gov/omb/bulletins/index.html.*

Under the ESRD PPS, we have adopted a wage index floor during the transition, though as we previously noted, we intend to gradually reduce the ESRD wage index floor (75 FR 49117, 75 FR 73486). We also use the labor-related share for both the ESRD PPS and the composite rate portion of the blend, as measured by the ESRDB market basket (see section I.c.2.b of this proposed rule). Finally, 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 OMB's rural definitions and corresponding wage index values.

With regard to the transition, as we noted in the CY 2011 PFS final rule (75 FR 40163), because ESRD facilities could elect to receive a blended payment 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 this proposed rule, we are not proposing any changes to the methodology for the wage index used to adjust the composite rate portion of the ESRD PPS blended payment. However, we are proposing to update the wage index values and the wage index budget-neutrality adjustment factor for CY 2012 for the composite rate portion of the blended payment under the transition.

In addition, in this proposed rule, we are not proposing to make any changes to the methodology for updating the CY 2012 wage index under the ESRD PPS (that is, for full ESRD PPS payments and the ESRD PPS portion of the blended payment under the transition). However, we are proposing a wage index budget-neutrality adjustment factor to be applied in CY 2012 and in subsequent years for the ESRD PPS which is discussed in detail below.

a. Proposed Reduction to the ESRD Wage Index Floor

In the CY 2011 ESRD PPS final rule, we stated our intention to continue to

reassess the need for a wage index floor (75 FR 49117). The wage index floor for CY 2011 is 0.600. For CY 2012 and CY 2013, we propose to continue to reduce the wage index floor by 0.05 for each of the remaining years of the transition (that is, for CY 2012, the wage index value would be reduced from 0.600 to 0.550, and further reduced to 0.500 for CY 2013). The ESRD wage index floor value of 0.550 would be applied to areas that are below the proposed wage index floor of 0.550. Beginning January 1, 2014, we propose that the wage index floor would no longer be applied because the wage index floor would be equal to or lower than areas with low wage index values. We continue to believe that a gradual reduction in the floor is needed to support continuing patient access to dialysis in areas that have low wage index values, especially in areas where the wage index values are below the current wage index floor—specifically, ESRD facilities located in Puerto Rico.

b. Proposed Policies for Areas With No Hospital Data

In the CY 2011 ESRD PPS final rule (75 FR 49117), we finalized the same methodology we have used for areas with no hospital data in the past, that is, we compute the average wage index value of all urban areas within the State and use that value as the wage index. In this proposed rule, we are not proposing to change the methodology that we have used in the past to compute a wage index value for areas with no hospital data.

We are for CY 2012 and for future years, proposing to continue to use the methodology we adopted for identifying the small number of ESRD facilities in both urban and rural geographic areas where there are no hospital wage data from which to calculate ESRD wage index values that we have used for CYs 2006 through 2010 under the composite payment system and for CY 2011 and which we described in the ESRD PPS final rule (75 FR 49116). Thus far, we note the following affected areas: Rural Puerto Rico, Yuba, CA (CBSA 49700) and the urban area Hinesville-Fort Stewart, GA (CBSA 25980).

For rural Puerto Rico, because all wage index values in Puerto Rico are below the wage index floor, we previously used the wage index floor as the wage index value for Puerto Rico. For CY 2012 and CY 2013, we propose to continue to use the methodology we have previously used for computing the wage index for Puerto Rico, that is, use the ESRD wage index floor.

c. Proposed Wage Index Budget-Neutrality Adjustment

As noted above, we have broad discretion under section 1881(b)(14)(D)(iv)(II) of the Act to develop a geographic wage index. In addition, that section cites the wage index under the basic case-mix adjustment payment system as an example. We have previously interpreted the statute for the prior basic case-mix adjusted composite payment system (section 1881(b)(12)(D) of the Act) as requiring that the geographic adjustment be made in a budget-neutral manner. In 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.

Given our authority to develop a wage index under section 1881(b)(14)(D)(iv)(II) of the Act, as well as the authority to use the geographic index under section 1881(b)(12)(D) of the Act (for purposes of the ESRD PPS geographic payment adjustment under section 1881(b)(14)(D)(iv)(II) of the Act), we propose to apply the wage index in a budget-neutral manner under the ESRD PPS using a wage budget-neutrality adjustment factor. However, as we discuss in greater detail below, with regard to the application of the wage index budget-neutrality adjustment factor, we are proposing that under the ESRD PPS, we would apply a wage index budget-neutrality adjustment factor to the ESRD PPS base rate.

Under the basic case-mix adjustment composite payment system, we began applying the wage index budget-neutrality adjustment factor in CY 2006 (70 FR 70171). During the transition, we are not proposing to change the application of the wage index budget-neutrality adjustment to the wage index of the composite rate portion of the ESRD PPS blended payment, because we do not believe that we should make changes to the methodology for updating the composite rate portion of the ESRD PPS blended payment as the composite rate portion of the blended payment will no longer apply after the transition ends in CY 2014. We believe that continuing to apply the budget-neutrality adjustment to the wage index for the composite rate portion of the ESRD PPS blended payment allows ESRD facilities going through the transition to continue to use a methodology that they are accustomed to and one that may have been the basis for facilities electing to receive a blended payment during the transition. However, under the ESRD PPS, we believe by applying the wage index budget-neutrality adjustment factor to the ESRD PPS base rate, we would be consistent with the application of the wage index budget-neutrality adjustment factor in other prospective payment systems. We also believe that applying the wage index budget-neutrality adjustment factor to the ESRD PPS base rate is simpler and more straightforward in application and calculation. Applying the wage index budget-neutrality adjustment factor to the ESRD PPS base rate produces results that are not measurably different from applying the adjustment factor to the wage index, as is done for the composite rate portion of the blended payment during the transition.

We are seeking comment on our proposal to apply the wage index budget-neutrality adjustment factor to the ESRD PPS base rate for purposes of the ESRD PPS payments and the ESRD PPS component of the ESRD PPS payments during the transition.

As discussed above, we are not proposing any changes to the wage index budget-neutrality adjustment factor application for the composite rate portion of the ESRD PPS payment. We would continue to apply the wage-index budget-neutrality adjustment factor directly to the ESRD wage index values for the composite rate portion of the ESRD PPS blended payment for CY 2012 and CY 2013. Because the ESRD wage index is only applied to the labor-related portion of the composite rate, we computed the wage index budget-neutrality adjustment factor based on that portion. That is, the labor portion of the composite rate portion of the ESRD PPS blended payment of 53.711 percent. This labor-related share was developed from the labor-related components of the 1997 ESRD composite rate market basket that was finalized in the 2005 PFS final rule (70 FR 70168).

As we discussed above, in CY 2012, we are proposing to apply the wage index budget-neutrality adjustment factor to the ESRD PPS base rate. That is, the wage index budget-neutrality adjustment factor, which includes 41.737 percent labor portion of the ESRD PPS payment rate.

To compute the proposed CY 2012 wage index budget-neutrality adjustment factors, we used the fiscal year (FY) 2012 pre-floor, pre-reclassified, non-occupational mix-adjusted hospital data to compute the wage index values, 2010 outpatient claims (paid and processed as of December 31, 2010), and geographic

location information for each facility which may be found through Dialysis Facility Compare Web page on the CMS Web site at *http://www.cms.hhs.gov/DialysisFacilityCompare/*. The FY 2012 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 2012 Proposed Rule Occupational Mix Adjusted and Unadjusted Average Hourly Wage and Pre-Reclassified Wage Index by CBSA.''

For this proposed rule, using treatment counts from the 2009 claims and facility-specific CY 2011 payment rates, we computed the estimated total dollar amount each ESRD provider would have received in CY 2011. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2012. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the proposed ESRD wage index for CY 2012. The total of these payments becomes the new CY 2012 amount of wage-adjusted payment rate expenditures for all ESRD facilities.

After comparing these two dollar amounts (target amount divided by the new CY 2012 amount), we calculated two wage index budget-neutrality adjustment factors that when multiplied by the applicable CY 2012 estimated payments would result in aggregate payments to ESRD facilities that would remain budget-neutral when compared against the target amount of payment rate expenditures. One factor would be applied to the ESRD PPS base rate. The second factor would be applied to the wage index value for the composite rate portion of the ESRD PPS payment. Therefore, in this proposed rule, for CY 2012, we are proposing a wage index budget-neutrality adjustment factor for the composite portion of the ESRD PPS blended payment of 1.002096, which would be 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 proposing to apply a wage index budget-neutrality adjustment factor of 1.001126 to the ESRD PPS base rate.

Because we are proposing to apply the wage index budget-neutrality adjustment factor to the wage index values to ensure budget-neutrality under the composite rate portion of the ESRD PPS blended payment, we also applied the wage index budget-neutrality adjustment factor to the wage index floor of 0.550 which results in an adjusted wage index floor of 0.551 (0.550×1.002096) for CY 2012.

d. ESRD PPS Wage Index Tables

The CY 2012 ESRD 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/ESRDPayment/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 portion of the blended payment to which the wage index budget-neutrality adjustment factor has been applied. Another 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 as we discussed above, we are proposing to apply the wage index budget-neutrality adjustment factor to the ESRD PPS base rate.

8. Drugs

a. Vancomycin

In the CY 2011 ESRD PPS final rule (75 FR 49050 through 49052), we stated that antibiotics used for the treatment of venous 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 in 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 also noted that the oral versions of Vancomycin are not used for ESRD-related conditions and, therefore, would not be considered a renal dialysis service. We further stated that any anti-infective drugs or biologicals used for the treatment ESRD-related conditions would be considered a renal dialysis service and, therefore, not eligible for separate payment. This policy also applies to any drug or biological that may be developed in the future.

Since the publication of the CY 2011 ESRD PPS final rule, we received numerous comments indicating that Vancomycin is indicated for both ESRD and non-ESRD conditions, such as skin infections. After consultation with our medical experts, we concur with our commenters. Therefore, in this proposed rule, we are proposing to eliminate the restriction on Vancomycin to allow ESRD facilities to receive separate payment by placing the AY modifier on the claim for Vancomycin when furnished to treat non-ESRD related conditions. In accordance with ICD–9 guidelines as described in the ESRD PPS final rule (75 FR 49107), the ESRD facility would also be required to indicate the diagnosis code for which the Vancomycin is indicated. We note that treatment of any skin infection that is related to renal dialysis access management would be considered a renal dialysis service and would continue to be paid under the ESRD PPS, and no separate payment would be made. We are soliciting public comments on our proposal to eliminate the restriction on Vancomycin to allow ESRD facilities to receive separate payment for these drugs when furnished to treat non-ESRD related conditions.

b. Drug Overfill

In the CY 2011 PFS final rule (75 FR 73466), we explained the methodology for Part B payment for drugs and biologicals which includes intentional overfill, and that the Medicare average sales price (ASP) payment limit is based on the amount of drug conspicuously indicated on the labeling approved by the Food and Drug Administration (FDA). We indicated that we have become aware of situations where manufacturers intentionally included a small amount of overfill in drug containers, and that this overfill is provided at no extra charge to the provider. We also noted that the intent of the intentional overfill was to compensate for product loss during the proper preparation and administration of a drug. We explained that ASP calculations are based on data reported by manufacturers, including ''volume per item''. Therefore, providers may only bill for the amount of drug product actually purchased and the cost that the product represents (75 FR 73467).

This Part B provision applies under the ESRD PPS. ESRD facilities receiving blended payments under the ESRD PPS transition will receive payments based on ASP for separately billable ESRD drugs and biologicals for the composite rate portion of the blend. In addition, under the ESRD PPS outlier policy, the ESRD-related drugs that ESRD facilities report on claims are priced for the outlier policy based on ASP. Therefore, ESRD facilities may only report units and charges for drugs or biologicals actually purchased.

9. Proposed Revisions to Patient-Level Adjustment for Body Surface Area (BSA)

Section 1881(b)(14)(D)(i)of the Act requires that the bundled ESRD PPS must include a payment adjustment based on case-mix that may take into

account patient weight, body mass index (BMI), body surface area (BSA), and other appropriate factors. In the CY 2077 ESRD PPS final rule, we explained that we evaluated height and weight because the combination of these two characteristics allows us to analyze two measures of body size: BSA and BMI. We further explained that both body size measures are strong predictors of variation in payment for ESRD patients (75 FR 49089 through 49090). As a result, in developing the ESRD PPS, we established a case-mix patient level adjustment for BSA that would be applied to each 0.1 m2 change in BSA compared to the national average (1.02).

In this proposed rule, we are proposing to make one change related to the use of the national BSA average value used in the calculation of the BSA adjustment applied to the composite rate portion of the blended payment for those dialysis facilities that undergo the transition. We believe this change is necessary because we believe that the BSA national average used to compute payment under the composite portion of the ESRD PPS blended rate and under the ESRD PPS should be both the most recent and consistent measurement available. For CY 2011, the BSA adjustment we calculated for the composite rate portion of the ESRD PPS blended rate used the BSA national average of 1.84, which reflected the average among Medicare dialysis patients in 2002. However, the BSA national average we used for computing the BSA under the ESRD PPS was 1.87, which reflects the average among Medicare dialysis patients in 2007. We did not realize that we had used 2 different national averages in CY 2011, nor was it brought to our attention during the comment period. We are proposing that for CY 2012 and in subsequent years, to use one national average for computing the BSA under the composite portion of the blended payment during the transition and under the ESRD PPS.

In the CY 2004 PFS final rule (69 FR 66329), we explained that the BSA factor was defined as an exponent equal to the value of the patient's BSA minus the reference. If, for example, a beneficiary with a BSA of 1.94 using the CY 2011 national average of 1.84 under the composite rate would yield a BSA adjustment factor of 1.0370. For the same patient using the national average used for the CY 2011 ESRD PPS BSA computation using 1.87 would yield a BSA adjustment factor of 1.0258, or a ratio or proportional difference of 1.0258 divided by 1.0370 equals .9892 difference the between the two BSA adjustment factors. This corresponds to a reduction of 1.08 percent (1–0.9892 = 0.0108) in the composite rate payment for ages 18 and older by increasing the BSA reference value from 1.84 to 1.87.

The impact on facility payments of increasing the composite rate BSA reference value from 1.84 to 1.87 is shown in Table 3 for each year from 2011 to 2014. These results apply only to dialysis facilities that go through the transition. The impact on facility payments would have been greatest in 2011, where the blended payment during the transition period was weighted more heavily towards the composite rate/separately billable system, and declines through 2014 when there is no impact on facility payments under a fully implemented expanded PPS.

The impact on the average payment in 2012 was calculated as $-0.0108 * 0.9979 * 0.6498 * 0.50 = -0.350$ percent. That is, the average facility payment for those facilities electing the ESRD PPS transition would be reduced by approximately 0.35 percent in 2012. We derived the -0.350 percent reduction from the following factors: the estimated reduction in BSA multipliers due to the increase in the BSA reference value (-0.0108); the proportion of patients 18 and older (0.9979); the percentage of composite rate and separately billable payments that are composite rate payments (0.6498); and the percentage of composite rate payments in CY 2012 (0.50). This reduction only applies to those ESRD facilities that elected to receive blended payments during the transition.

Table 3

Impact on average facility payments of increasing the composite rate BSA reference value from 1.84 to 1.87

Year	CR/SB portion of total facility payments during transition period	Change in average facility payment
2011	0.75	-0.525%
2012	0.50	-0.350%
2013	0.25	-0.175%
2014	0.00	0.000%

Therefore, we are proposing for CY 2012, to use the latest national average (that is, 1.87) as the reference point for the computation of the BSA adjustment for both the composite rate portion of the ESRD PPS blended payment and for the ESRD PPS. We are also proposing that we will review the BSAs on CY 2012 claims (and every 5 years thereafter) to determine if any adjustments to the national average will be required in the future. We are seeking comments on the proposal to use one national BSA average to compute the BSA under the composite portion of the ESRD PPS blended payment and under the ESRD PPS. We are also seeking comment on the proposal to review CY 2012 ESRD claims and every 5 years thereafter, to determine if a change to the BSA national average is warranted.

10. Proposed 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. 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).

Medicare regulation § 413.237(a)(1) provides that ESRD outlier services include: (1) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (3) 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 (4) 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. Drugs, laboratory tests, and medical/surgical supplies that we would recognize as outlier services were specified in Attachment 3 of Change Request 7064, issued August 20, 2010 under Transmittal 2033. Transmittal 2033 was rescinded and replaced by Transmittal 2094, dated November 17, 2010. The replacement document involved the (1) Deletion of several drugs; (2) identified drugs that may be eligible for ESRD outlier payment; (3) provided a list of laboratory tests that comprise the AMCC tests; (4) deleted several laboratory tests; and (5) included the latest version of the ESRD PRICER layout file.

Transmittal 2094 was subsequently rescinded and was replaced by Transmittal 2134 issued January 14, 2011. That transmittal was issued to correct the subject on the transmittal page and made no other changes.

Medicare regulations at § 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 threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) MAP plus the fixed dollar loss amount. In accordance with § 413.237(c) of the regulation, facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule, using 2007 data, we established the outlier percentage at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the fixed dollar loss amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and fixed dollar loss amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140).

a. Proposed Revisions Related to Outlier ESRD Drugs and Biologicals

Attachment 3 of Change Request 7064 issued August 20, 2010 under Transmittal 2033, as modified by Transmittal 2094 issued November 17, 2010 and Transmittal 2134 issued January 14, 2011, specified the former separately billable Part B drugs that are recognized as ESRD-related eligible outlier services. These drugs are classified under the categories of anemia management, antiemetics, anxiolytics, bone and mineral metabolism, cellular management, pain management, and anti-infectives (see Pub. 100–04, Chapter 8, section 60.2.1.1). Attachment 3 also identified the former Part D drugs by National Drug Code (NDC) for the three vitamin D analogues (calcitriol, paracalcitol, and doxercalciferol) and levocarnitine that are recognized as eligible outlier service drugs.

We had intended to update both the lists of former Part B drugs and biologicals and former Part D drugs that are outlier services (75 FR 49138). However, we have since concluded that any CMS prepared lists of drugs and biologicals recognized as outlier services may be difficult to keep up-to-date. This is attributed to the lag in the receipt of claims data; changes in ESRD practice patterns; and inadvertent omissions and oversights. Because of the number of Part B drugs and biologicals that may be considered ESRD outlier services, we are proposing to eliminate the issuance of a list of former separately payable Part B drugs and biologicals that would be eligible for outlier payments.

Medicare regulations at § 413.237(a)(1)(i) and (iv) specify that any ESRD-related drug or biological furnished by an ESRD facility that was or would have been considered separately billable under Part B or formerly covered under Part D prior to January 1, 2011, is an ESRD outlier service, excluding ESRD-related oral-only drugs. Because the regulation defines eligible outlier service drugs, we believe there is no need for CMS to issue a list of former separately payable Part B ESRD outlier services drugs. In addition, because the list of drugs is derived from paid ESRD claims, it would not be comprehensive, completely represent drugs and biologicals furnished to ESRD patients, accurate, or up-to-date. We note that, consistent with current policy, all composite rate drugs, as defined in the Medicare Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1, would not be eligible for an outlier payment, as these drugs would not have been separately paid under Part B or Part D prior to January 1, 2011, and do not meet the definition for ESRD outlier services.

Under current policy, antibiotics furnished in the home are considered to be composite rate drugs and therefore, not eligible for outlier payment. As discussed above, Pub. 100–02, chapter 11, section 30.4.1 lists the drugs covered under the composite rate. The list includes a statement that antibiotics when used at home by a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis are considered composite rate drugs. Because composite rate drugs and their administration (both the staff time and the supplies) are covered under the composite rate, antibiotics furnished in the patient's home used for the reasons noted above may not be billed and paid separately. However, antibiotics furnished in an ESRD facility were considered separately payable in accordance the Medicare Claims Processing Manual, Pub. 100–04, chapter 8, section 60.2.1.1.

In addition, Pub. 100–02, chapter 11, section 50.9 states that an antibiotic used at home by a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis is covered as home dialysis supplies included in the Method II (Direct Dealing) payment cap for home dialysis supplies administered by the Durable Medical Equipment (DME) Supplier. Prior to January 1, 2011, under Method II, durable medical equipment suppliers received direct payment from Medicare for furnishing dialysis services to home dialysis patients. Effective January 1, 2011, as indicated in § 413.210(b) of the regulations, CMS will not pay any entity or supplier other than ESRD facilities for covered items and services furnished to a Medicare

beneficiary. Therefore, payment to medical equipment suppliers for antibiotics under Method II could no longer be made. Additionally, under the ESRD PPS, the dialysis facility is responsible for furnishing all renal dialysis services, regardless of the site of service. Under the ESRD PPS, there is no payment distinction made as to the site where a renal dialysis service is provided (that is, in the home or in a facility). Therefore, we do not believe that it is appropriate to have a distinction in which antibiotics administered in an ESRD facility, used to treat an infection of the catheter or other access site, or peritonitis associated with peritoneal dialysis, would be considered as separately billable under the composite rate portion of the ESRD PPS and eligible for outlier payments under the ESRD PPS, while antibiotics used at home by home patients for the same purpose would be considered to be included in the composite rate and not eligible for outlier payments. Consequently, we are proposing to eliminate the inclusion of antibiotics when used in the home to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis as part of the composite rate drugs, and allow them to be separately paid under the composite portion of the ESRD PPS blended payment for ESRD facilities receiving payment during the transition. We are also proposing that antibiotic drugs used at home to treat catheter site infections or peritonitis associated with peritoneal dialysis will qualify as separately billable and eligible as ESRD outlier services. Antibiotics furnished in facility would continue to be recognized as separately billable for ESRD outlier payment purposes.

We are soliciting comments on our proposal to recognize antibiotics furnished in the home for catheter infections or peritonitis as ESRD outlier services and eligible for outlier payment. As we indicated above, we would no longer issue a list of ESRD-related drugs and biologicals eligible for outlier payments. However, under separate administrative issuances, we plan to continue to identify renal dialysis service drugs which were or would have been covered under Part D for outlier eligibility purposes in order to provide unit prices for calculating imputed outlier services. We believe that the elimination of a list of certain ESRD outlier services drugs we mentioned above and the inclusion of antibiotics used by home dialysis patients as outlier services would reduce confusion over drugs and biologicals that are eligible outlier services and eliminate the distinction in the eligibility of a drug for outlier eligibility based on where it is furnished. Accordingly, we are soliciting public comments on our proposal to eliminate the issuance of a specific list of eligible outlier service drugs which were or would have been separately billable under Medicare Part B prior to January 1, 2011.

As new drugs emerge, we intend to update the HCPCS codes corresponding to new drugs and biologicals for billing purposes, and to determine whether any of those drugs are considered to be composite rate drugs. Drugs and biologicals which were or would have been considered composite rate drugs are not eligible ESRD outlier services under § 413.237.

We are also proposing two modifications to the computation of the separately billable MAP amounts used to calculate outlier payments for the reasons described below. Subsequent to the publication of the CY 2011 ESRD PPS final rule, 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. As discussed in the ESRD Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1, drugs that are used as a substitute for any of the listed items or are used to accomplish the same effect, are covered under the composite rate. Because heparin, as a composite rate drug, could be used for access management, any drug or biological used for the same purpose may not be separately paid. As outlier payments are restricted, under § 413.237(a), to those items or services that were or would have been considered separately billable prior to January 1, 2011, we have recalculated the average outlier services MAP amounts to exclude these composite rate drugs.

In developing the outlier service MAP amounts for 2011, we excluded testosterone and anabolic steroids. We have subsequently learned from discussions with clinicians and ESRD facilities that these drugs can be used for anemia management. Because drugs used for anemia management in ESRD patients were or would have been considered separately billable under Medicare Part B, these drugs would be outlier eligible drugs under § 413.237(a)(1). Consequently, we have recomputed the outlier service MAP amounts for CY 2012 to include these drugs. As shown in Table 4, when comparing the outlier service MAP amounts based on the current definition of ESRD outlier services to the revised ESRD outlier definition, the net effect of these two revisions (the exclusion of thrombolytic drugs and inclusion of anabolic steroids) results in an increase to the outlier service MAP amounts by $2.21 for adult patients and a decrease of $4.58 for pediatric patients.

b. Proposed Exclusion of Automated Multi-Channel Chemistry (AMCC) Laboratory Tests From the Outlier Calculation

Medicare regulations at § 413.237 provide that ESRD-related laboratory tests that were or would have been considered separately billable under Medicare Part B prior to January 1, 2011, are eligible outlier services. Those laboratory tests were specified in Attachment 3 of Change request 7064 issued under Transmittal 2033, as modified by Transmittals 2094 and 2134. In the CY 2011 ESRD PPS final rule (75 FR 49135 through 49138), we indicated that in order to compute the outlier payment for laboratory tests, the 50 percent rule is required. In addition, because the 50 percent rule is necessary to calculate the composite rate portion of the blended payment during the 3-year transition period, we retained the 50 percent rule to determine whether Automated Multi-Channel Chemistry (AMCC) panel tests would be considered composite rate or separately billable for the ESRD portion of the blended payment (75 FR 49137). The AMCC panel tests and an explanation of the 50 percent rule are identified in Pub. 100–2, chapter 11, section 30.2.2. ESRD laboratory billing rules can be found in Pub 100.04, chapter 16, section 40.6.

The 50 percent rule provides that if 50 percent or more of covered laboratory tests comprising a panel of AMCC tests are included under the composite payment rate, then all submitted tests are included within the composite payment and, therefore, no laboratory tests are considered separately billable. Conversely, if less than 50 percent of the covered panel tests are composite rate tests, then all AMCC tests submitted for the date of service for that beneficiary are considered separately billable. In addition, Pub. 100–2, chapter 8, section 60.1 provides that an AMCC test that is a composite rate test, but is furnished beyond the normal frequency covered under the composite rate, is separately billable based on medical necessity.

After publication of the CY 2011 ESRD PPS final rule, we received numerous requests to eliminate the 50 percent rule due to the commenters' assertions that they were confused about its application. Unlike specific drugs which are classified as either composite

rate or separately billable for purposes of eligibility as an ESRD outlier service as discussed above, AMCC laboratory tests may be classified as either composite rate or separately billable depending upon the application of the 50 percent rule or the frequency at which the laboratory test is ordered. Therefore, the determination of ESRD-related laboratory tests as eligible outlier services depends upon the number of panel tests furnished or their subsequent classification based on the application of the 50 percent rule.

Because the AMCC laboratory tests included as eligible for an outlier payment are determined by the 50 percent rule, we believe that in the interests of administrative simplification and to minimize confusion, we propose to eliminate use of the 50 percent rule for the outlier policy and exclude the 23 AMCC laboratory tests, from the definition of eligible outlier services and from the computation of outlier payments. The elimination of the 50 percent rule for the ESRD PPS outlier payment policy with respect to the AMCC panel tests would result in the de facto treatment of those tests as composite rate tests. Accordingly, we propose to revise § 413.237(a)(1)(ii) of the regulations accordingly to exclude these laboratory tests from the definition of ESRD outlier services. The 50 percent rule would continue to apply to AMCC laboratory tests for classification as either composite rate or separately billable for the purpose of computing the composite rate portion of the blended rate for ESRD facilities which have elected to receive payments under the ESRD PPS blended rate. Because the transition period under the ESRD PPS ends on January 1, 2014, this provision would be time limited, and would expire when the transition period ends. This would occur because all ESRD payments would be under the ESRD PPS, there would no longer be a need to maintain the distinction between composite rate and separately billable laboratory services for application of the 50 percent rule, because the transition period will have ended. We are seeking comment on our proposal to exclude the AMCC laboratory tests and the 50 percent rule from the definition of eligible ESRD outlier services.

c. Impact of Proposed Changes to the Outlier Policy

Table 4 shows the impact of modifying the ESRD PPS outlier payment policy to: (1) exclude vascular access management drugs and include anabolic steroids as eligible outlier service drugs; and (2) exclude the 23 AMCC laboratory tests from the ESRD outlier services definition. The outlier services MAP amounts and fixed dollar loss amounts were inflation adjusted to reflect projected 2011 prices for outlier services for the first three columns (that is, outlier policy based on the current definition for ESRD outlier services, the revised ESRD outlier services definition with regard to drugs, and the revised ESRD outlier services definition plus the exclusion of the AMCC laboratory tests). The revised ESRD outlier services definitions are described in the first footnote to Table 4. For the last column, which describes the impact of the revised ESRD outlier services definition and the exclusion of the AMCC laboratory tests for CY 2012, the outlier services MAP amounts and fixed dollar loss amounts were inflation adjusted to reflect projected 2012 prices for outlier services.

TABLE 4—OUTLIER POLICY: IMPACT OF REVISING THE ESRD OUTLIER SERVICES DEFINITION AND EXCLUDING SEPARATELY BILLABLE AMCC LABORATORY TESTS ^

	Outlier policy based on current definition for ESRD outlier services, price inflated to 2011*		Revise ESRD outlier services definition, price inflated to 2011*		Revise ESRD outlier services definition and exclude AMCC lab tests, price inflated to 2011*		Revise ESRD outlier services definition and exclude AMCC lab tests, price inflated to 2012**	
	Age < 18	Age >= 18	Age < 18	Age >= 18	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment [1]	$50.85	$85.62	$45.14	$84.71	$44.67	$84.40	$46.27	$87.83
Adjustments Standardization for outlier services [2]	1.0136	0.9728	1.0136	0.9728	1.0136	0.9728	1.0136	0.9728
MIPPA reduction	0.98	0.98	0.98	0.98	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount [3]	$50.51	$81.62	$44.84	$80.75	$44.37	$80.46	$45.96	$83.73
Fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold [4]	$113.99	$139.20	$77.72	$136.93	$77.60	$136.88	$82.58	$145.25
Patient months qualifying for outlier payment	3.9%	5.6%	5.0%	5.6%	5.1%	5.6%	5.0%	5.5%

^ The revised ESRD outlier services definition excludes vascular access management drugs and includes anabolic steroids. Vascular access management drugs billed separately include the following: alteplase, reteplase, heparin, lepiridun, and urokinase. Anabolic steroids billed separately include the following: testosterone and nandrolone. Payments for separately billable automated multi-channel chemistry (AMCC) tests were identified using modifier codes 'CE' and 'CF' (where 'CE' indicates composite rate tests beyond the frequency covered under the rate but separately billable based on medical necessity, and 'CF' indicates tests that are separately billable).

* The outlier services MAP amounts and fixed dollar loss amounts were inflation adjusted to reflect 2011 prices for outlier services.

** The outlier services MAP amounts and fixed dollar loss amounts were inflation adjusted to reflect projected 2012 prices for outlier services.

[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 2009 data. The medically unbelievable edits of 400,000 units for EPO 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 2009 data to yield total outlier payments that represent 1% of total projected payments for the ESRD PPS.

Based on these proposals, using the average outlier service MAP amount per treatment which is based on payment amounts reported on 2009 claims and adjusted to reflect projected prices for 2011, in CY 2012, the average outlier services MAP per treatment amounts would be increased from $85.62 to $87.83 for adult patients and a reduction from $50.85 to $46.27 for pediatric patients. The primary reason for the difference in directionality of the changes is that there are differences in the types of outlier services that tend to be used by each age group. In particular, the exclusion of vascular access management drugs from the ESRD outlier services definition leads to a much larger decrease in the outlier services MAP amounts for ages <18 (decrease from $50.85 to $45.14) versus ages 18 and older (decrease from $85.62 to $84.71). This reflects relatively greater use of separately billable vascular access management drugs among ages <18. Unlike ages 18 and older, the decrease in the outlier services MAP for ages <18 when excluding these drugs is large enough to more than offset the increase that results in the last step when we adjust for 2012 price inflation.

Similarly, the fixed dollar loss amounts which were added to the predicted MAP amounts per treatment to determine the outlier thresholds would be revised from $139.20 to $145.25 for adult patients and from $113.99 to $82.58 for pediatric patients. We estimate that the patient months qualifying for outlier payments under the current policy (5.6 percent of those adult patient facility months and 3.9 percent of the pediatric patient facility months previously estimated to be eligible for outlier payments), would remain approximately the same for adult patients (5.5 percent), but would increase for pediatric patients (5.0 percent) in CY 2012 under our proposed revised outlier payment policy.

The variation seen in the pediatric fixed dollar loss amounts tend to be lower based on the 2009 data used for this proposed rule as compared with the 2007 data used in CY 2011. There is generally greater sensitivity in pediatric results due to the relatively small number of pediatric patients. This is even more true with the pediatric fixed dollar loss amounts, since the magnitude of the pediatric fixed dollar loss amounts is basically determined by a relatively small number of the highest cost pediatric patients. The much lower pediatric fixed dollar loss amounts based on data from 2009 (as compared with 2007), reflect the tendency to have less extreme high cost cases for pediatric patients in the 2009 claims. The expected result based on this update is that more pediatric claims will qualify for outlier payments based on 2009 data, but the average outlier payment among the pediatric outlier cases will be lower.

With the exception of the proposed revisions to the average outlier services MAP amounts per treatment and changes in the fixed dollar loss amounts, as set forth in Table 4, we are not proposing to make any other changes to the methodology for the calculation of outlier payments. These proposed revisions would only affect the ESRD PPS portion of the blended payment, not the basic case-mix adjusted portion. Because of the limited 3-year period in which the basic case-mix adjusted portion of the blended payment amount will apply, the 50 percent rule would automatically expire when the fully implemented ESRD PPS applies to all facilities. We believe the proposed changes to our outlier payment policy would simplify the identification and reporting of eligible outlier services.

D. Technical Corrections

1. Training Add-On

In the CY 2011 ESRD PPS final rule (75 FR 49062 through 49063), we explained the rationale for costs associated with self-dialysis training. We inadvertently listed an incorrect training add-on amount of $33.38. The correct training add-on amount is $33.44. Therefore, in this proposed rule, we are correcting the training add-on amount to $33.44 for costs associated with self-dialysis training on or after January 1, 2011. The geographic wage index will be applied to the $33.44. As described in the CY 2011 ESRD PPS final rule (75 FR 49063), the training add-on amounts after application of the wage index would range from $20.03 to $45.84.

2. ESRD-Related Laboratory Test

In the CY 2011 ESRD PPS final rule (Table F: ESRD-Related Laboratory Tests of the Appendix), we finalized a specific list of routine ESRD-related laboratory tests included as part of consolidated billing (75 FR 49213). However, we inadvertently omitted an ESRD-related laboratory test from Table F of the CY 2011 ESRD PPS final rule. In this proposed rule, we are correcting Table F by adding the ''Assay of protein by other source,'' which is identified by the Current Procedural Terminology code 84157. This laboratory test was a composite rate service under the basic case-mix adjusted composite payment system and, consequently, is considered a renal dialysis service under the ESRD PPS effective January 1, 2011. Therefore, the ''Assay of protein by other source'' should be furnished by the ESRD facility, either directly or under arrangement by another entity, to the ESRD patient and paid for through the ESRD PPS payment rate.

E. Clarifications to the CY 2011 ESRD PPS

1. ICD–9–CM Diagnosis Codes

In the CY 2011 ESRD PPS final rule, we discussed the ICD–9–CM diagnosis codes that are eligible for the co-morbidity payment adjustments (75 FR 49094 through 49107). We explained that it is important for ESRD facilities to report all patient co-morbidities accurately, regardless of whether or not these codes are or are not eligible for an ESRD PPS adjustment. We stated that the ICD–9–CM diagnosis codes should be reported in compliance with coding requirements on the ESRD 72x claim as well as the official ICD–9–CM Coding Guidelines (75 FR 49095).

In the CY 2011 ESRD PPS final rule, we provided the list of ICD–9–CM codes that are recognized for purposes of the co-morbidity payment adjustments in Table E: ICD–9–CM Codes Recognized for a Co-Morbidity Payment Adjustment of the Appendix (75 FR 49211). Although we discussed ICD–9–CM coding to be used to identify co-morbidity conditions on ESRD claims, we did not indicate that we would update the existing diagnostic categories and ICD–9–CM codes on an annual basis.

In this proposed rule, we are clarifying that the ICD–9–CM codes are subject to the annual ICD–9–CM coding changes that occur in the hospital inpatient PPS final rule and effective October 1st of every year. Any changes that affect the categories of co-morbidities and the diagnoses within the co-morbidity categories that are eligible for the co-morbidity payment adjustments, will be communicated to ESRD facilities through sub-regulatory guidance. In response to comments we have received, we believe that it is important to reiterate the discussion of co-morbidities that was detailed in the CY 2011 ESRD PPS final rule. ESRD facilities should continue to provide documentation in the patient's medical/clinical record to support any diagnosis recognized for a payment adjustment as this is a requirement to receive the co-morbidity payment adjustment (75 FR 49097). As we discussed in the CY 2011 ESRD PPS final rule, we have been and will continue to monitor the prevalence

of any co-morbidity diagnoses recognized for the co-morbidity payment adjustment under the ESRD PPS as compared to the prevalence of these categories over the past several years. Therefore, we would be able to identify any changes in the prevalence of any of the co-morbidity diagnoses recognized for purposes of the co-morbidity payment adjustment as compared to previous trends (75 FR 49099). We are monitoring the co-morbidities eligible for payment adjustment to determine if the co-morbidity adjustments need to be refined in future rulemaking.

2. Emergency Services to ESRD Beneficiaries

As we explained in the CY 2011 ESRD PPS final rule (75 FR 49056), inpatient services, emergency services, and outpatient services furnished in a hospital or in an ambulatory surgical center furnished to ESRD beneficiaries were not included in the ESRD PPS base rate, and none of these services are considered renal dialysis services for inclusion in the ESRD PPS payment bundle. These services are reimbursed under other Medicare payment systems. We also explained that certain outpatient procedures necessary to maintain vascular access (that is, those which cannot be addressed by the ESRD facilities using procedures that are considered part of routine vascular access), are excluded from the definition of renal dialysis services and are not included in the ESRD PPS payment. However, we consider the furnishing of certain medications, such as those used to flush a vascular access site of an ESRD patient, to fall within the definition of renal dialysis services.

As we discussed in the section on consolidated billing rules and edits in the CY 2011 ESRD PPS final rule (75 FR 49168), the ESRD PPS payment is an all-inclusive payment for renal dialysis services and the ESRD facility is responsible for all of the ESRD-related services that a patient receives. Payment for renal dialysis services under the ESRD PPS, including those that were formerly paid separately under the basic case-mix adjusted composite rate payment system, is no longer made to entities (such as laboratories and DME suppliers) other than the ESRD facility.

Subsequent to the publication of the CY 2011 ESRD PPS final rule, we have received requests that we further clarify whether certain renal dialysis services furnished in an emergency room or emergency department are considered renal dialysis services covered under the ESRD PPS. Accordingly, we are providing additional clarification below.

Renal dialysis services defined at § 413.171 of the regulations include diagnostic laboratory tests. In developing the ESRD PPS base rate, we included payments for outpatient laboratory tests billed on ESRD facility claims, as well as laboratory tests ordered by monthly capitation payment (MCP) physicians and billed on carrier claims (75 FR 49055), because we believe that these diagnostic laboratory tests furnished by ESRD facilities and MCPs meet the definition of renal dialysis services. We did not include laboratory tests ordered for Medicare ESRD patients undergoing treatment in hospital emergency departments or emergency rooms, because these tests are usually administered as part of a patient's clinical assessment of the condition requiring emergency room admission, which we believe are not generally related to the treatment of ESRD. Therefore, laboratory tests that are performed for Medicare ESRD beneficiaries in an emergency situation in an emergency room or emergency department as part of the general work-up of the patient, were excluded from the ESRD PPS payment bundle, and would not be considered renal dialysis services under the ESRD PPS.

We recognize that laboratory tests that could be used during dialysis and ordered for the treatment of ESRD also may be ordered for ESRD patients in an emergency department or emergency room for reasons other than ESRD (that is, as part of the assessment of the patient to obtain a diagnosis of the underlying condition which required emergency intervention). For example, an ESRD beneficiary in an emergency department because the beneficiary is unconscious or otherwise in crisis may have a CBC and other laboratory tests ordered to arrive at a diagnosis. Although such tests also may be used in dialysis treatment and in the treatment of ESRD, because laboratory tests ordered for ESRD patients treated in emergency departments or emergency rooms are needed to arrive at a diagnosis of the condition requiring emergency treatment, we do not consider the laboratory tests as renal dialysis services under the ESRD PPS. Accordingly, these laboratory tests were not used to develop the ESRD base rate. We would not expect that the laboratory tests provided in that circumstance to be subject to consolidated billing edits, resulting in denial of payment. That is, we would not consider such tests to be renal dialysis services in this emergency situation because they were not ordered for the treatment of ESRD, but instead, furnished as part of the general work-up of the patient necessary for diagnosis.

The exclusion of laboratory tests ordered in hospital emergency rooms or emergency departments from the consolidated billing edits does not mean that renal dialysis facilities should attempt to circumvent the application of the bundled ESRD PPS rate by directing patients to emergency rooms or emergency departments for obtaining ESRD-related laboratory tests, or the provision of other renal dialysis services. Because ESRD facilities are financially responsible for all ESRD-related laboratory tests, referring ESRD patients to the emergency room or emergency department for ESRD-related laboratory tests would be inappropriate. We note that it would also be inappropriate for ESRD facilities to refer its patients to the emergency room or emergency department for maintenance of access sites (including treatment for access infections) or the administration of ESRD-related drugs that are considered renal dialysis services under the ESRD PPS. We are monitoring the provision of renal dialysis services to ESRD patients in an emergency room or emergency department.

II. End-Stage Renal Disease Quality Incentive Program for Payment Years (PYs) 2013 and 2014

A. Background for the End-Stage Renal Disease Quality Incentive Program for PYs 2013 and PY 2014

1. Overview of Quality Monitoring Initiatives

For over 30 years, monitoring the quality of care provided to end-stage renal disease (ESRD) patients and provider/facility accountability have been important components of the Medicare ESRD payment system. We view the ESRD Quality Incentive Program (QIP), required by section 1881(h) of the Social Security Act (the Act), as the next step in the evolution of the ESRD quality program that began more than three decades ago. Our vision is to continue to implement a robust, comprehensive ESRD QIP that builds on the foundation that has already been established. The payment year (PY) 2012 ESRD QIP was finalized in two regulations: One that finalized the three measures (75 FR 49030, 49182 (August 12, 2010) (hereinafter referred to as the ''CY 2011 ESRD PPS final rule'')); and one that finalized other aspects of the 2012 ESRD QIP, including the scoring methodology and payment reduction scale (76 FR 628 through 646) (hereinafter referred to as the ''2012 ESRD QIP final rule'').

2. Statutory Authority for the ESRD QIP

Section 1881(h) of the Act, as added by section 153(c) of MIPPA, requires the Secretary to develop a QIP that will result in payment reductions to providers of services and dialysis facilities that do not meet or exceed a total performance score with respect to performance standards established for certain specified measures. As provided under this section, payment reductions of up to 2.0 percent of the payments otherwise made to providers and facilities under section 1881(b)(14) of the Act will apply to payment for renal dialysis services furnished on or after January 1, 2012. Under section 1881(h)(1)(C) of the Act, payment reductions will only apply with respect to the year involved for a provider/facility and will not be taken into account when computing future payment rates for the impacted provider/facility.

For the ESRD QIP, section 1881(h) of the Act generally requires the Secretary to: (1) Select measures; (2) establish the performance standards that apply to the individual measures; (3) specify a performance period with respect to a year; (4) develop a methodology for assessing the total performance of each provider and facility based on the performance standards with respect to the measures for a performance period; and (5) apply an appropriate payment reduction to providers and facilities that do not meet or exceed the established total performance score.

3. Payment Year (PY) 2012 ESRD QIP

As required by section 1881(h)(2)(A)(i) of the Act, we selected three measures for the payment year (PY) 2012 QIP. We finalized two anemia management measures that reflect the labeling approved by the Food and Drug Administration (FDA) for the administration of erythropoiesis stimulating agents (ESAs) and one hemodialysis adequacy measure. The following are the three measures (finalized in the CY 2011 ESRD PPS final rule) for the PY 2012 ESRD QIP:

- Percentage of Medicare patients with an average Hemoglobin < 10.0g/dL (Hemoglobin Less Than 10g/dL Measure)
- Percentage of Medicare patients with an average Hemoglobin > 12.0g/dL (Hemoglobin Greater Than 12g/dL Measure)
- Percentage of Medicare patients with an average Urea Reduction Ratio (URR) ≥ 65 percent (URR Hemodialysis Adequacy Measure).

A full description of the methodologies used for the calculation of the measures can be reviewed at: *http://www.dialysisreports.org/pdf/esrd/public/DFRGuide.pdf* (see the ''Facility Modality, Hemoglobin, and Urea Reduction Ratio'' section of the document).

Other aspects of the PY 2012 ESRD QIP finalized in the PY 2012 ESRD QIP final rule included the establishment of performance standards for these measures (including applying the special rule under section 1881(h)(4)(E) of the Act) and establishing a scoring methodology for calculating individual total performance scores ranging from 0–30 points based on the three finalized measures. As part of our methodology for calculating the provider/facility total performance score, we weighted the Hemoglobin Less Than 10g/dL Measure at 50 percent of the score, while the other hemoglobin measure and the URR Hemodialysis Adequacy Measure were weighted at 25 percent of the score. We also finalized a policy under which providers/facilities that did not meet or exceed a total performance score of 26 points would receive a payment reduction ranging from 0.5 percent to 2.0 percent.

B. Provisions of the Proposed Regulations for End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for PY 2013 and PY 2014

This proposed rule proposes to adopt new ESRD QIP requirements for payment years (PYs) 2013 and 2014. We believe that this approach is the most efficient way to make improvements to the program, adopt additional measures for the program in a timely fashion, and provide sufficient notice to ESRD providers and facilities so that they can most effectively and efficiently implement any changes needed to meet the requirements of the ESRD QIP.

1. Proposed PY 2013 ESRD QIP Requirements

a. Overview of the Proposed PY 2013 ESRD QIP

This section summarizes the requirements that we are proposing implement for the PY 2013 ESRD QIP. We are proposing that ESRD providers and facilities that do not meet these requirements would receive a reduction to the payments otherwise made under section 1881(b)(14) with respect to PY 2013 services, in accordance with section 1881(h)(1)(A) of the Act. In general, for the PY 2013 ESRD QIP, we propose to calculate individual total performance scores ranging from 0–30 points for providers and facilities based on two of the three measures that we adopted for the PY 2012 ESRD QIP. We propose to weight the total performance score for each provider/facility such that the proposed Hemoglobin Greater Than 12g/dL measure makes up 50 percent of the total performance score and the proposed URR Hemodialysis Adequacy measure makes up 50 percent of the total performance score. We are proposing that a provider/facility that does not meet or exceed a total performance score of 30 would receive a payment reduction in PY 2013 ranging from 0.5 percent to 2.0 percent, depending upon how far below this minimum total performance score its performance falls. Our specific proposals are discussed below.

b. Proposed Performance Measures for the PY 2013 ESRD QIP

Section 1881(h)(2)(A) of the Act requires that the measures specified for the ESRD QIP include measures on anemia management that reflect the labeling approved by the FDA for such management; measures on dialysis adequacy; to the extent feasible, a measure or measures on patient satisfaction; and such other measures that the Secretary specifies, including (to the extent feasible) measures on iron management, bone mineral metabolism, and vascular access, including for maximizing the placement of arterial venous fistula. As explained in detail below, we are proposing to adopt a number of new measures for the PY 2014 ESRD QIP, including a Kt/V measure, a vascular access infections measure, a vascular access type measure, a Standardized Hospitalization Ratio (SHR) Admissions measure, a patient experience of care reporting measure, a bone mineral metabolism reporting measure, and a NHSN dialysis event blood stream infection reporting measure. We are also continuing to develop additional measures on topics such as fluid weight management and pediatric ESRD treatment. However, in selecting measures for the PY 2013 ESRD QIP, we examined whether it would be feasible to propose to adopt any new measures for the program. In light of our proposal to select CY 2011 as the performance period (discussed more fully below), and that it is not feasible to adopt any of the measures mentioned above until the PY 2014 ESRD QIP, we have determined that there are no new measures available for adoption at this time.

We also carefully reexamined the three measures that we adopted for the 2012 ESRD QIP, and for the reasons discussed below, we are proposing to continue including only two of them, the Hemoglobin Greater Than 12g/dL measure and the URR Hemodialysis

Adequacy measure, in the PY 2013 ESRD QIP measure set. We are proposing to retire the Hemoglobin Less Than 10g/dL measure beginning with the PY 2013 ESRD QIP.

We have recently reassessed the evidence for the use of ESAs in patients with kidney disease through a National Coverage Analysis (CAG–00413N) and, while we did not seek to limit the coverage of these agents at this time, we could not identify a specific hemoglobin lower bound level that has been proven safe for all patients treated with ESAs. We found that randomized, controlled trials targeting patients to higher, rather than lower hemoglobin levels, or comparing the effect of ESAs against a placebo have indicated an increased risk of myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and overall mortality, and, in patients with a history of cancer, tumor progression or recurrence. The mechanism underlying this increased risk is not yet fully understood but could result from the actual hemoglobin level itself, the rate at which the hemoglobin level rises, the variability in hemoglobin levels achieved as a result of ESA use, or the ESA dose required. Regardless of the reason(s) for these risks, such findings indicate that safety is a valid concern for a subset of patients treated with ESAs. Because we cannot yet identify which patients would be included in this subset, and accordingly exclude them from the specifications for the Hemoglobin Less Than 10g/dL measure, we have concluded that it would not be appropriate to continue to incentivize ESRD providers and facilities to achieve hemoglobin levels above 10g/dL in all patients. In addition we believe that this change is reflective of the FDA modified dosing recommendation for erythropoiesis stimulating agents (*http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm*). We have discussed with the FDA our proposal to retire the Hemoglobin Greater Than 10 g/dL measure starting in PY 2013. Since this measure encourages providers to keep hemoglobin above 10 g/dL in all patients, the FDA agrees that removing this measure is consistent with the new labeling for erythropoeisis stimulating agents approved by the FDA. The previous labeling recommendations to maintain hemoglobin levels between 10 and 12 g/dL are no longer appropriate and have been removed from the drug label. We, therefore, propose to retire the Hemoglobin Less Than 10g/dL measure from the ESRD QIP measure set, beginning with the PY 2013 program.

We propose to maintain the Hemoglobin Greater Than 12g/dL measure as a measure of anemia management because studies have been unable to establish that higher hemoglobin levels are clinically beneficial. In addition, the studies continue to show that targeting hemoglobin levels above this level through the use of ESAs can contribute to adverse patient outcomes.[1] This measure, consistent with the requirement under section 1881(h)(2)(A)(i) of the Act, also continues to reflect the labeling approved by the FDA for anemia management. The FDA has stated that using ESAs to target a hemoglobin level of greater than 11g/dL increases the risk of serious adverse cardiovascular events and has not been shown to provide additional patient benefit. The Hemoglobin Greater Than 12g/dL measure focuses on achieved hemoglobin levels, not simply hemoglobin level targets, and these levels also reflect patient factors such as underlying causes of anemia and sensitivity to treatment. Since these factors can vary over time in an unpredictable fashion, even within an individual patient, we believe that the current anemia measure allows for these unanticipated excursions of the *achieved* hemoglobin while continuing to highlight that higher hemoglobin targets can result in adverse patient outcomes. We plan to revisit this measure with the input of stakeholders and will replace or update the measure for future years of the ESRD QIP if deemed appropriate. We seek public input on the continued inclusion of the Hemoglobin Greater Than 12g/dL measure in the PY 2013 ESRD QIP.

We are also proposing to retain the URR Hemodialysis Adequacy measure, which assesses the percentage of Medicare patients with an average URR ≥ 65 percent for PY 2013. Section 1881(h)(2)(A)(i) states that the measures specified under the ESRD QIP for a payment year shall include measures on dialysis adequacy. For the reasons stated in the CY 2011 ESRD PPS final rule (75 FR 49182) we believe that URR hemodialysis adequacy continues to be an appropriate and accurate measure of hemodialysis adequacy, although we note that we are proposing below to adopt an alternative measure of dialysis adequacy for the PY 2014 ESRD QIP.

Therefore, for the PY 2013 ESRD QIP, we propose to continue to use the following two measures previously adopted for the PY 2012 ESRD QIP:

- Hemoglobin Greater Than 12g/dL Measure.
- URR Hemodialysis Adequacy Measure.

We also propose to continue to use the specifications for these measures that we finalized for the PY 2012 ESRD QIP. Consistent with the PY 2012 ESRD, we are also proposing to require providers/facilities to have at least 11 cases that meet the reporting criteria for a measure in order to be scored on the measure. As we noted in the 2012 ESRD QIP final rule (76 FR 639), we believe that this minimum case threshold will help prevent the possibility that a small number of poor outcomes artificially, and for reasons unrelated to the quality of care, skews a small provider/facility's performance score. Additionally, eleven cases is a statistically valid threshold that will give us confidence that a provider or facility's total performance score is an accurate reflection of the quality of care it furnishes.

We seek public comments on our proposed selection of these two measures for the PY 2013 ESRD QIP.

c. Proposed Performance Period for the PY 2013 ESRD QIP

Section 1881(h)(4)(D) of the Act requires the Secretary to establish a performance period with respect to a year, and for that performance period to occur prior to the beginning of such year. We selected all of CY 2010 as the performance period for the PY 2012 ESRD QIP because we believe that it best balanced the need to collect and analyze sufficient data, allowed sufficient time to calculate total performance scores and prepare the pricing files needed to implement applicable payment reductions beginning on January 1, 2012, and allowed providers and facilities time to preview their performance scores and inquire about their scores prior to finalizing their scores and making performance data public (76 FR 631).

In determining what performance period to propose to select for the PY 2013 ESRD QIP, we carefully considered the impact of selecting all or part of CY 2011 as well as including part of CY 2012. We determined that using less than a 12-month period could reduce the validity of provider/facility performance data and that using data from multiple calendar years (and still making payments on time) would necessitate using data from multiple data sets collected over two different payment periods, and, therefore, would not provide sufficient time to compile the data files to make accurate provider/

[1] KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target, *American Journal of Kidney Diseases,* 50(3): Pages 471–530 (September 2007).

facility payments beginning with January 1, 2013 services. In light of the new ESRD PPS, we believe that it is important to assess the quality of care being furnished to ESRD patients, and that a year's worth of data will provide us with enough data to accurately and fairly determine whether a provider/facility has met or exceeded the proposed performance standards with respect to the proposed measures. For these reasons, we propose to select all of CY 2011 as the performance period for the PY 2013 ESRD QIP. We seek public comments on this proposal.

d. Proposed Performance Standards for the PY 2013 ESRD QIP

For the PY 2012 ERSD QIP, we established the performance standard for the measures using the special rule under section 1881(h)(4)(E) of the Act (76 FR 629). We selected as the performance standard for PY 2012 the lesser of (1) the performance of a provider or facility on each measure during 2007 (the year selected by the Secretary under the second sentence of section 1881(b)(14)(A)(ii) of the Act, referred to as the base utilization year), or (2) the national performance rate (calculated at the national aggregate level as the number of Medicare patients for whom the measure was achieved divided by the total number of Medicare patients eligible for inclusion in the measure) for each measure in a period determined by the Secretary. With respect to the second prong of this standard, the period we selected for the PY 2012 ESRD QIP was calendar year 2008 because data from that year was, at that time, the most recent publicly available data prior to the beginning of the performance period. As reported on the Dialysis Facility Compare Web site in November 2009, the 2008 national performance rates for the anemia management measures and the URR hemodialysis adequacy measure were:

- For the Hemoglobin Less Than 10g/dL measure (which is based on the national performance percentage of Medicare patients who have an average hemoglobin value less than 10g/dL): 2 percent.
- For the Hemoglobin More Than 12g/dL measure (which is based on the national performance percentage of Medicare patients who have an average hemoglobin value greater than 12g/dL): 26 percent.
- For the URR Hemodialysis Adequacy Measure (which is based on the national percentage of Medicare patients who have an average URR level of at least 65 percent): 96 percent.

In considering what performance standards to select for the PY 2013 ESRD QIP, we took into account the fact that we had selected a one year period for the PY 2012 ESRD QIP and that for the reasons discussed above, we would be proposing to select the next one year performance period for the PY 2013 ESRD QIP. We determined that comparing provider/facility performance over time based on data from successive years would be beneficial as this method would allow the public to most accurately gauge provider/facility improvement. We also noted that due to operational issues, it was not feasible for us to establish performance standards prior to the beginning of the proposed performance period, as required in order to establish performance standards under section 1881(h)(4)(A) of the Act. For these reasons, we propose to continue using the performance standard under section 1881(h)(4)(E) of the Act for the PY 2013 QIP. Under this proposed standard, providers/facilities would be evaluated based on the lesser of (1) the performance of the provider/facility in 2007, which is the year selected by the Secretary under the second section of section 1881(b)(14)(A)(ii), or (2) a performance standard based on the national performance rates for the measures in a period determined by the Secretary. With respect to the second prong, we propose to select CY 2009 because that is the most recent year-long period for which data is publicly available prior to the beginning of the proposed performance period. As reported on the Dialysis Facility Compare Web site, the 2009 national performance rates for the Hemoglobin Greater Than 12g/dL measure and the URR Hemodialysis Adequacy measure are:

- For the Hemoglobin Greater Than 12g/dL measure: 16 percent.
- For the URR Hemodialysis Adequacy Measure: 96 percent.

We seek public comments about the proposed selection of this performance standard for the PY 2013 ESRD QIP.

e. Proposed Methodology for Calculating the Total Performance Score for the PY 2013 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 provider and facility based on performance standards with respect to the measures selected for a performance period. Section 1881(h)(3)(A)(iii) of the Act states that the scoring methodology must include a process to weight the performance scores with respect to individual measures to reflect priorities for quality improvement, such as weighting scores to ensure that providers/facilities have strong incentives to meet or exceed anemia management and dialysis adequacy performance standards, as determined appropriate by the Secretary.

For the PY 2012 ESRD QIP, we finalized a scoring methodology under which we will calculate the performance of each provider and facility on each of the three measures by assigning 0–10 points based on how well the provider/facility performed on the measure during the CY 2010 performance period. For example, if a provider or facility meets or exceeds the performance standard for one measure, then it will receive 10 points for that measure. Providers or facilities that do not meet or exceed the performance standard for a measure will receive fewer than 10 points for that measure, with the exact number of points corresponding to how far below the performance standard the provider/facility's actual performance falls. Two points will be subtracted for every one percentage point the provider's/facility's performance falls below the performance standard (76 FR 632). The full rationale for this scoring methodology is presented in detail in the PY 2012 ESRD QIP final rule (76 FR 629 through 634).

For the PY 2013 ESRD QIP, we propose to adopt the same methodology for scoring provider/facility performance on each of the proposed measures that we adopted for the PY 2012 ESRD QIP. As discussed in the 2012 ESRD QIP final rule (76 FR 633), we believe that it is important to provide a clear-cut method for calculating scores initially while providers and facilities are becoming familiar with the program. Under this methodology, we would calculate the performance of each provider/facility on each measure by assigning points based on how well it performed on the measure in CY 2011 relative to the proposed performance standard (discussed above). If a provider or facility meets or exceeds the performance standard for a measure, then it would receive 10 points for that measure. We would award points for each measure based on a 0 to 10 point scale and would subtract 2 points for every 1 percentage point the provider or facility's performance during 2011, the proposed performance period, falls below the performance standard.

For the PY 2012 ESRD QIP, we also finalized a weighting methodology that weighted the Hemoglobin Less Than 10g/dL measure at 50 percent of the total performance score, with the remaining 50 percent of the total

performance score divided equally between the Hemoglobin Greater Than 12g/dL measure (25 percent) and the URR Hemodialysis Adequacy Measure (25 percent) (76 FR 633).

For the PY 2013 ESRD QIP, we are proposing to weight the total performance score for each provider/facility such that the proposed Hemoglobin Greater Than 12g/dL measure makes up 50 percent of the score and the proposed URR Hemodialysis Adequacy measure makes up 50 percent of the score. To be consistent with the scoring methodology that we finalized for the PY 2012 ESRD QIP, we propose award up to 30 points to a provider/facility based on its performance on the proposed measures. However, because we are only proposing to adopt two measures for the PY 2013 ESRD QIP measure set, we propose to calculate a provider's/facility's total performance score by multiplying each measure score (0–10 points) by 1.5, and adding both measure scores together to result in a 0–30 point range.

We seek public comments about the proposed scoring and weighting methodologies for the PY 2013 ESRD QIP.

f. Proposed Payment Reductions for the PY 2013 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 reductions in payments among providers and facilities achieving different levels of total performance scores, with providers and facilities achieving the lowest total performance scores receiving the largest reductions.

We implemented a sliding scale of payment reductions for the PY 2012 ESRD QIP, setting the minimum total performance score that providers/facilities will need to achieve in order to avoid a payment reduction at 26 points (76 FR 634). Providers/facilities that score between 21–25 points will receive a 0.5 percent payment reduction; between 16–20 points, a 1.0 percent payment reduction; between 11–15 points, a 1.5 percent payment reduction; and between 0–10 points, providers/facilities will receive the full 2.0 percent payment reduction (76 FR 634).

To ensure that providers/facilities are properly incentivized to provide quality care, we propose to implement a more rigorous sliding scale of payment reductions for the PY 2013 ESRD QIP and raise the minimum total performance score that providers/facilities would need to achieve in order to avoid a payment reduction from 26 to 30 points. Providers/facilities that score between 26–29 points would receive a 1.0 percent payment reduction; between 21–25 points, a 1.5 percent payment reduction; and between 0–20 points, providers/facilities would receive the full 2.0 percent payment reduction (see Table 5 below). We believe that applying a payment reduction of 2.0 percent to providers/facilities whose performance falls significantly below the performance standards, coupled with applying two intermediate payment reduction levels to providers/facilities based on lesser degrees of performance deficiencies, will provide proper incentives for all providers/facilities to improve the quality of their care.

TABLE 5—PROPOSED PY 2013 PAYMENT REDUCTION SCALE

Total performance score	2013 Percent of payment reduction
30 Points	0.0
26–29	1.0
21–25	1.5
0–20	2.0

TABLE 6—FINALIZED PY 2012 PAYMENT REDUCTION SCALE

Total performance score	2012 Percent of payment reduction
30–26 Points	0.0
21–25	0.5
16–20	1.0
11–15	1.5
0–10	2.0

We seek public comments on this proposal.

2. Proposed PY 2014 ESRD QIP

a. Overview of the Proposed PY 2014 ESRD QIP

This proposed rule also proposes to implement requirements that will apply to the PY 2014 ESRD QIP. In general, we propose to calculate individual total performance scores ranging from 0–100 points for providers and facilities based on eight measures that we propose to adopt for the PY 2014 ESRD QIP. We propose to continue using the Hemoglobin Greater Than 12g/dL measure that we are proposing to use for the PY 2013 ESRD QIP, and to adopt four additional clinical measures: Kt/V Dialysis Adequacy measure; Vascular Access Type measure; Vascular Access Infections measure; and Standardized Hospitalization Ratio (SHR) Admissions measure. We also propose to adopt three additional measures that would be scored differently from the proposed clinical measures. These proposed measures are the National Health Safety Network (NHSN) Dialysis Event reporting measure, the Patient Experience of Care reporting measure (using the In-Center Hemodialysis Consumer Assessment of Healthcare Advisors (ICH CAHPS) survey tool), and the Mineral Metabolism reporting measure. Providers/facilities that do not meet or exceed a certain total performance score would receive a payment reduction ranging from 0.5 percent to 2.0 percent.

b. Proposed Performance Measures for the PY 2014 ESRD QIP

For the PY 2014 ESRD QIP, we propose to continue using the Hemoglobin Greater Than 12g/dL measure, adopt seven new measures (Kt/V Dialysis Adequacy, Vascular Access Type, Vascular Access Infections, SHR Admissions, NHSN Dialysis Event reporting, Patient Experience of Care reporting, and Mineral Metabolism reporting) and to retire the URR Hemodialysis Adequacy measure. We strongly believe that the eight proposed measures individually and collectively provide information useful for assessing provider/facility quality, for informing patient decision-making, and for furthering CMS and HHS priorities for quality improvement activities.

We note that we are proposing for the first time to adopt measures under section 1881(h)(2)(A)(iii) of the Act. In specifying such measures, we recognize that section 1881(h)(2)(B)(i) of the Act requires that they must have been endorsed by the entity with a contract under section 1890(a) of the Act (that entity is currently the National Quality Forum (NQF)) unless the exception in clause (ii) applies. That provision provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practicable measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by consensus organizations identified by the Secretary.

i. Proposed Anemia Management Measure (Hemoglobin Greater Than 12g/dL)

Section 1881(h)(2)(A)(i) of the Act requires that the measures specified for the ESRD QIP include measures on anemia management that reflect the

labeling approved by the FDA for such management. For the PY 2014 ESRD QIP, we propose to retain the Hemoglobin Greater Than 12g/dL measure that we adopted for the PY 2012 ESRD QIP and that we are proposing to retain for the PY 2013 ESRD QIP. We are making this proposal for the same reasons (discussed above) we proposed to retain this measure for the PY 2013 ESRD QIP measure set.

We also propose to continue to use the specifications for this measure that we finalized for the PY 2012 ESRD QIP and which we have proposed for the PY 2013 ESRD QIP. We also propose to continue requiring that providers/facilities have at least 11 cases that meet the reporting criteria in order to be scored on the measure. As noted above, we believe that this minimum case threshold will help prevent the possibility that a small number of poor outcomes artificially, and for reasons unrelated to the quality of care, skew a small provider/facility's performance score. Also, eleven cases is a statistically valid threshold that will give us confidence that a provider or facility's total performance score is an accurate reflection of the quality of care it furnishes. As a result, this threshold will help preserve beneficiary access to care at much needed small providers/facilities in rural and/or underserved areas.

Technical details on the methodology used to calculate the Hemoglobin Greater Than 12g/dL measure are available on the Arbor Research Collaborative for Health and University of Michigan Kidney Epidemiology and Cost Center Web site: *http://www.dialysisreports.org/pdf/esrd/public/DFRGuide.pdf.*

We seek public comment on the use of the Hemoglobin Greater Than 12g/dl measure in the PY 2014 ESRD QIP.

ii. Proposed Kt/V Dialysis Adequacy Measure

For the PY 2014 ESRD QIP, we are proposing to retire the URR Hemodialysis Adequacy measure we adopted for the PY 2012 ESRD QIP and proposed to retain for the PY 2013 ESRD QIP. In its place, we are proposing to adopt a Kt/V measure of dialysis adequacy (K = dialyzer clearance, t = dialysis time, and V = volume of distribution) for the PY 2014 ESRD QIP. We note that we have asked all providers/facilities to report the Kt/V value and the date of the value on all ESRD claims since July 1, 2010 (see Change Request (CR) 6782).

Kt/V has been advocated by the renal community as a more widely accepted measure of dialysis adequacy. Specifically, Kt/V more accurately measures how much urea is removed during dialysis, primarily because the Kt/V calculation also takes into account the amount of urea removed with excess fluid. Further, this proposed measure assesses Kt/V levels in both hemodialysis (HD) patients (in-center and home (HHD)) and peritoneal dialysis (PD) patients, and is based on two Kt/V measures of dialysis adequacy that have been endorsed by the National Quality Forum (#0250 and #0321). Specifically, the proposed measure assesses the percent of Medicare dialysis patients (PD, HD and HHD) meeting the modality specific Kt/V threshold. For hemodialysis patients (home and in-center patients), we would measure the percentage of adult (≥ 18 years old) Medicare patients who have been on hemodialysis for 6 months or more and dialyzing thrice weekly whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a Kt/V of at least 1.2 during the proposed performance period. For peritoneal dialysis patients, we would measure the percentage of adult (≥ 18 years old) Medicare patients whose average delivered peritoneal dialysis dose was a weekly Kt/V urea of at least 1.7 (dialytic + residual) during the proposed performance period. At this time, the measure specifications exclude pediatric patients because there is not a consensus on what an adequate Kt/V level should be in this patient population.

In light of the fact that the renal community has advocated the use of this measure, it is based on two NQF endorsed measures of Kt/V dialysis adequacy, and our belief that Kt/V is an accurate measure of dialysis adequacy, we propose to adopt the Kt/V Dialysis Adequacy measure for the PY 2014 ESRD QIP. We also propose to require that providers/facilities have at least 11 cases that can be reported under the measure specifications to be scored on this measure. As stated above, we believe that this minimum case threshold will help prevent the possibility that a small number of poor outcomes artificially, and for reasons unrelated to the quality of care, skew a small provider/facility's performance score. Technical details on the proposed methodology we would use to calculate this measure are available at: *http://www.arborresearch.org/ESRD_QMS.aspx.*

We seek public comments on the retirement of the URR Hemodialysis Adequacy measure and the proposed adoption of the Kt/V Dialysis Adequacy measure for the PY 2014 ESRD QIP. We also seek public comments on the exclusion of pediatric patients from this proposed measure.

iii. Proposed Vascular Access Type Measure

Section 1881(h)(2)(A)(iii) of the Act states, in part, that the measures specified for the ESRD QIP shall include other measures as the Secretary specifies, including, to the extent feasible, measures on vascular access, including for maximizing the placement of arterial venous fistula.

Arteriovenous fistulas (AV fistulas) are the preferred type of vascular access for patients on maintenance hemodialysis. Because of the lower complication rates (including reduced infections), decreased risk of patient mortality, and greater cost efficiency associated with this type of vascular access for eligible patients,[2, 3] we propose to adopt a Vascular Access Type measure, which is based on two measures that are endorsed by the NQF. These measures assess 1. the percentage of a provider's/facility's patients on hemodialysis using an autogenous AV fistula with two needles during the last HD treatment of the month (NQF #0257); and 2. the percentage of provider's/facility's hemodialysis patients who have an intravenous catheter in place for 90 days or longer prior to the last hemodialysis session (NQF #0256).

While catheter reduction and increased use of arteriovenous fistula are both important steps to improve patient care, we recognize that these two events are tightly interrelated and do not want to penalize providers/facilities twice for related outcomes. We are therefore proposing to combine these two separate measures into one measure to contribute jointly to the Total Performance Score. Because the rates and goals for each subcomponent measure are very different, we are proposing to calculate two measure rates for the measure, based on a provider/facility's performance on each subcomponent measure, and to adopt a different methodology (discussed below) for purposes of setting performance standards and scoring providers/facilities on this measure. We seek public comment on the proposed combination of these two measures into one overall score for the Vascular Access Type measure versus separating the measures into two separate

[2] *http://www.kidney.org/professionals/kdoqi/guideline_uphd_pd_va/va_guide2.htm.*

[3] *http://www.fistulafirst.org/AboutAVFistulaFirst/History.aspx.*

measures which would then contribute separate scores to the overall Total Performance Score equally weighted with the other clinical measures.

As explained above, 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 the NQF). Under the exception set forth in section 1881(h)(2)(B)(ii), in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We believe that assessing the type of vascular access used in hemodialysis patients is important because clinical evidence, as noted previously, has shown that proper vascular access reduces the risk of adverse outcomes such as infections. In determining how to best measure vascular access type for purposes of the ESRD QIP, we considered proposing to adopt the two NQF-endorsed measures noted above (#0256 and #0257). However, under the NQF-endorsed specifications for each of these measures, data must be collected from all hemodialysis patients. We currently collect this data via claims forms for Medicare patients only. We believe that expanding this data collection to all patients would be overly burdensome for ESRD providers/facilities and would not allow us to collect this data in time for the PY 2014 program. For these reasons, we are proposing to limit the patient population to which this proposed measure applies to the Medicare hemodialysis patient population, and to collect the data via Medicare claims. Accordingly, we are proposing to adopt this measure under section 1881(h)(2)(B)(ii) of the Act.

We note that since July 1, 2010, we have asked dialysis providers/facilities to submit vascular access type data on ESRD claims (Change Request 6782). We also note that hemodialysis patients with acute renal failure, peritoneal dialysis patients, and patients under 18 years of age would be excluded from this proposed measure. Medicare patients with acute renal failure receive treatment for a relatively short period of time as kidney function is usually restored after an acute episode, thus making a fistula unnecessary; those on peritoneal dialysis require access through the peritoneal cavity; and the access considerations are different for those in the pediatric population. We also believe that adoption of this measure would be consistent with the efforts of the Fistula First initiative, which advances the use of fistulas proven to reduce the risk of infection/morbidity and mortality.[4]

Finally, we propose to require that providers/facilities have at least 11 cases that meet the reporting criteria for this proposed measure to be scored on it. As stated above, we believe that this minimum threshold will help prevent the possibility that a small number of poor outcomes artificially, and for reasons unrelated to the quality of care, skew a small provider/facility's performance score. Technical details on the methodology we propose to use to calculate this measure are available at: *http://www.arborresearch.org/ESRD_QMS.aspx*.

We seek public comment on the proposed adoption of this measure for the PY 2014 ESRD QIP.

iv. Proposed Vascular Access Infections Measure

Infections are one of the leading causes of hospitalizations and death among hemodialysis patients.[5] The reduction of healthcare-associated infections (HAI), which are infections that may have been contracted in process of receiving care, is a key priority area for the Department of Health and Human Services. We have engaged in national efforts such as the National Patient Safety Initiative and the Partnership for Patients to reduce the number of preventable infections across healthcare settings, and have worked with dialysis providers/facilities as part of this effort. Use of effective infection control measures have proven successful in reducing the risk of life-threatening infections.

We propose to measure dialysis access-related infection rates by assessing the number of months in which a monthly hemodialysis claim reports a dialysis access-related infection using HCPCS modifier V8, and we note that since July 1, 2010, we have asked dialysis providers/facilities to code all Medicare claims for dialysis access-related infections using this modifier (Change Request 6782). Pediatric patients (patients < 18 years of age) would be excluded from this measure because pediatric access considerations are greatly different than those of the adult patient population. Peritoneal dialysis patients would also be excluded from the calculation of the measure because there is no consensus on how to best measure dialysis access-related infection rates from catheters in these patients. We plan, however, to convene an expert panel for the purpose of trying to determine how to best address this issue in the pediatric and peritoneal dialysis patient populations.

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 the NQF). Under the exception set forth in section 1881(h)(2)(B)(ii), in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. While the proposed Vascular Access Infections measure is not NQF endorsed, we believe that the incidence of dialysis access-related infections is a significant patient safety concern. We are not aware of any measures endorsed by a consensus entity for vascular access infections for the ESRD population, and, at this time, the proposed Vascular Access Infections measure is also the only measure for which we have the necessary data to measure provider/facility performance. Thus, we are proposing to adopt this measure in order to promote patient safety in this area.

Technical details on the methodology used to calculate this measure are available at: *http://www.arborresearch.org/ESRD_QMS.aspx*.

We seek public comments on our proposal to adopt this measure in the PY 2014 ESRD QIP.

v. Proposed Standardized Hospitalization Ratio—Admissions Measure

Hospitalizations are an important indicator of patient quality of life and morbidity. According to 2009 data provided by the United States Renal Disease Data System, dialysis patients

[4] *See http://www.fistulafirst.org/* for further information regarding this initiative.

[5] *http://www.cdc.gov/media/releases/2011/p0301_vitalsigns.html.*

are hospitalized, on average, twice a year. The proposed Standardized Hospitalization Ratio-Admissions (SHR-Admissions) measure is a risk-adjusted measure of hospitalizations for Medicare dialysis patients. The data needed to calculate the proposed SHR-Admissions measure has been regularly reported to Dialysis Facility Reports (DFR) since 1995 (previously known as Unit-Specific Reports) and has been used by providers/facilities and ESRD Networks for quality improvement activities. These reports contain critical information on topics such as patient characteristics, treatment patterns, hospitalizations, mortality, and provider/facility characteristics.

As explained above, 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 the NQF). Under the exception set forth in section 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed measures for hospital admissions applicable to the ESRD population. We are unaware of any other measures for hospital admissions that have been approved by voluntary consensus standards bodies and/or endorsed by NQF for ESRD patients. Therefore, we are proposing to adopt this SHR-Admissions measure as it is directly applicable to the Medicare ESRD population. This measure is undergoing NQF review for endorsement, and we intend to revisit this measure in the future if this review results in substantive changes to this measure.

While we recognize that this is an ''all-cause'' measure, meaning that hospitalizations related to other medical conditions outside of ESRD are included in the measure, our review of the data listing the most frequent 100 in-patient diagnoses for ESRD patients demonstrate that a clear majority, estimated at 90 percent or greater, of admitting diagnoses are related to ESRD. The use of a subset of diagnoses was considered when the measure was reviewed by a Technical Expert Panel in 2007 convened by us, in part, to discuss this issue, but the panel concluded that use of specific diagnoses were more prone to poor inter-rater variation and variation in diagnosis coding, and for this reason, recommended that the measure be calculated using all admissions, regardless of the cause.

The proposed SHR-Admissions measure is claims-based and describes, as a ratio, the number of ESRD Medicare patient actual admissions versus expected hospitalizations adjusted for the provider's/facility's Medicare patient case mix. For inclusion in this measure, patients must have received services from the provider/facility for 60 days or more, and the provider/facility must have at least 5 patient years at risk (meaning the provider/facility must have at least 5 years of patient data aggregated across all patients at the facility during the performance period, for example, 10 patients with 6 months of data each, or 5 patients with 12 months of data each) to receive an SHR score. Technical details on the methodology we are proposing to use to calculate this measure, including the adjustment for patient mix, are available at: *http://www.arborresearch.org/ESRD_QMS.aspx.*

We seek public comments on our proposal to adopt this measure for the PY 2014 ESRD QIP.

vi. Proposed National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure

Healthcare-associated infections (HAI) are a leading cause of preventable mortality and morbidity across different settings in the healthcare sector, including at dialysis facilities. In a national effort to reduce this outcome, Department of Health and Human Services agencies, including CMS, are partnering with the Centers for Disease Control and Prevention (CDC) to encourage providers to report to the National Healthcare Safety Network (NHSN) as a way to track and facilitate action for reducing HAIs.

The NHSN is currently a voluntary, 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 2008 with acute care hospitals, long term acute 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 providers/facilities would support national goals for patient safety, and particularly goals for the reduction of healthcare-associated infections. Accordingly, we have developed a measure that would assess whether providers/facilities enroll and report dialysis event data to the NHSN.

By measuring only whether providers/facilities report dialysis event data to the NHSN, we believe that we can allow providers/facilities time to become familiar with the NHSN reporting process. We intend in the future to propose to adopt a measure that would score providers/facilities based on actual dialysis events reported to the NHSN.

Specifically, we are proposing that providers/facilities: (1) Enroll in the NHSN and complete any training required by the CDC; and (2) submit three or more consecutive months of dialysis event data to the NHSN. Under this proposal, providers/facilities would be able to submit data to the NHSN until the end of the month following the month for which it collected data. For example, if a provider/facility chose to submit data for October 2012, it would have until November 30, 2012 to submit that data. Information regarding NHSN enrollment and training can be accessed at: *http://www.cdc.gov/nhsn/enroll.html.* Section 1881(h)(2)(B)(i) of the Act requires that unless the exception set forth in section 1881(h)(2)(B)(ii) applies of the Act, 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 the NQF). Under the exception set forth in section 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Although a measure calculated using NHSN dialysis event data results is currently under review by the NQF, we are not aware that any measure similar to the reporting measure we are proposing to adopt has been endorsed or adopted by any consensus building entity. As we explained above, we are proposing to adopt a limited reporting measure because we believe it is important to incentivize providers/facilities to report so that providers/facilities will have a process for such

reporting should we consider measuring providers/facilities on the incidence of these dialysis events in future years. Accordingly, we are proposing to adopt this measure under the exception authority in section 1881(h)(2)(B)(ii) of the Act. We note that because HAIs are a significant patient safety concern, we intend to propose to adopt one or more measures that assess actual dialysis event rates in the future.

We seek public comments on our proposal to adopt the NHSN Dialysis Event reporting measure for the PY 2014 ESRD QIP.

vii. Proposed Patient Experience of Care Survey Usage Measure

Section 1881(h)(2)(A)(ii) of the Act states that the measures specified for the ESRD QIP shall include, to the extent feasible, a measure (or measures) of patient satisfaction as the Secretary shall specify. Information on patient experience with care at a provider/facility is an important quality indicator to help providers/facilities improve services to their patients and to assist patients in choosing a provider/facility at which to seek care. We propose to adopt a measure for the PY 2014 ESRD QIP that assesses provider/facility usage of the In-Center Hemodialysis (ICH) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey. The intent of including this reporting measure is to assess the degree to which providers/facilities are providing their patients with a voice in their quality of hemodialysis care.

The ICH CAHPS Survey was developed by the Agency for Healthcare Research and Quality (AHRQ) to assess the experience of hemodialysis patients receiving in-center dialysis. The areas evaluated by the ICH CAHPS Survey include:

- Nephrologists' communication and caring.
- Quality of dialysis center care and operations.
- Providing information to patients.
- Rating of kidney doctors.
- Rating of dialysis center staff.
- Rating of dialysis center.

The results of this survey have been used since January 2006 by many providers/facilities as well as ESRD Networks for improving the care and services furnished to beneficiaries receiving hemodialysis. We have also required that providers/facilities include patient experience of care or satisfaction as a component of their quality assessment and performance improvement program as part of the conditions for coverage since 2008. While we did not specifically require use of the standardized ICH CAHPS tool, we strongly encouraged providers/facilities to use it to assess patient experience of care (73 FR 20415).

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 the NQF). Under the exception set forth in section 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Although the ICH CAHPS Survey itself has been endorsed by the NQF (#0258), the measure we are proposing to adopt, which assesses the extent to which providers/facilities use the survey, has not, and we are not aware that such a measure has been endorsed or adopted by any consensus building organization. However, as explained above, we believe it is important to incentivize providers/facilities to administer the survey. Therefore, we are proposing to adopt this measure under the exception in section 1881(h)(2)(B)(ii) of the Act, and we note that we intend to propose to adopt in the future a measure that would be calculated using the actual ICH CAHPS survey results.

Specifically, we propose to measure whether a provider/facility has attested that it successfully administered the ICH CAHPS survey during the proposed performance period for the PY 2014 program.

We propose that providers/facilities would be required to submit this attestation through CROWNWeb, which will be implemented nationally in 2012, by January 30, 2013 at 11:59 p.m. EST. We seek comments on the feasibility of this electronic submission through CROWNWeb and further request comments on whether providers/facilities should be allowed to elect to submit these attestations in paper format.

As noted above, we are only proposing to measure whether a provider/facility administers the survey, and are not proposing to measure a provider's/facility's actual performance based on the survey results. We expect to adopt the ICH CAHPS survey itself as a measure for the ESRD QIP in future rulemaking. For purposes of reporting this proposed measure for the ESRD QIP, we will consider the ICH CAHPS survey to have been administered if the provider/facility administered it in accordance with the current specifications endorsed for the survey. These specifications can be accessed at: *https://www.cahps.ahrq.gov/content/products/ICH/PROD_ICH_Intro.asp?p=1022&s=222*. We seek public comments on our proposal to adopt the Patient Experience of Care Survey reporting measure for the PY 2014 ESRD QIP.

viii. Proposed Mineral Metabolism Reporting Measure

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 (calcium and phosphorus) are exceedingly common and contribute significantly to morbidity and mortality in patients with advanced chronic kidney disease. Numerous studies have associated disorders of mineral metabolism with morbidity, including fractures, cardiovascular disease, and mortality. Overt symptoms of these abnormalities often manifest in only the most extreme states of calcium-phosphorus dysregulation, which is why we believe that routine blood testing of calcium and phosphorus is necessary to detect abnormalities.[6]

The Kidney Disease: Improving Global Outcomes (KDIGO) 2009 guideline[7] recommends that the serum phosphorus level in a dialysis patient generally be lowered toward the normal range, but does not recommend a specific target level that would apply to all patients. The guideline also recommends that therapy to correct for abnormal levels be administered based on the health needs of the individual patient. Accordingly, we do not feel it is appropriate at this time to propose to adopt a measure that would penalize providers/facilities if they did not achieve a specific target serum

[6] Kidney Disease: Improving Global Outcomes (KDIGO) CKD–MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease–mineral and bone disorder (CKD–MBD). *Kidney International* 2009; 76 (Suppl 113): S1–S130.)

[7] Kidney Disease: Improving Global Outcomes (KDIGO) CKD–MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of chronic kidney disease–mineral and bone disorder (CKD–MBD). *Kidney International* 2009; 76 (Suppl 113): S1–S130.)

phosphorus level in all patients. We also note that there is currently no NQF endorsed measure dealing with the achievement of specific target phosphorus levels.

The KDIGO recommendation regarding serum calcium levels for dialysis patients is also to maintain serum calcium in the normal range. We note that the NQF is currently considering whether to endorse the following mineral metabolism measure:

- The percentage of patients in a dialysis facility with a 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.

Go to *http://www.qualityforum.org/Projects/e-g/End_Stage_Renal_Disease_2010/End_Stage_Renal_Disease_2010.aspx* to find more information regarding the National Voluntary Consensus Standards for ESRD.

Despite the current lack of consensus on specific target ranges for both phosphorus and calcium levels in dialysis patients, we believe there is consensus that monthly monitoring of calcium and phosphorus is important for early detection of abnormalities. We also note that the NQF has endorsed phosphorus and calcium monitoring measures (NQF #0261 and NQF #0255) and, in 2008, we adopted serum calcium and serum phosphorus monitoring as CPM measures (*http://www.arborresearch.org/ESRD_QMS.aspx*).

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 the NQF). Under the exception set forth in section 1881(h)(2)(B)(ii) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Although we gave due consideration to the NQF endorsed measures on phosphorus and calcium level monitoring in dialysis patients, it is not feasible for us to propose to adopt either of them at this time as we do not currently collect data on whether these levels are checked for each patient each month to allow calculation of the measure rates. We are also not aware that any other consensus building entity has endorsed or adopted measures on this topic. Therefore, we have developed a mineral metabolism reporting measure that is based on the two NQF-endorsed measures but requires providers/facilities to attest to compliance with monthly monitoring and propose to adopt it under section 1881(h)(2)(B)(ii) of the Act. This proposed measure will assess whether providers/facilities monitor a patient's phosphorus and calcium levels on a monthly basis throughout the portion of the proposed performance period during which the patient was treated. Although we will not be collecting actual serum calcium and serum phosphorus level data, or data regarding how these levels are being managed, we believe that routine monitoring of these levels is extremely important for the purpose of detecting abnormal states of calcium and phosphorous levels in this population, which this proposed measure will help address.

We propose that providers/facilities would be required to submit an attestation that they have conducted the appropriate monitoring through CROWNWeb, which will be implemented nationally in 2012. We further propose that this reporting must be electronically submitted by January 30, 2013 at 11:59 p.m. EST. We seek comments on the feasibility of this electronic submission through CROWNWeb and further request comments on whether providers/facilities should be allowed to elect to submit these attestations in paper format.

We seek public comment on our proposal to adopt the Mineral Metabolism reporting measure for the PY 2014 ESRD QIP.

We also note that we anticipate adopting for future years of the ESRD QIP one or more mineral metabolism clinical measures in addition to or in replacement of the proposed Mineral Metabolism reporting measure. Those measurement data will be collected via CROWNWeb under the authority of the Conditions for Coverage ESRD Final Rule (73 FR 20370) published in the **Federal Register** on April 15, 2008. We seek public comment on the clinical evidence that would support the establishment of specific target levels for serum phosphorus for purposes of developing one or more future ESRD QIP measures. We also seek public comment on the above calcium measure that has been submitted to the NQF for endorsement.

c. Proposed Performance Period for the PY 2014 ESRD QIP

Having decided to propose to adopt all of CY 2011 as the performance period for the PY 2013 QIP, we examined what performance period would be most appropriate for the PY 2014 ESRD QIP. We believe that a 12-month performance period is most appropriate for the ESRD QIP at this point in the program. A period of a year accounts for seasonal variations, but also provides a timely incentive and feedback for providers/facilities, as well as timely performance information for Medicare beneficiaries. We have also determined that CY 2012 is the first feasible period during which we can collect sufficient performance period data for all of the proposed measures. Therefore, we propose to select all of CY 2012 as the performance period for the PY 2014 ESRD QIP.

We seek public comments about the proposed selection of CY 2012 as the performance period for the PY 2014 QIP. We also seek public comments on the use of shorter performance periods in future years of the ESRD QIP.

d. Proposed Performance Standards for the PY 2014 ESRD QIP

For the PY 2014 ESRD QIP, we are proposing to establish performance standards under section 1881(h)(4)(A) of the Act because it is feasible to establish them prior to the beginning of CY 2012, the proposed start of the performance period. This section generally provides that the Secretary shall establish performance standards with respect to measures selected for the ESRD QIP for a performance period with respect to a year. Furthermore, under section 1881(h)(4)(B) of the Act, these performance standards must include levels of achievement and improvement, as determined appropriate by the Secretary. To establish performance standards under section 1881(h)(4)(A) of the Act, the Secretary must also comply with section 1881(h)(4)(C) of the Act, which requires the Secretary to establish performance standards prior to the beginning of the performance period for the year involved.

With respect to three of the proposed clinical measures (Hemoglobin Greater Than 12g/dL, Kt/V Dialysis Adequacy, and Vascular Access Infections), we propose to set the achievement performance standard under section 1881(h)(4)(A) of the Act as the national performance rate on each measure during a proposed baseline period. We propose that the national performance rate for each measure would be calculated at the national aggregate level

as the number of Medicare patients for whom the measure was achieved divided by the total number of Medicare patients eligible for inclusion in the measure. Additionally, we propose to set the improvement performance standard as the national performance rate on each measure during the same proposed baseline period because we believe that it is important to encourage the utmost improvement in quality and care. We believe that selecting the national performance rate as the performance standard for both the improvement and achievement performance standards (collectively, the performance standards) represents a meaningful and achievable standard of provider/facility performance because it represents how well providers/facilities are actually performing on each measure during a previous baseline period while still allowing significant room for improvement. Our goal is to incentivize providers/facilities to achieve these national performance rates, whether they do so by attaining achievement points or improvement points under our proposed scoring methodology (discussed below). We expect that the national performance rate on each measure will increase in future years of the ESRD QIP because it will reflect overall improved levels of performance.

To ensure that these proposed performance standards are based on a full calendar year of performance data that is as close as possible to the proposed performance period, we propose to use a baseline period from July 1, 2010 to June 30, 2011. This proposed baseline period will enable us to calculate national performance rate values for these proposed clinical measures before the beginning of the performance period, and we intend to specify those values in the final rule.

With respect to the proposed Vascular Access Type measure, we are proposing to set performance standards using the same methodology and baseline period that we are proposing to use for the three proposed clinical measures discussed above, however we would set performance standards for each of the subcomponent measures rather than for the overall combined measure. We seek public comment on this methodology for setting the performance standards for this measure.

With respect to the proposed SHR-Admissions measure, we also propose to establish the performance standards as the national performance rate during a proposed baseline period. However, we propose to establish CY 2010 as the baseline period. Because this measure would be calculated using hospital claims, we have determined that we need additional time to calculate and finalize the performance standards in order to specify the precise values in the final rule.

We specify example performance standards, generally using data from July 1, 2010 through November 30, 2010 for the proposed Hemoglobin Greater Than 12g/dL, Kt/V Dialysis Adequacy, Vascular Access Type, and Vascular Access Infections measures, and CY 2009 for the proposed SHR–Admissions measure in Table 7, below. We note that because the proposed Vascular Access Type measure subcomponents would only include patients who have been on a catheter for 90 days, we are only able to provide example performance standards from October 1, 2010 through November 30, 2010 for the catheter subcomponent of the Vascular Access Type measure.

TABLE 7—EXAMPLE ACHIEVEMENT AND IMPROVEMENT PERFORMANCE STANDARDS FOR THE PY 2014 ESRD QIP

Proposed measure	Example achievement/ improvement performance standard (percent)
Hemoglobin Greater Than 12 g/dL Measure	15
Dialysis Adequacy Measure (Kt/V)	94
Vascular Access Type Measure	XX
% Fistula	55
% Catheter	12
Vascular Access Infections Measure[1]	0.2
SHR–Admissions Measure[2]	1.0

[1] Measured as hemodialysis access-related bacteremia rate per 1000 hemodialysis days.
[2] Measured as ratio of observed hospitalizations to hospitalizations expected based on facility patient case mix.

We propose to establish the achievement performance standard for the proposed NHSN Dialysis Event reporting measure as the successful completion by providers/facilities of: (1) Enrollment in the NHSN and completion of the required training during the performance period (as verified by a digital certificate obtained from CDC), or, in the case of providers/facilities that have previously enrolled, continued enrollment throughout the entirety of the performance period; and (2) submission to the NHSN of at least 3 consecutive months of dialysis event data gathered during the performance period.

We propose to establish the achievement performance standard for the proposed Patient Experience of Care reporting measure as an attestation by the provider/facility at the end of the performance period that it successfully administered the ICH CHAPS survey during the proposed performance period.

We propose to establish the achievement performance standard for the proposed Mineral Metabolism reporting measure as whether the provider/facility measured the serum calcium and serum phosphorus levels of Medicare patients treated by the provider/facility at least once within the month throughout the duration of the proposed performance period.

As noted above, section 1881(h)(4)(B) of the Act provides that the performance standards established under section 1881(4)(A) of the Act must include levels of achievement and improvement, as determined appropriate by the Secretary. We have determined that an improvement performance standard is not appropriate for the proposed reporting measures because it is not feasible to measure improvement on these measures at this time because we do not have any existing data we can use to compare provider/facility performance.

We seek public comments on the proposed performance standards for all of the proposed PY 2014 ESRD QIP measures and the proposed baseline periods that we would use to establish the performance standards for the five proposed clinical performance measures.

We also note that we do not interpret section 1881(h)(1)(B) of the Act to require that providers/facilities meet or exceed the performance standards we establish with respect to each individual ESRD QIP measure. Rather, we are proposing to implement a scoring methodology that enables a provider/facility to avoid a payment reduction as long as it achieves a minimum total performance score that, as discussed more fully below, is equal to the total performance score it would have received, if it had met the performance standards for all of the proposed measures. We believe that this approach best balances the goal of incentivizing providers/facilities to provide quality care across all of the measures with recognizing the higher quality of care provided by those providers/facilities that exceed the performance standards on certain measures. We seek comment on this proposed approach to scoring providers/facilities.

Additionally, beginning in PY 2015, we intend to propose to establish floors for performance such that performance standards would never be lower than those set for the previous year, even if

provider/facility performance fails to improve, or even declines, over time. Although we would consider continuing to set the national performance rate as the achievement and/or improvement performance standard, we would also consider establishing future performance standards that reflect performance goals widely recognized by the ESRD medical community as demonstrating high quality care for ESRD patients, should such a consensus be reached. We welcome comments on this proposed approach.

e. Proposed Methodology for Calculating the Total Performance Score for the PY 2014 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 provider and facility based on the performance standards with respect to the measures selected for the performance period. Section 1881(h)(3)(B) of the Act requires the Secretary to calculate separate performance scores for each measure.

The final rule entitled, ''Medicare Programs; Hospital Inpatient Value-Based Purchasing Program,'' appeared in the **Federal Register** on May 6, 2011 (76 FR 26490). In this final rule, we stated our view that value-based purchasing represents an important step in revamping how care and services are paid for, allowing CMS to move increasingly toward rewarding better value, outcomes, and innovations instead of merely paying for volume (76 FR 26491). The final rule also set forth principles guiding the development of performance scoring methodologies, including:

- Providers should be scored on their overall achievement relative to national or other appropriate benchmarks. In addition, scoring methodologies should consider improvement as an independent goal.
- Measures or measurement domains need not be given equal weight, but over time, scoring methodologies should be more weighted towards outcome, patient experience and functional status measures.
- Scoring methodologies should be reliable, as straightforward as possible, and stable over time and enable consumers, providers, and payers to make meaningful distinctions among providers' performance.

For the first year of the ESRD QIP (PY 2012), we finalized a scoring methodology that provides a straightforward approach for assessing provider/facility performance intended for use with a very limited number of measures, and we are proposing to continue using this methodology for the PY 2013 ESRD QIP. We have recognized that this straightforward approach might not be appropriate as we adopt for the program new measures for which there could be wider variability in performance (75 FR 49222). For the PY 2014 ESRD QIP, we propose to adopt a new performance scoring methodology to replace the methodology we are using for the PY 2012 ESRD QIP and that we have proposed to use for the PY 2013 ESRD QIP. We believe that this scoring methodology will more accurately reflect a provider's/facility's performance on the measures proposed for the FY 2014 ESRD QIP because it will enable us to differentiate between providers/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 believe that this scoring methodology more closely aligns with the scoring methodology we have adopted for the Hospital Inpatient Value-Based Purchasing Program, and that it can readily accommodate the adoption of new ESRD QIP measures in the future. We further believe that the proposed methodology will better incentivize providers and facilities to both achieve high total performance scores and improve the quality of care they provide. The proposed performance scoring methodology is based on the methodology developed for the Hospital Value-Based Purchasing (VBP) program (76 FR 26513 through 26526). It is important to note that, while we have attempted to align the two scoring methodologies as much as possible, the ESRD QIP and the Hospital VBP program present distinct statutory and programmatic requirements that necessitate differences between the two scoring methodologies.

i. Setting Performance Benchmarks and Thresholds

Under the proposed scoring methodology for the PY 2014 ESRD QIP, a provider's/facility's performance on each of the five proposed clinical measures would be determined based on the higher of (1) an achievement score or (2) an improvement score. In determining the achievement score, we propose that providers/facilities would receive points along an achievement range, defined as a scale that runs from the achievement threshold to the benchmark. We are proposing to define the achievement threshold for each of these proposed measures as one standard deviation below the achievement performance standard for the measure (which we proposed above to set as the national performance rate on the measure during the baseline period). We believe that setting the achievement threshold at one standard deviation below the national performance rate will enable us to reserve greatest penalty to those providers/facilities whose performance is substantially below the national performance rate. Performance at this level represents a significant deviation in care from the performance standard (performance worse than about 84% of providers/facilities based on a normal distribution), while at the same time, accounting for the degree of variance across provider/facility performance levels. We also believe that it will provide an incentive for providers/facilities to continuously improve their performance while not reducing the payments made to providers/facilities that score at or above the national performance rate. We are proposing to define the benchmark as provider/facility performance at the mean of the top decile of provider/facility performance during the baseline period because it represents a demonstrably high but achievable standard of excellence that the best performing providers/facilities reached during the baseline period. This approach is consistent with the approach adopted in the Hospital Inpatient Value-Based Purchasing Program (76 FR 26515).

In determining an improvement score for the five proposed clinical measures, we propose that providers/facilities would receive points along an improvement range, defined as a scale running between the provider's/facility's performance on the measure (the improvement threshold) during the baseline period and the benchmark. The provider/facility's improvement score would be calculated by comparing its performance on the measure during the performance period to its performance on the measure during the baseline period.

Under this proposed methodology, we propose to establish the benchmarks and achievement thresholds for three of the proposed clinical measures (Hemoglobin Less Than 12g/dL, Kt/V Dialysis Adequacy, and Vascular Access Infections), using national data from a one-year baseline period from July 2010 to June 2011 (discussed above in section II.B.2.d of this proposed rule). For the proposed Vascular Access Type measure, we propose to establish a separate benchmark and achievement threshold for each of the two subcomponent measures using national data from the proposed July 1, 2010 to June 30, 2011 baseline period. For the proposed SHR-Admissions measure, we

propose to establish the benchmark and achievement threshold using national data from CY 2010 as the baseline period.

In view of our desire to adopt a scoring methodology that will allow us to distinguish between providers and facilities that do not meet or exceed the performance standards established with respect to an individual measure, we are proposing to set the achievement threshold for the 2014 ESRD QIP at one standard deviation below the national performance rate of provider/facility performance during the baseline period. Setting the achievement threshold in this manner complies with the ESRD QIP statutory requirements, and enables us to provide discrete scores to providers/facilities based on how far their performance is below or above the performance standards. This proposed methodology will incentivize providers/facilities to continuously improve their performance, and will not penalize a provider/facility whose total performance score is equal to or above the performance standards for all measures.

ii. Scoring Provider and Facility Performance on Clinical Measures Based on Achievement

For four of the proposed clinical measures (Hemogloblin Greater Than 12g/dL, Kt/V Dialysis Adequacy, Vascular Access Infections, and SHR-Admissions), we propose to award between 0 and 10 points for achievement based on where a facility's/provider's performance falls relative to the proposed achievement threshold (which we propose above to define as one standard deviation below the national performance rate on a given proposed measure during the baseline period) and the proposed benchmark (which we propose to define above as performance at the mean of the top decile of national facility/provider performance during the baseline period), according to the following formula:

[9* ((Provider's performance period score—achievement threshold)/(benchmark—achievement threshold))] +.5, where the provider performance period score falls in the range from the achievement threshold to the benchmark.

All achievement points would be rounded to the nearest integer (for example, an achievement score of 4.5 would be rounded up to 5). If a provider's/facility's score was:

- Equal to or greater than the benchmark, the provider/facility would receive 10 points for achievement
- Equal to or greater than the achievement threshold (but below the benchmark), the provider/facility would receive a score of 1 to 9 points based on a linear scale established for the achievement range (which distributes 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.)
- Less than the achievement threshold (that is, the lower bound of the achievement range), the provider/facility would receive 0 points for achievement.

iii. Scoring Provider/Facility Performance on Clinical Measures Based on Improvement

Similar to the performance scoring model finalized in the Hospital VPB Program final rule (76 FR 26516 through 26526), we propose that providers/facilities would earn between 0 and 9 points on each of the four proposed clinical measures (Hemoglobin Greater Than 12/dL, Kt/V Dialysis Adequacy, Vascular Access Infections, SHR-Admissions) based on how much their performance on the measure during the performance period improved from their performance on the measure during the proposed baseline period. A unique improvement range for each measure would be established for each provider/facility which we propose to define as the distance between the provider's/facility's baseline period score and the benchmark for the measure (the mean of the top decile), according to the following formula:

[10 * ((Provider performance period score—provider baseline period score)/(Benchmark—provider baseline period score))] -.5, where the provider performance score falls in the range from the provider's baseline period score to the benchmark.

All improvement points would be rounded up to the nearest integer. If a provider's/facility's score on the measure during the performance period was:

- Greater than its baseline period score but below the benchmark (within the improvement range), the provider/facility would receive a score of 0 to 9 points based on the linear scale that defines the improvement range.
- Equal to or lower than its baseline period score on the measure, the provider/facility would receive 0 points for improvement.

iv. Calculating the Proposed Vascular Access Type Measure Score

We propose to calculate the Vascular Access Type measure score by first calculating the measure rate according to measure specifications for each of the two measure subcomponents. Those two rates would then be converted into separate achievement and improvement scores for each subcomponent using achievement and improvement ranges specific to each subcomponent measure as proposed. The higher of the achievement or improvement score for each measure component would then be averaged to produce one overall score for the Vascular Access Type measure. We believe that this method of calculating this measure stresses the importance of both vascular access sub-measures without penalizing providers/facilities for two similar measures or unduly weighting a provider's/facility's total performance score in favor of vascular access type measures.

v. Calculating the Proposed NHSN Dialysis Event Reporting Measure, Patient Experience Survey Usage Reporting Measure and Mineral Metabolism Reporting Measure Scores

We propose to adopt a different scoring methodology for the proposed NHSN Dialysis Event reporting measure, Patient Experience of Care Survey Usage reporting measure, and Mineral Metabolism reporting measure.

With respect to the proposed NHSN Dialysis Event Reporting measure, we propose to assign providers/facilities a score of 0, 5 or 10 points as follows:

- Providers/facilities that enrolled or were previously enrolled and continue to be enrolled in the NHSN during the performance period, completed the required training, and successfully reported at least 3-consecutive months of dialysis event data to the NHSN before January 30, 2013 for the period of January 1, 2012–December 31, 2012 would receive 10 points.
- Providers/facilities that enrolled in the NHSN and completed the required training during the performance period, but did not report at least 3-consecutive months of dialysis event data to the NHSN before January 30, 2013 for the period January 1, 2012 through December 31, 2012 would receive 5 points.
- Providers/facilities that failed to enroll in the NHSN and/or complete the required training during the proposed performance period would receive 0 points.

We propose to assign providers/facilities a score of 10 points if they attest that they successfully administered the ICH CAHPS survey during the performance period according to the specifications referenced above, while providers/facilities that did not provide such an attestation would receive 0 points.

We propose to assign providers/facilities that measured the serum calcium and serum phosphorus levels of all adult Medicare patients treated by the provider/facility at least once within the month throughout the duration of the proposed performance period a score of 10 points, while providers/facilities that did not do so would receive 0 points. This will be accomplished by a facility furnished attestation at the end of the performance period. Those facilities that do not provide this attestation will receive 0 points.

vi. Examples to Illustrate Proposed 2014 ESRD QIP Performance Scoring Model As Applied to Clinical Measures

Three examples are presented to illustrate how the proposed performance scoring model would be applied in the context of the PY 2014 ESRD QIP using previous data from 2008. Figure 1 shows Facility A's performance on the proposed Hemoglobin Greater Than 12g/dL measure. The example benchmark calculated for this measure in this case is 2 percent (mean of the top decile during the baseline period), while the example achievement threshold is 44 percent (one standard deviation below the national performance rate during the baseline period). Facility A's performance rate of 2 percent during the performance period meets the benchmark, 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. Example of Dialysis Facility Earning Points by Achievement or Improvement: Facility A

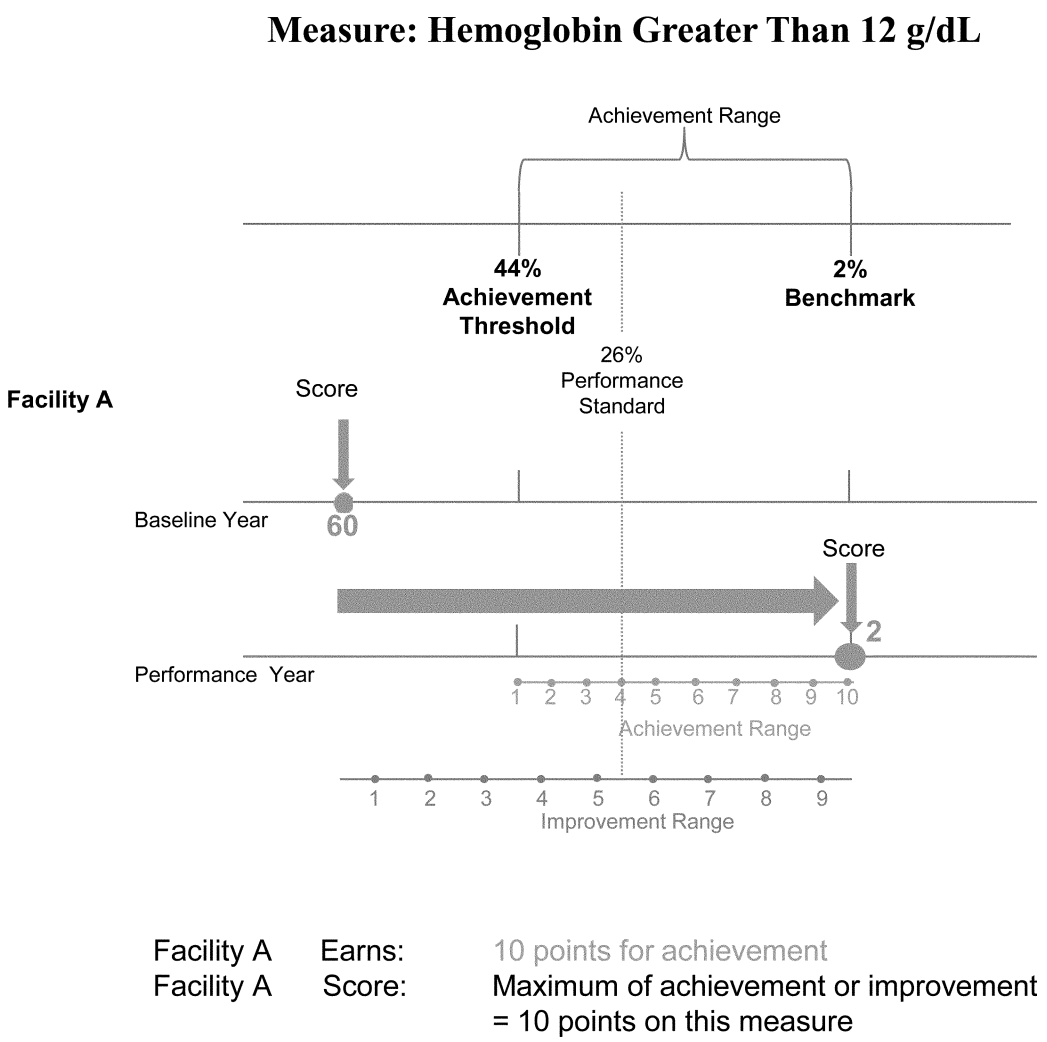
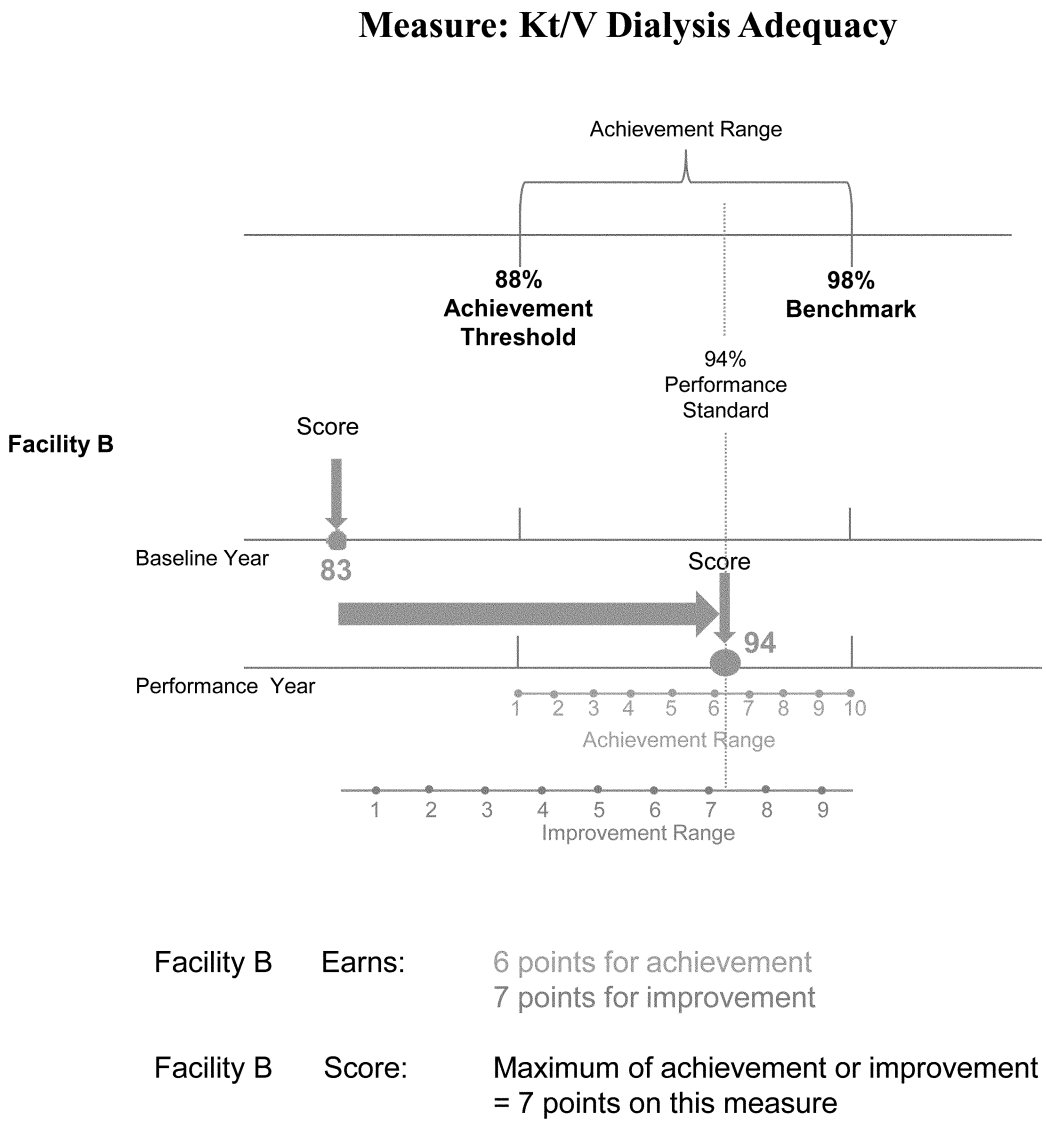


Figure 2 shows the scoring for another facility, Facility B. As illustrated below, the facility's performance on the Kt/V Dialysis Adequacy measure went from 83 percent in the baseline period to 94 percent during the performance period.

Figure 2. Example of Dialysis Facility Earning Points by Achievement or Improvement: Facility B



Applying the achievement scale, Facility B would earn 6 points for achievement, calculated as follows:

$9 * [(94 - 88)/(98 - 88)] + .5 = 5.4 + .5 = 5.9$, which is rounded to 6 points

However, because Facility B's performance during the performance period is also greater than its baseline period performance (but Facility B's performance period score is less than the benchmark), it would be scored based on improvement as well.

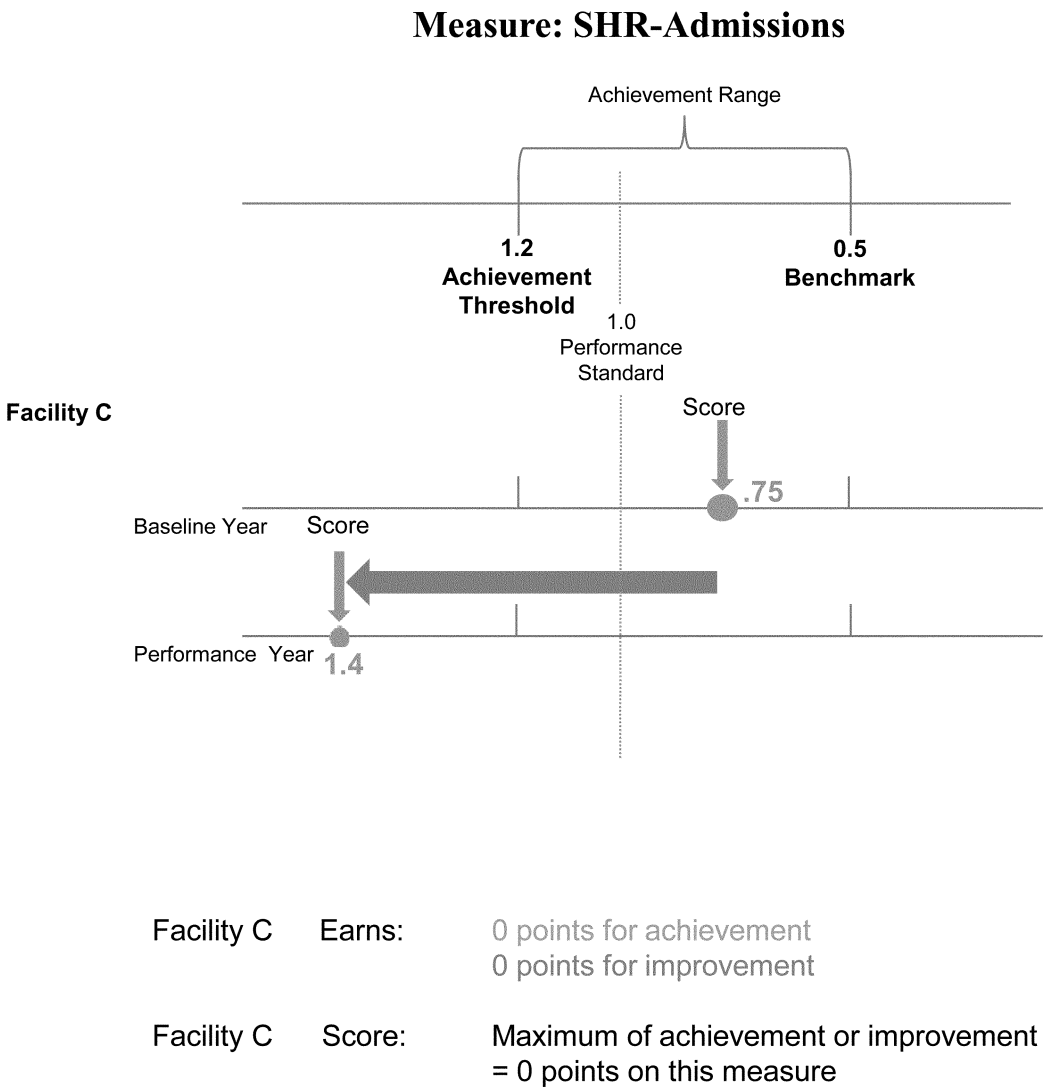
Applying the improvement scale, based on Facility B's period-to-period improvement, from 83% percent to 94% percent, Facility B would earn 7 improvement points, calculated as follows:

$10 * [(94 - 83)/(98 - 83)] - .5 = 7.3 - .5 = 6.8$, which would be rounded to 7 points

Because the higher of the two scores is used for determining the measure score, Facility B would receive 7 points for this measure.

In Figure 3 below, Facility C's performance on the proposed SHR measure drops from .75 in the baseline period to 1.4 in the performance period, a decline of .65. We note that a lower performance score on this proposed measure indicates better performance because it indicates that a provider/facility had fewer than expected hospital admissions.

Figure 3. Example of Dialysis Facility Earning Points by Achievement or Improvement: Facility C



Because Facility C's performance during the performance period falls below the achievement threshold of 1.2, it would receive no points for achievement. Facility C would also receive zero points for improvement because its performance during the performance period was lower than its performance during the baseline period. In this example, Facility C would receive zero points for the SHR Measure.

vii. Proposed Weighting of the PY 2014 ESRD QIP Measures and Calculation of the PY 2014 ESRD QIP Total Performance Score

Section 1881(h)(3)(A)(iii) of the Act provides that the methodology for assessing provider/facility total performance must include a process to weight the performance scores with respect to individual measures to reflect priorities for quality improvement, such as weighting scores to ensure that providers and 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 2014 ESRD QIP measures for purposes of calculating total performance scores, we considered a number of criteria. Specifically, we considered the number of measures we have proposed to include in the PY 2014 ESRD QIP as well as CMS and Departmental quality improvement priorities. We believe that weighting the five proposed clinical measures equally will incentivize providers/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. For these reasons, we propose to assign equal weight to the five proposed clinical performance measures: Hemoglobin Greater Than 12g/dL measure, Kt/V Dialysis Adequacy measure, Vascular Access Type measure, Vascular Access Infections measure, and SHR-Admissions measure; with those equal weights adding up to 90 percent of the total performance score. We believe that while the proposed reporting measures are valuable, the five proposed clinical measures measure actual patient outcomes and therefore, justify a proposed combined weight of 90 percent. We propose that the remaining 10 percent of the total performance score would be comprised of the three proposed reporting measures, with each

measure weighted equally. We believe it is of utmost importance to incentivize providers/facilities to improve clinical care, and, therefore, we believe it is necessary to heavily weight these measures. We recognize, however, that reporting is an important component in quality improvement, and that this type of measure should also be included in the ESRD QIP, although at a substantially lower weight.

We also considered whether and how we could award a total performance score to providers/facilities that do not report data on at least 11 cases with respect to one or more of the proposed clinical measures. As we stated above, we are proposing that this minimum number of cases must be reported with respect to each proposed clinical measure in order for the provider/facility to receive a score on that measure. We also note that we finalized a policy for the PY 2012 ESRD QIP that providers/facilities that reported less than 11 cases meeting the reporting criteria for each of the measures would not receive a total performance score (76 FR 639). Now that we are proposing to adopt additional measures, we believe it is appropriate to propose to calculate total performance scores for all providers/facilities. In the case of a provider/facility that has sufficient data from the performance period, but lacks sufficient data from the baseline period, we propose to only calculate its achievement score, since it would not be possible to calculate its improvement score. We believe that this approach is necessary to ensure that as many providers/facilities receive a score as possible. We are proposing that the combined weight of the clinical performance measures that are scored would still be equal to 90 percent of the total performance score, but only those measures for which providers/facilities report a minimum of 11 cases or more would be included in determining this score, with each such measure being weighting equally. We believe that this approach achieves that goal of including as many providers/facilities as possible, while ensuring the reliability of the measure scores.

Similarly, we propose to assign equal weight to the proposed NHSN Dialysis Event reporting measure, Patient Experience Survey reporting measure, and Mineral Metabolism reporting measure, with those equal weights adding up to 10 percent of the total performance score. Applying the proposed weighting criteria to a provider/facility that receives a score on all eight proposed measures, we propose to calculate the provider/facility total performance score using the following formula:

Total Performance Score = [(.1800 * Hemoglobin Greater Than 12g/dL Measure) + (.1800 * Kt/V Dialysis Adequacy Measure) + (.1800 * Vascular Access Type Measure) + (.1800 * Vascular Access Infections Measure) + (.1800 * SHR − Admissions)] + [(.0333 * NHSN Dialysis Event Reporting Measure) + (.0333 * Patient Experience Survey Reporting Measure) + (.0333 * Mineral Metabolism 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 provider/facility did not receive a score on the proposed Vascular Access Type and Vascular Access Infections measures, the provider's/facility's total performance score would be calculated as follows:

Total Performance Score = [(.3000 * Hemoglobin Greater Than 12g/dL Measure) + (.3000 * Kt/V Dialysis Adequacy Measure) + (.3000 * SHR) + (.0333 * NHSN Reporting Measure) + (.0333 * Patient Experience Survey Reporting Measure) + (.0333 * Mineral Metabolism Reporting Measure)] * 10, (the Total Performance Score will be rounded to the nearest integer (and any values ending in .5 would be rounded to the next higher integer)).

viii. Example of Applying the Proposed PY 2014 ESRD QIP Performance Scoring Model and Calculating the Total Performance Score

To illustrate the application of the proposed 2014 ESRD QIP performance scoring model, we offer the following example:

For the performance period, Facility D reports and receives raw scores on the measures as set forth in columns 5 and 6 of Table 8 below. For this example, we calculated sample benchmarks and achievement thresholds using 2009 National Facility Values data as the baseline period, except for the proposed SHR measure, for which we used 2008 National Facility Values. Columns 7 and 8 of Table 8 below display the individual measure scores (on achievement and improvement), while column 9 displays the earned points for each measure. Finally, row 9 displays the total performance score Facility D would receive after applying the proposed performance scoring and weighting methodology.

TABLE 8—EXAMPLE OF CALCULATION OF PROVIDER/FACILITY TOTAL PERFORMANCE SCORE BASED ON PROPOSED 2014 ESRD QIP SCORING METHODOLOGY

Quality measure	Measure description/definition	Achievement threshold (one standard deviation from the national performance rate)*	Benchmark (mean of the top decile)*	Provider/facility baseline score	Provider/facility performance score	Achievement points	Improvement points	Earned points (higher of achievement and improvement)
Hemoglobin greater than 12 g/dL measure.	% of patients with hemoglobin greater than 12 g/dL.	44%	2%	22.0%	14.0%	7	4	7
Dialysis Adequacy Measure (Kt/V).	% of hemodialysis (HD) patients with Kt/V ≥ 1.2.	85%	100%	80.0%	95.0%	7	8	8
Vascular Access Type Measure.	Average of the two sub-measures.	.....	.....	.....	.....	.....	.....	3
(Fistula)	*% of patients receiving treatment with fistulae.*	*40%*	*73%*	*25.0%*	*40.0%*	*0*	*3*	*3*
(Catheter)	*% of patients receiving treatment with catheter.*	*38%*	*11%*	*29%*	*30%*	*3*	*0*	*3*

TABLE 8—EXAMPLE OF CALCULATION OF PROVIDER/FACILITY TOTAL PERFORMANCE SCORE BASED ON PROPOSED 2014 ESRD QIP SCORING METHODOLOGY—Continued

Quality measure	Measure description/ definition	Achievement threshold (one standard deviation from the national performance rate)*	Benchmark (mean of the top decile)*	Provider/ facility baseline score	Provider/ facility performance score	Achievement points	Improvement points	Earned points (higher of achievement and improvement)
Vascular Access Infections Measure.	Overall access-related bacteremia: Rate of access-related bacteremia among adult chronic HD patients (Express as: Rate per 1000 HD patient days).	3.1	0.0	0.5	1.1	6	0	6
SHR-Admissions Measure.	Standardized Hospitalization Ratio.	1.35	0.58	1.32	1.54	0	0	0
NHSN Dialysis Event Reporting Measure.	Enroll and report at least 3 months of dialysis event data.	N/A	N/A	N/A	10	N/A	N/A	10
Patient Experience of Care Survey Usage Reporting Measure.	Providers/facilities must attest that they successfully fielded survey during the performance period.	N/A	N/A	N/A	10	N/A	N/A	10
Mineral Metabolism Reporting Measure.	Measure serum calcium and serum phosphorus levels of Medicare patients.	N/A	N/A	N/A	10	N/A	N/A	10
					Provider/Facility Total Performance Score:			53.19

* Achievement Thresholds and Benchmarks are based on 2009 National Facility Values (except for the SHR-Admissions Measure, which is based on 2008 National Facility Values).

We solicit public comment on the proposed performance scoring methodology.

f. Proposed Payment Reductions for the PY 2014 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 providers and facilities such that providers and facilities achieving the lowest total performance scores receive the largest payment reductions. We have implemented a sliding scale of payment reductions for the PY 2012 ESRD QIP, (76 FR 634) and are proposing a similar scale for the PY 2013 ESRD QIP. In developing a payment reduction scale for the PY 2014 ESRD QIP, we sought to create an approach that would retain aspects of the tiered sliding scale selected for the PY 2012 ESRD QIP, but also reflect the change in provider/facility scores under the new scoring methodology. Under this proposed approach, a provider/facility would not be required to meet or exceed the performance standards with respect to each of the eight proposed measures in order to avoid receiving a payment reduction under the ESRD QIP. Rather, even if a provider/facility failed to meet or exceed the performance standards with respect to one or more of these measures, the provider/facility could avoid a payment reduction if it achieved a minimum total performance score that is equal or greater than the minimum total performance score it would receive if it had met the performance standards for each proposed measure, or, in the case of the Vascular Access Type measure, for the two subcomponent measures. Because we are proposing to establish the performance standards, achievement thresholds, and benchmarks for each of the proposed clinical measures based on provider/facility performance during the respective proposed baseline period that applies to the measure, we will not know what each of those values will be until those baseline periods have concluded. However, because we have proposed to assign 10 points to each provider/facility that meets the achievement performance standard on each of the three reporting measures, we know how performance on these measures will factor into this minimum total performance score. We estimate at this time that the minimum total performance score that a provider/facility would have to achieve to avoid a payment reduction would be 60 points, and we will specify the exact number in the final rule. We propose to implement at least a 1.0 percent payment reduction for all providers/facilities that fail to meet or exceed this minimum total performance score.

To ensure that the proposed payment reduction methodology complies with the section 1881(h)(3)(A)(ii) requirement that providers and facilities achieving the lowest total performance scores receiving the largest reductions, we propose to increase the payment reduction from 1.0 percent to 1.5 percent for all providers/facilities that fail to achieve a total performance score that is 10 points below the minimum total performance score (described above). Additionally, we propose to increase the payment reduction to 2.0 percent for all providers/facilities that fail to achieve a total performance score that is 20 points below the minimum total performance score (described above). We believe that such a sliding scale will incentivize providers/facilities to meet the performance standards and continue to improve their performance because even if a provider/facility fails to achieve the minimum total performance score, such provider/facility will still be incentivized to

strive for, and attain, better performance in order to reduce the amount of its payment reduction. We will review this data to ensure that all providers/facilities will be sufficiently incentivized to provide high quality care. If we determine that the proposed approach for selecting the minimum total performance score is not rigorous enough we may finalize a higher minimum total performance score or a scalable approach to the scoring methodology. As stated above, the specific total performance score that a provider/facility would be required to achieve to avoid a payment reduction will be specified in the final rule.

We seek public comments on the proposed payment reductions for the PY 2014 ESRD QIP.

3. Proposed Public Reporting Requirements

Section 1881(h)(6)(A) of the Act requires the Secretary to establish procedures for making information regarding performance under the ESRD QIP available to the public, including information on the total performance score (as well as appropriate comparisons of providers and facilities to the national average with respect to such scores) and performance scores for individual measures achieved by each provider and facility. Section 1881(h)(6)(B) of the Act further requires that a provider or facility has an opportunity to review the information to be made public with respect to that provider/facility prior to its publication.

In addition, section 1881(h)(6)(C) of the Act requires the Secretary to provide each provider and 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 providers/facilities and performance-score data on a CMS-maintained Web site.

For both the PY 2013 and PY 2014 ESRD QIP, we propose no change in the implementation of these statutory provisions (section 1881(h)(6)(A) through section 1881(h)(6)(A)(D) of the Act) from the proposals finalized in the 2012 ESRD QIP final rule (76 FR 636 through 639), wherein we finalized the establishment of procedures for providers/facilities to review the information to be made public, and the procedures for informing the public through facility-posted certificates.

We seek public comments on the proposed public reporting requirements for the PY 2013 and PY 2014 ESRD QIP.

4. Future QIP Measures

As part of our effort to continuously improve the ESRD QIP, we are working to adopt additional robust measures that provide valid assessments of the quality of care delivered to ESRD beneficiaries. To that end, we are developing measures that apply to all modalities (including home and in-center dialysis) and the pediatric population. We are considering the adoption of measures on pediatric anemia (for example, iron targets), and fluid management for future years.

We also seek public comment on the inclusion of iron management measures, serum calcium management measures, and serum phosphorus management measures for future years of the QIP. Specifically, we seek public comment on:

- Measurement of Serum Calcium Concentration.
- Measurement of Serum Phosphorus Concentration.
- Assessment of Iron Stores.

These measures are currently collected through CROWNWeb as part of the Clinical Practice Measures set. The full specifications for these measures may be accessed at: *http://www.arborresearch.org/ESRD_QMS.aspx.*

5. Proposed Process of Updating Measures

Section 1881(h)(2)(C) of the Act enables the Secretary to establish a process for updating the measures specified under subparagraph (A) in consultation with interested parties. Occasionally there are changes in science or new issues arise related to patient safety concerns that may impact the measures that have been adopted through the rulemaking process. Therefore, for such cases where new information is available that specifically relates to patient safety concerns, we are proposing that we would post a notice of the updates we intend to make to the measure(s) in the **Federal Register**. We would specify in the Notice a time period during which we would accept comments from the public. We would consider these comments and post a Notice in the **Federal Register** finalizing any updates that we make to the measure(s). This process will enable us to make necessary updates to the ESRD QIP measures to ensure that the measures are based on the best available scientific data.

We request comment on this proposed procedure for updating ESRD QIP measures in accordance with section 1886(h)(2)(C) of the Act.

III. Ambulance Fee Schedule

A. Section 106 of the Medicare and Medicaid Extenders Act of 2010 (MMEA)

1. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008 and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

For covered ground ambulance transports which originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.

For covered ground ambulance transports which do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

Sections 3105(a) and 10311(a) of the Affordable Care Act further amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also applied to covered ground ambulance transports furnished on or after January 1, 2010 and before January 1, 2011. In the CY 2011 physician fee schedule final rule (75 FR 73385 and 73386, 73625), we revised § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Subsequently, section 106(a) of the Medicare and Medicaid Extenders Act of 2010 (MMEA) again amended section 1834(l)(13)(A) of the Act to extend the payment add-ons described above for an additional year, such that these add-ons also apply to covered ground ambulance transports furnished on or after January 1, 2011 and before January 1, 2012.

Accordingly, we are proposing to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary. For further information regarding the extension of these payment add-ons, please see Transmittal 706 (Change Request 6972) dated May 21, 2010 and the CMS Web

site, *http://www.cms.gov/AmbulanceFeeSchedule/02_afspuf.asp.*

2. Amendment to Section 146(b)(1) of MIPPA

Section 146(b)(1) of the MIPPA amended the designation of rural areas for payment of air ambulance services. The statute originally specified that any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, shall continue to be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through December 31, 2009.

Sections 3105(b) and 10311(b) of the Affordable Care Act amended section 146(b)(1) of MIPPA to extend this provision for an additional year, through December 31, 2010. In the CY 2011 physician fee schedule final rule (75 FR 73385 through 86, 73625 through 26), we revised § 414.610(h) to conform the regulations to this statutory requirement.

Subsequently, section 106(b) of the MMEA amended section 146(b)(1) of MIPPA to extend this provision again through December 31, 2011. Thus, we are proposing to revise § 414.610(h) to conform the regulations to this statutory requirement. This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of a rural indicator, and does not require any substantive exercise of discretion on the part of the Secretary. Accordingly, for areas that were designated as rural on December 31, 2006, and were subsequently re-designated as urban, we have re-established the ''rural'' indicator on the ZIP Code file for air ambulance services through December 31, 2011.

For further information regarding the extension of this MIPPA provision, please see Transmittal 706 (Change Request 6972) dated May 21, 2010 and the CMS Web site, *http://www.cms.gov/AmbulanceFeeSchedule/02_afspuf.asp.*

3. Amendment to Section 1834(l)(12) of the Act

Section 414 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) added paragraph (12) to section 1834(l) of the Act, which originally specified that in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a ''qualified rural area''; that is, to transports that originated in a rural area included in those areas comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract).

Sections 3105(c) and 10311(c) of the Affordable Care Act amended section 1834(l)(12)(A) of the Act to extend this rural bonus for an additional year through December 31, 2010. In the CY 2011 PFS final rule (75 FR 73385 through 73386 and 73625), we revised § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

Subsequently, section 106(c) of the MMEA again amended section 1834(l)(12)(A) of the Act to extend the rural bonus described above for an additional year, through December 31, 2011. Therefore, as directed by the MMEA, we are continuing to apply the rural bonus described above (in the same manner as in previous years), to ground ambulance services with dates of service on or after January 1, 2011 and before January 1, 2012 where transportation originates in a qualified rural area.

This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims adjudicative process via the use of a data field included on the CMS supplied ZIP Code File.

Accordingly, we are proposing to revise § 414.610(c)(5)(ii) to conform the regulations to the statutory requirement set forth at section 106(c) of the MMEA. This statutory requirement is self-implementing. The statute requires a one-year extension of the rural bonus (which was previously established by the Secretary), and does not require any substantive exercise of discretion on the part of the Secretary. For further information regarding the extension of this rural bonus, please see Transmittal 706 (Change Request 6972) dated May 21, 2010 and the CMS Web site, *http://www.cms.gov/AmbulanceFeeSchedule/02_afspuf.asp.*

B. Technical Correction

In addition, we are making a technical correction to § 414.610(c)(1). In the CY 2011 physician fee schedule final rule (75 FR 73386, 73625), CMS made technical changes to reformat § 414.610(c)(1). However, in making these revisions, language was inadvertently left out of this regulation. Specifically, the following sentence was inadvertently omitted from revised § 414.610(c)(1): ''The CF is multiplied by the applicable RVUs for each level of service to produce a service-level base rate.'' Prior to the changes made in the CY 2011 physician fee schedule final rule, this was the first sentence under § 414.610(c)(1)(i). We did not intend to delete this language in making the CY 2011 formatting changes. Thus, we are proposing to revise § 414.610(c)(1) to reinstate this sentence which was inadvertently deleted in the CY 2011 physician fee schedule final rule.

IV. Durable Medical Equipment and Supplies

A. Background for Durable Medical Equipment and Supplies

Title XVIII of the Social Security Act (the Act) governs the administration of the Medicare Program. The statute provides coverage for broad categories of benefits, including inpatient and outpatient hospital care, skilled nursing facility care, home health care, physician services, and durable medical equipment (DME). DME is covered by Medicare based, in part, upon section 1832(a) of the Act, which describes the scope of benefits under the supplementary medical insurance program (Medicare Part B). Section 1861(s)(6) of the Act defines ''medical and other health services'' to include DME as a separate benefit for which payment is authorized by section 1832 of the Act. Section 1861(m)(5) of the Act specifically includes DME in the definition of the term ''home health services.''

In accordance with section 1861(n) of the Act, the term ''durable medical equipment'' includes iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient's home whether furnished on a rental basis or purchased. The patient's home includes an institution used as his or her home other than an institution that meets the requirements of section 1861 (e)(1) or

section 1819(a)(1) of the Act. Besides being subject to this provision, the coverage of DME must also meet the requirements of section 1862(a)(1)(A) of the Act, which in general excludes from payment any items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and section 1862(a)(6) of the Act, which (except for certain specified exceptions) precludes payment for personal comfort items.

Section 1834(a) of the Act, as added by section 4062 of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), Public Law 100–203, sets forth the payment rules for DME furnished on or after January 1, 1989. The Medicare payment amount for a DME item is generally equal to 80 percent of the lesser of the actual charge or the fee schedule amount for the item, less any unmet Part B deductible. The beneficiary coinsurance for such items is generally equal to 20 percent of the lesser of the actual charge or the fee schedule amount for the item once the deductible is met. The fee schedule amounts are generally calculated using average allowed charges from a base period and then updated by annual update factors. Sections 1834(a)(2) through (a)(7) of the Act set forth six separate classes of DME and separate payment rules for each class. The six classes of items are: inexpensive and other routinely purchased DME; items requiring frequent and substantial servicing; customized items; oxygen and oxygen equipment; other covered items (other than DME); and capped rental items. For DME in general, § 414.210(f) specifies that payment can be made for replacement of DME that is lost, stolen, irreparably damaged, or has been in continuous use for the equipment's reasonable useful lifetime (RUL). In general, the RUL for DME is established as 5 years. Computation of the RUL is based on when the equipment is delivered to the beneficiary, not the age of the equipment. The 5-year standard is set forth in section 1834(a)(7)(C)(iii) of the Act for capped rental DME, but was applied to all DME through the regulations. The RUL is used to determine how often it is reasonable to pay for replacement of DME under the program and is not specifically set forth as a minimum lifetime standard. Therefore, we are using our discretion to propose a rule regarding how long equipment must withstand repeated use to be considered durable medical equipment.

Payment for inexpensive or routinely purchased DME is made on a purchase or rental basis, with total payments being limited to the purchase fee schedule amount for the item. The regulation at 42 CFR § 414.220 provides that inexpensive DME have an average purchase price of $150 or less and routinely purchased DME are items that have historically been acquired on a purchase basis 75 percent of the time or more. Accessories used with DME are also included in the inexpensive or routinely purchased DME class. Payment is generally made on a monthly rental basis with no cap on the number of rental payments made for items such as ventilators that require frequent and substantial servicing. Payment for items meeting the definition of customized DME set forth at § 414.224 is made on a lump sum purchase basis in an amount established based on the Medicare claims processing contractor's individual consideration and judgment of a reasonable payment amount for each item. Payment for oxygen equipment set forth at § 414.226 is made on a monthly basis for up to 36 months of continuous use. The supplier retains ownership of the oxygen equipment following the 36-month cap, but must continue to furnish the equipment for the remainder of the equipment's 5-year RUL, at which point the beneficiary can elect to obtain new equipment. Payment for capped rental items set forth at § 414.229(f) is made on a monthly rental basis for up to 13 months of continuous use. The supplier must transfer title to the equipment to the beneficiary on the first day following the 13th month of continuous use.

In establishing regulations for the purpose of implementing the payment rules mandated by OBRA 87, 42 CFR § 414.202 sets forth the basic definition of DME that was originally established and elaborated upon in program instructions discussed below. Section 414.202 defines DME as equipment furnished by a supplier or a home health agency that—

- Can withstand repeated use;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to an individual in the absence of an illness or injury; and
- Is appropriate for use in the home.

The benefit for DME as it was initially defined at section 1861(s)(6) of the Act was a benefit for ''rental of durable medical equipment.'' The owner of rented equipment is paid for the use of the equipment. When the equipment is no longer needed, it is returned to the owner and can then be rented by another customer. Items that are disposable cannot be rented and items that last for short periods of time are not likely to be items that would be rented. The Act was amended by section 16 of the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977 (P.L. 95–142) to allow for purchase of DME in cases where purchase is less costly or more practical than rental. In 1978, program instructions were added to the Medicare Part B Carriers Manual (HCFA-Pub. 14–3, Rev. 3–669) to further define DME and durability of an item, that is, when an item is considered durable. The instructions are now included in section 110.1 of chapter 15 of the Medicare Benefit Policy Manual (CMS-Pub. 100–02). In specifying which items satisfy the durability criteria, these program instructions provide that ''an item is considered durable if it can withstand repeated use, that is, the type of item which could normally be rented'' and excludes items that are ''of an expendable nature.'' The instructions do not specify exactly how long an item must last to be considered a durable item that would normally be rented as opposed to a disposable item or an item that would not normally be rented.

CMS has provided program instructions for coverage of supplies and accessories at Section 110.3 in Chapter 15 of the Medicare Benefits Policy Manual. The instructions provide that payment may be made for supplies that are necessary for the effective use of DME, such as lancets used to draw blood for use with a home blood glucose monitor. The lancet itself is disposable and would not be covered as DME, but it is a covered item that falls under the general DME benefit because it is necessary for the effective use of DME—the home blood glucose monitor. Supplies necessary for the effective use of DME also include oxygen and those drugs and biologicals which must be inserted directly into the equipment for the effective use of DME.

The Healthcare Common Procedure Coding System (HCPCS) is a standardized coding system used to process claims submitted to Medicare, Medicaid, and other health insurance programs by providers, physicians, and other suppliers. The HCPCS Code Set is divided into two principal subsystems, referred to as level I and level II of the HCPCS:

Level I of the HCPCS codes is comprised of Current Procedural Terminology (CPT) codes, which are copyrighted by the American Medical Association, and are used primarily to identify medical services and procedures furnished by physicians and other healthcare professionals that are billed to public or private health insurance programs.

Level II of HCPCS is a standardized coding system used primarily to identify products and supplies that are not included in the CPT codes, such as DME, orthotics, prosthetics, and supplies when used outside a physician's office. Assignment of HCPCS code is not a coverage determination and does not imply that any payer will cover the items in the code category. In October 2003, the Secretary delegated authority under the Health Insurance and Portability Act of 1996 to CMS to maintain and distribute HCPCS Level II codes.

B. Current Issues

Section 1861(n) of the Act defines DME to include items such as iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient's home whether furnished on a rental basis or purchased. The regulation at § 414.202 defines DME as equipment furnished by a supplier or a home health agency that—

- Can withstand repeated use;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to an individual in the absence of an illness or injury; and
- Is appropriate for use in the home.

CMS program instructions at section 110.1 of chapter 15, Medicare Benefits Policy Manual further clarify that an item can be considered durable if it can withstand repeated use, in other words, the type of item that could normally be rented. Section 1834(a)(7)(C) of the Act sets forth the provisions for the establishment of RUL for certain items of DME, payment for replacement of items and the length of RUL. However, the RUL is not specifically set forth as a minimum lifetime standard. Computation of the RUL is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

The regulation and program instructions do not lend any guidance regarding the specific period of time that equipment must function in order to be considered ''durable''. In addition, the regulation does not provide specific guidance or criteria regarding how to determine if new devices consisting of a system of durable and non durable components that together serve a medical purpose fall within the DME benefit category. Therefore, we believe it is necessary to revise the regulation at this time to include a definition of DME that uses more specific language to define the term ''durable'' for the purpose of determining whether equipment is DME. The issue of linking durability to the lifetime of equipment and where to draw the line has come to the forefront in light of the recent technology and engineering in the field of medical devices and equipment. Establishing a minimum lifetime criteria would help facilitate the benefit category determination process for items that clearly last longer or shorter than the minimum lifetime threshold.

In cases where it is not clear that the equipment can function for the specified minimum period of time, reviewing additional information and evidence consistent with the present benefit category determination process would be necessary to determine the expected life of the equipment. CMS and CMS contractors would base the decision on various sources of information including but not limited to the HCPCS request form, pre-market clearance documents from the Food and Drug Administration (FDA), product warranty documents, product Web site, product marketing materials, product user guides, product operating manuals, consumer product reviews, subject matter expert reviews, industry product standards data, and product data created as a result of clinical studies or standardized test results. A minimum lifetime standard for DME may also help facilitate the HCPCS process. The current application form used to request new HCPCS codes for items includes the question regarding whether equipment is durable and, if so, instructs the applicant to provide an explanation of how the item can withstand repeated use. We have received requests from several entities including DME stakeholders for additional clarification regarding the durability standard for DME. Comments from some of these entities indicate that there is limited direction on what is required for an item to be considered ''durable'' in the current regulation. Additional clarification of the term ''durable'' would be helpful to industry stakeholders such as manufacturers in anticipating how their products would be treated under coding classification and benefit category determinations.

C. Provisions of the Proposed Regulations

We are proposing changes to the definition of DME at 42 CFR § 414.202 in order to clarify the meaning of the term ''durable'' and reflect our current interpretation of the statute. Specifically, we propose to establish a 3-year minimum lifetime requirement that equipment must meet in order to be considered DME. Section 1861(n) of the Act provides examples of items such as wheelchairs, power operated vehicles, hospital beds, ventilators, and oxygen equipment to illustrate the DME benefit. The citation of these examples in the statutory language for many years indicates that the DME benefit was intended to be limited to medical items designed to be durable. Although the ability to pay on a purchase basis for certain items was added to the statute, the addition of this flexibility to the program did not fundamentally alter the types of items included in the DME benefit category or the requirement that the equipment must be durable.

Section 1861(n) of the Act states that items may be included under the DME benefit whether furnished on a rental basis or purchased. The regulation at § 414.202 and program instructions at Section 110.1 of Chapter 15 of the Medicare Benefits Policy Manual specify that an item is considered durable if it can withstand repeated use, that is, the type of item that could normally be rented. This excludes items that are of a disposable or single use nature. Based upon the statute and current regulations, equipment could be eliminated from the DME benefit category if it could not withstand repeated use or be reused by successive patients or the same patient. Although the capacity for reuse is in itself a logical characteristic of durability, it is not clear how many months or years an item must withstand repeated use in order to be considered durable. The Merriam Webster dictionary defines ''durable'' as the ability to exist for a long time without significant deterioration. The United States Department of Commerce uses a durability standard of 3 years for consumer durable goods for National Income and Accounts estimates.[8] Furthermore, economics dictionaries,[9] various encyclopedias,[10] and economics textbooks [11] define durable goods as goods that are expected to last longer than 3 years.

In addition, information gathered from various sources such as Rehabilitative Engineering and Assistive Technology Society of North America (RESNA),[12] product catalogs, product warranty documents, and consumer product reviews indicate that

[8] The NIPA Handbook (Concepts and Methods of the U.S National Income and Product Accounts, Chapter 5—Personal Care Expenditures. The handbook is available at *http://www.bea.gov/national/pdf/NIPAhandbookch5.pdf.*

[9] The McGraw Hill Dictionary of Modern Economics by Douglas Greenwald & Associates, Economics dictionary by Donald Moffat, Dictionary of Business and Economics by Christine Ammer and Dean Ammer.

[10] Encyclopedia of Business, Britannica Encyclopedia and Gale Encyclopedia.

[11] A Lexicon of Economics by Kenyon A. Knopf.

[12] *http://resna.org/.*

conventional DME items such as wheelchairs, hospital beds, and ventilators specified in section 1861(n) of the Act typically have a useful life of 3 or more years before they need to be replaced or need major repairs. Therefore, we propose a 3-year minimum lifetime standard for items to meet the durability criterion for DME.

A minimum lifetime standard would increase the clarity of the current definition and give regulatory weight to a reasonable benchmark for a minimum period of durability or repeated use that would need to be met in order for the equipment to be considered DME. In addition, the revised regulation would provide clear guidance to CMS and other stakeholders for making consistent informal benefit category determinations and national coverage determinations for DME. It would assist manufacturers in designing and developing new medical equipment to have a better understanding of how long a period of time an item must be able to withstand repeated use in order to be considered DME for Medicare purposes. It is important to note that the 3-year minimum period of durability does not replace the RUL standard established by section 1834(a)(7)(C) of the Act for payment purposes. The RUL rules are used to determine how often payment can be made for replacement items and is not a minimum lifetime requirement for DME. Although the proposed 3-year lifetime would be a requirement for determining whether an item is durable, it is not an indication of the typical or average lifespan of DME, which in many cases may last for much longer than 3 years.

1. Application of the 3-Year Lifetime Standard to Items Currently Covered as DME and to Supplies and Accessories of Covered DME

The 3-year minimum lifetime requirement would be prospective only and would not apply to items classified as DME before the proposed rule would be implemented. We expect that a vast majority of the categories of items that are currently classified as DME function for 3 or more years. In addition, the proposed regulation would allow for continued coverage of attendant supplies that are necessary for the effective use of DME. Such supplies include drugs and biologicals which must be inserted directly into the equipment for the effective use of DME. Finally, we do not propose to apply the 3-year lifetime requirement to accessories used with DME.

2. Application of the 3-Year Minimum Lifetime Criteria to Multi-Component Devices

In some cases, a device may be a system consisting of durable and non-durable components that together serve a medical purpose. Currently, a multi-component device consisting of durable and non-durable components is considered non-durable if the component that performs the medically necessary function of the device is non-durable, even if other components that are part of the device are durable. Therefore, if the proposed regulation to establish a minimum 3-year lifetime standard for DME is applied to these devices, the component(s) of a multi-component device that performs the medically necessary function of the device would need to meet the 3-year minimum lifetime requirement. Although we are not proposing to change our policy with regard to these types of systems at this point, we are seeking public comments on this topic. Specifically, we are soliciting public comments on various ways we might consider applying the 3-year rule to multi-component devices consisting of both durable and non-durable components. Various options might include the following:

1. Apply the 3-year lifetime standard to the component(s) that performs the entire medically necessary function of the device.

2. Apply the 3-year lifetime standard to the component(s) that performs a vital part of the medically necessary function of the device.

3. Consider a device/system to be durable only if the cost of the durable component(s) over a period of time (for example, 5 years) makes up greater than 50 percent of the overall cost of the device/system over the same period.

V. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection 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 are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

As discussed in section I.C.5 of this proposed rule, to receive the low-volume adjustment, an ESRD facility would need to provide an attestation to their Fiscal Intermediary or Medicare Administrative Contractor (FI/MAC) that it has met the criteria to qualify as a low-volume facility prior to November 1st of each year. The FI/MAC would verify the ESRD facility's attestation of their low-volume status for the 3-consecutive years immediately preceding the payment year, using the ESRD facility's most recent final-settled or as-filed 12-month cost reports.

The burden associated with the requirement is the time and effort necessary for an ESRD facility attesting as a low-volume facility to develop an attestation and submit it to their FI/MAC. In this proposed rule, for CY 2012, we estimate that it would require an administrative staff member from each low-volume facility 10 minutes to obtain the total number of treatments in the cost reports necessary for eligibility determination, develop the attestation, and submit it to their FI/MAC. For this proposed rule, using 2009 claims our contractor, UM–KECC, identified 939 ESRD facilities as providing treatments below the low-volume threshold of 4,000 treatments in 2009. Of these 939 facilities, we estimated that 358 met the additional low-volume criteria as specified in § 413.232. Further, due to the historical trend of increase in the number of small dialysis facilities, we believe that several dozen additional ESRD facilities may meet the criteria of a low-volume facility prior to the CY 2012 payment year. To take these facilities into account, we have rounded the total number of estimated low-volume facilities to 400. Therefore, for CY 2012, we estimate that the total initial ESRD facility burden would be 67 hours. The estimated cost associated with compliance with this requirement is $2.61 per ESRD facility and total of $1,044 for all 400 facilities. These costs are estimated using the 2010 estimate for the occupational code 43–0000 Office and Administrative Support

Occupation mean hourly wage of $15.66 as stated by the U.S. Bureau of Labor Statistics.

C. Additional Information Collection Requirements

This proposed rule imposes collection of information requirements as outlined in the regulation text and specified above. However, this proposed rule also makes 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, some of which have already received OMB approval.

1. Proposed Display of Certificates for PY 2013 and PY 2014 ESRD QIP

Section II.B of this proposed rule discusses a disclosure requirement for both the PY 2013 and the PY 2014 ESRD QIP. As stated earlier in this proposed rule, section 1881(h)(6)(C) of the Act requires the Secretary to provide certificates to dialysis care providers and facilities about their total performance scores under the QIP. This section also requires each provider and facility that receives a QIP certificate to display it prominently in patient areas.

To comply with this requirement, we are proposing to issue a PY 2013 and PY 2014 QIP certificate to providers and facilities via a generally accessible electronic file format. We propose that each provider and facility would be required to prominently display the applicable QIP certificate in patient areas. In addition, we propose that each provider and facility will take the necessary measures to ensure the security of the certificate in the patient areas. Finally, we propose that each provider/facility would be required to have staff available to answer questions about the certificate in an understandable manner, taking into account that some patients might have limited English proficiency. These proposals represent no change from the policy finalized for the 2012 ESRD QIP.

The burden associated with the aforementioned requirements is the time and effort necessary for providers and facilities to print the applicable QIP certificate, display the certificate prominently in patient areas, ensure the safety of the certificate, and respond to patient inquiries in reference to the certificates. We estimate that approximately 5,227 providers and facilities will receive a QIP certificate in PY 2013 and PY 2014 and will be required to display it. We also estimate that it will take each provider or facility 10 minutes per year to print, prominently display and secure the QIP certificate, for a total estimated annual burden of 871 hours at a cost of $30,000. We estimate that approximately one-third of ESRD patients will ask a question about the QIP certificate. We further estimate that it will take each provider/facility approximately 5 minutes to answer each patient question about the applicable QIP certificate, or 1.65 hours per provider or facility each year. The total estimated annual burden associated with this requirement is 8,625 hours. The total estimated annual burden for both displaying the QIP certificates and answering patient questions about the certificates is 9,496 hours (for each of PY 2013 and PY 2014). While the total estimated annual burden associated with both of these requirements as discussed is 9,496 hours, we do not believe that there will be a significant cost associated with these requirements because we are not proposing to require providers/facilities to complete new forms. As discussed in section A.1.3 of this proposed rule, we estimate that the total cost for all ESRD providers/facilities to comply with the collection of information requirements associated with the certificate each year would be less than $300,000.

2. Proposed NHSN Reporting Requirement for the PY 2014 ESRD QIP

As stated above in section II.B.2.b.vi of this proposed rule, we propose to include reporting dialysis events to the National Healthcare Safety Network (NHSN) as a reporting measure for the PY 2014 ESRD QIP. Specifically, we would require providers/facilities to: (1) enroll in the NHSN and complete required training as verified by a digital certificate obtained from CDC; and (2) submit at least 3-consecutive months of dialysis event data to the NHSN.

The burden associated with these requirements is the time and effort necessary for providers and facilities to enroll in the NHSN and conduct the required training and submit 3 months of data. We estimate that approximately 5,227 providers and facilities will enroll in the NHSN and submit the necessary data. We also estimate that it will take each provider or facility 48 hours per year to enroll in the NHSN and complete the required training, for a total estimated annual burden of 250,896 hours. Based on the Bureau of Labor Statistics we estimate the average inflation adjusted salary to be $34.63 per hour. Thus, average cost for each provider/facility would be $1,662.24 (48 hours times $34.63 per hour). Across all 5,227 providers/facilities, this would equal $8.7 million. However, we further estimate that the number of dialysis events in a 3-month period will be 125,680 for the 2014 ESRD population. We estimate it will require 10 minutes to collect and submit data on these events and the estimated burden for submitting 3 months of data will be 20,947 hours. If the dialysis events were distributed evenly across all 5,227 providers/facilities, that would result in an additional 4 hour burden ($138.78) for each provider/facility. The total estimated annual burden for enrolling in the NHSN, conducting the required training, and submitting 3 consecutive months of data is 271,843 hours. We estimate that the total cost for all ESRD providers/facilities to comply with the proposed collection of information requirements associated with NHSN reporting requirement each year would be less than $9.5 million, with the total average cost per provider/facility approximately $1,801.02.

3. Proposed Patient Experience Survey Usage Requirement for the PY 2014 ESRD QIP

As stated above in section B.A.2. of this proposed rule, we propose to include a measure that assesses provider/facility usage of the In-Center Hemodialysis (ICH) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey as a reporting measure for the PY 2014 ESRD QIP. The burden associated with this requirement is the time and effort necessary for providers and facilities to administer the ICH CAHPS survey and submit an attestation to CMS that they successfully administered the survey.

We estimate that approximately 5,227 providers and facilities will administer the ICH CAHPS survey and submit an attestation to that affect. We estimate that it will take each provider or facility 16 hours per year to be trained on the survey features. We further estimate that it will take each provider/facility approximately 5 minutes to submit the attestation each year. The estimated total annual burden on providers/facilities is estimated to be 84,068 hours which is valued at $2.9 million, or $556.97 per provider/facility. We estimate that administering the survey would take 45 minutes per patient (to account for variability in education levels) and 200 surveys per year which equals 154 hours or $2,707.32 per facility-year to administer the ICH CAHPS survey for an estimated annual burden of 804,958 hours which is valued at $14.1 million. As discussed in section A. of this proposed rule, we estimate that the total cost for ESRD providers/facilities to comply with the collection of information requirements associated with administering the ICH CAHPS survey each year would be

approximately $3,264.29, or $17.1 million across all ESRD providers/facilities.

4. Proposed Mineral Metabolism Reporting Requirement for the 2014 ESRD QIP

As stated above in section B.A.2. of this proposed rule, we propose to include a Mineral Metabolism reporting measure as part of the PY 2014 ESRD QIP. The burden associated with this requirement is the time and effort necessary for providers and facilities to review their records and submit an attestation to CMS that they had monitored on a monthly basis, the serum calcium and serum phosphorus levels of all patients each month.

We estimate that approximately 5,227 providers and facilities will submit the attestation. We estimate that it will take each provider or facility approximately 18 hours to review its records and submit the attestation each year. The estimated total annual burden on providers/facilities is estimated to be 94,086 hours which is valued at $3.3 million, or $623 per provider/facility.

To obtain copies of the supporting statement and any related forms for the proposed 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 do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–1577–P]. Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov.*

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this proposed rule as required by Executive Orders 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 an ''economically'' significant rule, 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 proposed rule. We solicit comment on the Regulatory Impact Analysis provided.

2. Statement of Need

This rule proposes a number of routine updates for renal dialysis services in CY 2012, implementing the second year of the transition, and making several policy and technical changes to the CY 2011 ESRD PPS final rule as well as proposed revisions to the regulations. This includes proposed updates to the ESRD PPS and composite rate base rates, wage index values, wage index budget-neutrality adjustment factors, outlier payment policy, low-volume adjustment and transition budget-neutrality adjustment. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2012.

In addition, this rule implements a QIP for Medicare ESRD dialysis providers and facilities with payment reductions beginning January 1, 2013. Under section 1881(h) of the Act, after selecting measures, establishing performance standards that apply to each of the measures, specifying a performance period, and developing a methodology for assessing the total performance of each provider and facility based on the specified performance standards, the Secretary is required to apply an appropriate reduction to ESRD providers and facilities that do not meet or exceed the established total performance score. Our vision is to continue to implement a robust, comprehensive ESRD QIP that builds on the foundation that has already been established in providing incentives to providers/facilities to improve the quality of care they provide to Medicare beneficiaries.

Also, this proposed rule would revise the ambulance fee schedule regulations to conform with the requirements of section 106 of the Medicare and Medicaid Extenders Act of 2010 Public Law 111–309 (MMEA). Finally, this proposed rule revises the definition of durable medical equipment. The revision adds a 3-year minimum lifetime criterion that must be met by an item or device in order to be considered durable for the purpose of classifying the item under the Medicare benefit category for DME. The proposed rule would not impact items classified and covered as DME before the new rule takes effect or supplies and accessories used with covered DME.

3. Overall Impact

We estimate that the proposed revisions to the ESRD PPS will result in an increase of approximately $200 million in payments to ESRD facilities in CY 2012. Furthermore, as a result of implementing the QIP for Medicare outpatient ESRD dialysis providers and facilities, we estimate aggregate payment reductions in payment years 2013 and 2014 would be $47.2 million and $14 million, respectively. However, given the lack of data for several measures, the actual impact of the proposed 2014 QIP may vary significantly from the values provided herein. Lastly, the aggregate costs associated with the QIP collection of information requirements described in section III.1 of this proposed rule (Display of Certificates for the 2013 ESRD QIP) are estimated to be $300,000 for all ESRD facilities in 2013. The additional estimated aggregate costs associated with the collection of information requirements described in sections III.1. (Display of Certificates for the 2013 and 2014 ESRD QIP), III.2 (NHSN Reporting Requirement for the 2014 ESRD QIP), III.3 (CAHPS Survey Requirement for the 2014 ESRD QIP) and III.4 (Mineral Metabolism Reporting Requirement for the 2014 ESRD QIP) in this proposed rule are expected to be approximately less than $24 million for all participating ESRD facilities.''

The impact of section 106 of the MMEA, requiring the extension of certain add-on payments for ground ambulance services, and the extension of certain rural area designations for

purposes of air ambulance payment, through CY 2011, is estimated to be $20 million (for CY 2011).

Finally, the fiscal impact of the proposed 3-year minimum lifetime standard cannot be estimated because it is difficult to predict how many different types of devices will be introduced in the market in the future that may or may not qualify as DME items as a result of the new rule. However, we would expect that this proposed rule would have a small, if any, savings impact on the program.

B. Detailed Economic Analysis

1. CY 2012 End-Stage Renal Disease Prospective Payment System

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments (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 (that is, payments made under the 100 percent ESRD PPS and those under the ESRD PPS blended payment during the transition) in CY 2011. To estimate the impact among various classes of ESRD facilities, it is imperative that the estimates of payments in CY 2011 and CY 2012 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities that we are able to calculate both current payments and new payments.

We used the June 2010 update of CY 2009 National Claims History file as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2009 claims to 2011 and 2012 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 I.C.7 of this proposed rule. In addition, in order to prepare an impact analysis, since some providers 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 2009 amounts as the CY 2011 and CY 2012 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 is not increased; thus we used no price update. 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 where ASP data was available. We updated the last available quarter of actual ASP data for the top twelve drugs (the second quarter of 2011) thru 2012 by using the quarterly growth in the Producer Price Index for Drugs (PPI), consistent with the method for addressing price growth in the ESRDB market basket. This resulted in 1.5 percent, 1.0 percent, 1.7 percent, 1.2 percent, 1.2 percent and 0.2 percent increase, respectively, for the third quarter of 2011 thru the fourth quarter of 2012. 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 9 below shows the updates used for the drugs.

We updated payments for laboratory tests paid through the laboratory fee schedule to 2011 and 2012 using the statutory required update of the CPI–U increase with any legislative adjustments. For this proposed rule, the growth from 2009 to 2011 is −3.6 percent and the growth from 2009 to 2012 is −5.1 percent.

TABLE 9—PRICE INCREASES FROM 2009 TO 2011 AND 2009 TO 2012 OF SEPARATELY BILLABLE PART B DRUGS

Drugs and biologicals	Price update 2009 to 2011 (percent)	Price update 2009 to 2012 (percent)
EPO	3.9	9.1
Paricalcitol	−16.2	−14.6
Sodium_ferric_glut	5.1	9.6
Iron_sucrose	−6.0	−1.6
Levocarnitine	1.4	15.5
Doxercalciferol	8.0	15.7
Calcitriol	−6.4	−2.0
Iron_dextran	−4.3	0.5
Vancomycin	1.6	7.2
Alteplase	15.9	21.6
Aranesp	3.0	8.6
Daptomycin	16.6	22.5
Other Injectibles	0.8	5.5

Table 10 shows the impact of the proposed estimated CY 2012 ESRD payments compared to estimated payments to ESRD facilities in CY 2011.

TABLE 10—IMPACT OF PROPOSED CHANGES IN PAYMENT TO ESRD FACILITIES FOR CY 2012 ESRD PROPOSED RULE

[(Percent change in total payments to ESRD facilities (both program and beneficiaries))]

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2012 changes in outlier policy percent	Effect of 2012 changes in wage indexes percent	Effect of total 2012 changes [3] percent
	A	B	C	D	E
All Facilities	5,304	38.4	0.2	0.0	2.1
Type:					
Freestanding	4,759	34.8	0.3	0.0	2.1
Hospital based	545	3.6	−0.1	−0.3	1.7
Ownership Type:					
Large dialysis organization	3,396	24.8	0.3	0.0	2.2
Regional chain	848	6.4	0.1	−0.1	1.8
Independent	624	4.3	0.0	0.0	2.0
Hospital based [1]	430	2.8	−0.1	−0.4	1.7
Unknown	6	0.0	0.2	0.2	2.1
Geographic Location:					
Urban	4,117	31.9	0.2	0.0	2.0
Rural	1,187	6.4	0.3	−0.1	2.1
Census Region:					
East North Central	875	5.9	0.2	−0.2	1.9
East South Central	415	2.9	0.4	−0.2	2.0
Middle Atlantic	584	4.7	0.1	0.0	2.1
Mountain	321	1.7	0.1	0.1	2.1
New England	163	1.3	0.2	0.1	2.1
Pacific	620	5.0	0.1	0.2	2.2
South Atlantic	1,180	8.7	0.3	−0.3	1.9
West North Central	389	2.1	0.2	0.2	2.2
West South Central	718	5.5	0.3	0.3	2.4
Puerto Rico and Virgin Islands	39	0.4	0.2	−2.5	0.0
Facility Size:					
Less than 4,000 treatments [2]	939	2.0	0.2	−0.1	2.1
4,000 to 9,999 treatments	2,101	10.9	0.3	−0.1	2.0
10,000 or more treatments	2,214	25.4	0.2	0.0	2.1
Unknown	50	0.2	0.1	−0.4	1.8
Percentage of Pediatric Patients:					
Less than 2%	5,192	37.8	0.2	0.0	2.1
Between 2% and19%	55	0.5	0.1	−0.3	1.8
Between 20% and 49%	7	0.0	0.0	0.2	1.8
More than 50%	50	0.0	0.0	−0.3	1.3

[1] Includes hospital based facilities not reported to be part of a large dialysis organization or part of regional chain ownership.

[2] Of the 939 Facilities with less than 4,000 treatments, only 358 qualify for the low-volume adjustment. The low-volume adjustment was not applied to pediatric patients. The estimated impact to these Low volume Facilities is a 2.4% increase in payments.

[3] Includes the effect of the ESRDB Market Basket minus productivity adjustment, which results in an increase of 1.8% to the ESRD PPS base and the Composite Rate portion of the blended payment for those facilities that opted to be paid under the transition. Also Includes the effect of the change in the drug add-on percentage from 14.7% to 14.4% to the composite ration portion of the blended payment for those facilities that opted to be paid under the transition. Includes the effect of the blended payment changing from 75/25 to 50/50 from CY 2011 to CY 2012 for those facilities that choose to be paid under the transition.

NOTE: Totals do not necessarily equal the sum of rounded parts.

Column A of 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 proposed changes in outlier payment policy and the proposed change for the BSA national average described in section I.C.10 and section I.C.9, respectively, of this proposed rule, are shown in column C. For CY 2012, the impact on all facilities of our proposed changes in outlier payment policy and the proposed BSA national average would be a 0.2 percent increase in estimated payments. The estimated impact of our proposed changes in outlier payment policy and the BSA national average ranges from -0.1 percent decrease to a 0.4 percent increase. Most ESRD facilities are anticipated to have a positive effect on the estimated CY 2012 payments as a result of the proposed outlier and BSA national average changes.

Column D shows the effect of the wage index on ESRD facilities and reflects the CY 2012 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 2.5 percent decrease in estimated payments in CY 2012. Since most of the facilities in this category are located in Puerto Rico, the decrease is primarily due to the proposed reduction in the wage index floor (which only affects facilities in Puerto Rico in CY 2012). Renal dialysis facilities outside of Puerto Rico would experience changes in estimated payments ranging from a 0.4 percent decrease to a 0.3 percent increase due to changes in the wage index.

Column E reflects the overall impact (that is the effects of the proposed outlier and BSA national average changes, the proposed wage index, the effect of the ESRDB market basket increase minus productivity adjustment, and the effect of the change in the blended payment percentage from 75 percent of payments based on the composite rate system and 25 percent based on the ESRD PPS in 2011, to 50/

50, respectively, for 2012, for those facilities that opted to be paid under the transition). It is expected that overall ESRD facilities will experience a 2.1 percent increase in estimated payments in 2012. Puerto Rico is expected to receive no increase in their estimated payments in CY 2012 primarily due to the negative impact of the wage index. The remainder of ESRD facilities are expected to be positively impacted ranging from an increase of 1.3 percent to 2.4 percent in their 2012 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 by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2012, the second year of the ESRD PPS, we estimate that the proposed 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 2012 will be approximately $8.3 billion. This estimate is based on various price update factors discussed in section VII of this proposed rule. In addition, we estimate that there will be an increase in fee-for-service Medicare beneficiary enrollment of 4.2 percent in CY 2012.

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 that have chosen the ESRD PPS transition. As a result of the projected 2.1 percent overall increase in the proposed ESRD PPS payment amounts in CY 2012, we estimate that there will be an increase in beneficiary co-insurance payments of 2.1 percent in CY 2012, which translates to approximately $40 million.

e. Alternatives Considered

In developing this proposed rule, we considered eliminating all laboratory tests from the outlier policy, but instead we are proposing to eliminate only the Automated Multi-Channel Chemistry (AMCC) panel tests. We believe this proposed approach would continue to recognize expensive laboratory tests in the outlier policy while reducing the burden associated with the 50 percent rule (see section I.C.10 of this proposed rule).

We also considered alternatives for applying the wage index budget-neutrality adjustment factor under the ESRD PPS for purposes of the full ESRD PPS payments and ESRD PPS portions of the blended payment during the transition, such as applying the wage index budget-neutrality adjustment factor to the ESRD PPS wage index values, but instead we proposed applying the wage index budget-neutrality adjustment factor to the ESRD PPS base rate and ESRD PPS portions of the transition blended payment to be consistent with how these adjustments are applied in other PPSs (see section I.C.c of this proposed rule for additional information on how we propose to apply the wage budget-neutrality adjustment factor).

2. End-Stage Renal Disease Quality Incentive Program (QIP)

a. Effects of the Proposed 2013 and 2014 ESRD QIP

This proposed rule is intended to mitigate 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 a QIP that would reduce ESRD payments by up to 2 percent to dialysis providers/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 proposing to determine a provider/facility's performance score is described in section IV.A.3 (Methodology for Calculating the Total Performance Score for the 2013 ESRD QIP) and section IV.A.2.e (Methodology for Calculating the Total Performance Score for the PY 2014 ESRD QIP) of this proposed rule. Any reductions in ESRD payment would begin on January 1, 2013 for services furnished on or after January 1, 2013 for the 2013 ESRD QIP and any reductions in ESRD payment would begin on January 1, 2014 for services furnished on or after January 1, 2014 for the 2014 ESRD QIP.

As a result, based on the QIP outlined in this proposed rule, we estimate that approximately 38.8 percent or 2,059 of total ESRD dialysis facilities would likely receive a payment reduction for PY 2013. In PY 2014, we estimate that approximately 13.8 percent or 737 of total ESRD facilities would likely receive some type of payment reduction.

The QIP impact assessment assumes an initial count of 5,430 dialysis facilities with paid Medicare dialysis claims in 2009. The PPS analysis, presented earlier, excludes 126 facilities for PPS-specific reasons thereby narrowing the final analytic sample to 5,304. Specifically, facilities excluded include those they do not have information on the PPS phase-in election. Most of these facilities closed during 2009 or 2010. In addition, they exclude a relatively small number of facilities that were either located in certain US territories (Guam, American Samoa, Marianna Islands) where a different payment approach has been used (they have not been paid under the Composite Rate system) or that represented facilities with no payments reported on the very small number of claims they submitted. As a result, Table 11 shows the overall estimated distribution of payment reductions resulting from the PY 2013 ESRD QIP. Table 12 shows the overall estimated distribution of payment reductions resulting from the PY 2014 ESRD QIP.

TABLE 11—ESTIMATED DISTRIBUTION OF CY 2013 ESRD QIP PAYMENT REDUCTIONS.

Payment reduction percent	Number of facilities	Percent of facilities percent
0.0	3,245	61.2
1.0	741	14.0
1.5	755	14.2
2.0	563	10.6

TABLE 12—ESTIMATED DISTRIBUTION OF CY 2014 ESRD QIP PAYMENT REDUCTIONS.

Payment reduction percent	Number of facilities	Percent of facilities percent
0.0	4,567	86.1
1.0	434	8.2
1.5	211	4.0
2.0	92	1.7

[1] CY 2014 QIP Scores estimated using the measures Hemoglobin > 12 g/dl, Urea Reduction Ratio ≥ 65% as a proxy for the Kt/V measure, and Standard Hospitalization Ratio.

To estimate the total payment reductions in 2013 and 2014 resulting from the proposed rule for each facility, we multiplied the number of patients treated at each facility receiving a reduction times an average of three

treatments per week. We then multiplied this product by a base rate of $229.63 per dialysis treatment (before an adjustor is applied) to arrive at a total ESRD payment for each facility: ((Number of patients treated at each facility × 3 treatments per week) × base rate).

Finally, we applied the estimated payment reduction percentage expected under the QIP, yielding a total payment reduction amount for each facility: (Total ESRD payment × estimated payment reduction percentage).

For payment consequence year 2013, totaling all of the payment reductions for each of the 2,059 facilities expected to receive a reduction leads to a total payment reduction of approximately $47.2 million. Further, we estimate that the total costs associated with the collection of information requirements described in section III.1, of this proposed rule (Display of Certificates for the 2013 ESRD QIP) would be less than $300,000 for all ESRD facilities in 2013.

For payment consequence year 2014, totaling all of the payment reductions for each of the 737 facilities expected to receive a reduction leads to a total payment reduction of approximately $14 million. Further, we estimate that the total costs associated with the collection of information requirements described in sections III.1. (Display of Certificates for the 2013 and 2014 ESRD QIP), III.2 (NHSN Reporting Requirement for the 2014 ESRD QIP), III.3 (Patient Experience Survey Usage Reporting Requirement for the 2014 ESRD QIP) and III.4 (Mineral Metabolism Reporting Requirement for the 2014 ESRD QIP) of this proposed rule would be less than $24 million for all ESRD facilities.

As a result, we estimate that ESRD facilities will experience an aggregate impact of $47.5 million for 2013 and $38 million payment reduction for 2014.

Table 13 below shows the estimated impact of the proposed QIP payment reductions to all ESRD facilities for payment consequence year 2013. The table details the distribution of ESRD providers/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).

TABLE 13—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR CY 2013

	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	5,304	38.4	4,709	2,059	−0.57
Facility Type:					
Freestanding	4,759	34.8	4,334	1,874	−0.57
Hospital-based	545	3.6	375	185	−0.57
Ownership Type:					
Large Dialysis	3,396	24.8	3,145	1,326	−0.56
Regional Chain	848	6.4	755	348	−0.62
Independent	624	4.3	519	250	−0.60
Hospital-based (non-chain)	430	2.8	288	135	−0.52
Unknown	6	0	2	0	0.00
Facility Size:					
Large Entities	4,302	31.7	3,953	1,700	−0.57
Small Entities [1]	1,054	7.1	807	385	−0.57
Unknown	6	0	0	0	–
Urban/Rural Status:					
Urban	4,117	31.9	3,630	1,581	−0.56
Rural	1,187	6.4	1,079	478	−0.60
Census Region:					
Northeast	746	6.1	671	284	−0.58
Midwest	1,258	8	1,075	479	−0.57
South	2,311	17.1	2,123	980	−0.61
West	939	6.8	806	303	−0.46
US Territories [2]	39	0.4	34	13	−0.52
Unknown	11	0	0	0	–
Census Division:					
East North Central	875	5.9	730	330	−0.56
East South Central	415	2.9	384	189	−0.69
Middle Atlantic	584	4.7	526	232	−0.61
Mountain	321	1.7	276	87	−0.40
New England	163	1.3	145	52	−0.50
Pacific	620	5	530	216	−0.49
South Atlantic	1,180	8.7	1,088	514	−0.62
West North Central	389	2.1	345	149	−0.61
West South Central	718	5.5	651	277	−0.56
US Territories [2]	39	0.4	34	13	−0.52
Facility Size (# of total treatments):					
Less than 4,000 treatments	939	2	514	171	−0.29
4,000–9,999 treatments	2,101	10.9	2,006	846	−0.60
Over 10,000 treatments	2,214	25.4	2,177	1,038	−0.66
Unknown	50	0.2	12	4	−0.19

[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.

We note that for the 2014 ESRD QIP we lacked performance data on the Vascular Access Type Measure (Fistula), Dialysis Adequacy Measure (Kt/V), the Vascular Access Type Measure (Catheter), and the Vascular Access Infections Measure to conduct an analysis at this time and we have omitted those measures from these estimates. Rather, we conducted a simulation using the latest available performance data on the Hemoglobin Greater Than 12g/dL measure, the Dialysis Adequacy (URR) measure (as a proxy for the Dialysis Adequacy Measure (Kt/V)), and the SHR measure to estimate the impact of this proposed rule as accurately as possible. These simulated analyses were performed using 2009 claims data as the performance year and 2008 claims data as the baseline year for the Hemoglobin Greater Than 12g/dL measure and the Dialysis Adequacy Measure (URR); SHR performance data was extracted from the 2010 DFR data set using 2008 as the performance year and 2007 as the baseline year.

Using these conditions, we calculated estimated national achievement threshold and benchmark values for the Hemoglobin Greater than 12g/dL, Dialysis Adequacy (URR), and SHR measures using all facilities present in the data set. Equal weighting was applied in calculating total performance scores. Given the lack of data for several measures, the actual impact of the proposed 2014 QIP may vary significantly from the values provided here.

Using the above assumptions, Table 14 below shows the estimated impact of the proposed QIP payment reductions to all ESRD facilities for payment consequence year 2014. The table details the distribution of ESRD providers/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).

TABLE 14—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR CY 2014

	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	5,304	38.4	4,238	737	−0.17
Facility Type:					
Freestanding	4,759	34.8	4,077	712	−0.18
Hospital-based	545	3.6	161	25	−0.06
Ownership Type:					
Large Dialysis	3,396	24.8	2,981	497	−0.18
Regional Chain	848	6.4	671	108	−0.16
Independent	624	4.3	477	115	−0.24
Hospital-based (non-chain)	430	2.8	109	17	−0.05
Unknown	6	0	0	0	0.00
Facility Size:					
Large Entities	4,302	31.7	3,696	616	−0.18
Small Entities[1]	1,054	7.1	586	132	−0.16
Unknown	6	0	0	0	–
Urban/Rural Status:					
Urban	4,117	31.9	3,289	587	−0.18
Rural	1,187	6.4	949	150	−0.16
Census Region:					
Northeast	746	6.1	579	116	−0.19
Midwest	1,262	8	937	189	−0.19
South	2,312	17.1	1,994	329	−0.18
West	939	6.8	703	94	−0.12
US Territories[2]	39	0.4	25	9	−0.28
Unknown	6	0	0	0	–
Census Division:					
East North Central	875	5.9	643	128	−0.18
East South Central	415	2.9	364	64	−0.19
Middle Atlantic	584	4.7	447	98	−0.21
Mountain	321	1.7	230	26	−0.10
New England	163	1.3	132	18	−0.12
Pacific	620	5	473	68	−0.14
South Atlantic	1,180	8.7	1,014	175	−0.18
West North Central	389	2.1	294	61	−0.20
West South Central	718	5.5	616	90	−0.16
US Territories[2]	39	0.4	25	9	−0.28
Facility Size (# of total treatments):					
Less than 4,000 treatments	939	2	384	63	−0.09
4,000–9,999 treatments	2,101	10.9	1,822	332	−0.20
Over 10,000 treatments	2,214	25.4	2,023	338	−0.18
Unknown	50	0.2	9	4	−0.22

[1] Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.
[2] Includes Puerto Rico and Virgin Islands.
[3] CY 2014 QIP Scores estimated using the measures Hemoglobin > 12 g/dl, Urea Reduction Ratio ≥ 65%, and Standard Hospitalization Ratio.

b. Alternatives Considered for 2013 and 2014 ESRD QIP

In developing the proposed PY 2013 ESRD QIP, we carefully considered the size of the incentive to providers and facilities to provide high-quality care. We also selected the measures adopted for the PY 2013 ESRD QIP because these measures are important indicators of patient outcomes and quality of care. For example, inadequate dialysis can lead to avoidable hospitalizations, decreased quality of life, and death. Thus, we believe the measures selected will allow CMS to continue focusing on improving the quality of care that Medicare beneficiaries receive from ESRD dialysis providers and facilities.

Additionally, for 2013 we considered whether to leave the Hemoglobin Measure Less Than 10g/dL in the program. Ultimately we decided that the clinical evidence shows that this measure is not conducive to improving the patient quality of care that the QIP strives for. The ESA labeling approved by the FDA on June 24, 2011 states that no trial has identified a hemoglobin target level that does not increase risks, and that ''in controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target a hemoglobin level of greater than 11g/dL. We have decided to retire the Hemoglobin Less Than 10g/dL measure from the program, and are requesting the public's comments on this proposal.

As stated previously for the PY 2014 ESRD QIP, we propose to implement a QIP for Medicare ESRD dialysis providers and facilities with payment reductions beginning January 1, 2014. Under section 1881(h) of the Act, after selecting measures, establishing performance standards that apply to each of the measures, specifying a performance period, and developing a methodology for assessing the total performance of each provider and facility based on the specified performance standards, the Secretary is required to apply an appropriate reduction to ESRD providers and facilities that do not meet or exceed the established total performance score. In developing the proposed QIP, we carefully considered the size of the incentive to providers and facilities to provide high-quality care. We also selected the measures adopted for the 2014 ESRD QIP because these measures are important indicators of patient outcomes and quality of care. Poor management of anemia and inadequate dialysis, for example, can lead to avoidable hospitalizations, decreased quality of life, and death. Infections are also a leading cause of death and hospitalization among hemodialysis patients, but there are proven infection control methods that have been shown effective in reducing morbidity and mortality. Thus, we believe the measures selected will allow CMS to continue focusing on improving the quality of care that Medicare beneficiaries receive from ESRD dialysis providers and facilities.

In proposing the scoring methodology for the 2014 ESRD QIP, we considered a number of alternatives, including continuing to use the existing scoring model. In proposing to move to a new scoring approach for the 2014 ESRD QIP, we aim to design a scoring methodology that is straightforward and transparent to providers/facilities, patients, and other stakeholders. We believe that all scoring methodologies for Medicare Value-Based Purchasing programs should be aligned as appropriate given their specific statutory requirements.

3. Ambulance Fee Schedule

Section 106 of the Medicare and Medicaid Extenders Act of 2010 (MMEA)

As discussed in section V. of this proposed rule, section 106 of the MMEA requires the extension of certain add-on payments for ground ambulance services, and the extension of certain rural area designations for purposes of air ambulance payment, through CY 2011. As further discussed in section V, we are proposing to amend the Medicare program regulations to conform the regulations to this section of the MMEA. This MMEA section is essentially prescriptive and does not allow for discretionary alternatives on the part of the Secretary.

As discussed in the July 1, 2004 interim final rule (69 FR 40288), in determining the super-rural bonus amount under section 1834(l)(12) of the Act, we followed the statutory guidance of using the data from the Comptroller General (GAO) of the U.S. We obtained the same data as the data that were used in the GAO's September 2003 Report titled ''Ambulance Services: Medicare Payments Can Be Better Targeted to Trips in Less Densely Populated Rural Areas'' (GAO report number GAO–03–986) and used the same general methodology in a regression analysis as was used in that report. The result was that the average cost per trip in the lowest quartile of rural county populations was 22.6 percent higher than the average cost per trip in the highest quartile. As required by section 1834(l)(12) of the Act, this percent increase is applied to the base rate for ground ambulance transports that originate in qualified rural areas, which were identified using the methodology set forth in the statute. Payments for ambulance services under Medicare are determined by the point of pick-up (by zip code area) where the beneficiary is loaded on board the ambulance.

We determined that ground ambulance transports originating in 7,842 zip code areas (which were determined to be in ''qualified rural areas'') out of 42,879 zip code areas, according to the July 2010 zip code file, will realize increased base rate payments under section 106(c) of the MMEA for CY 2011; however, the number and level of services that might occur in these areas for CY 2011 is unknown at this time. Similarly, for purposes of assessing the impact of MMEA section 106(a) and (b), the number and level of services that might occur during CY 2011 in rural and urban areas generally is unknown at this time. While many elements may factor into the final impact of section 106 of the MMEA, our Office of the Actuary (OACT) estimates the impact of this section to be $20 million for CY 2011.

4. Durable Medical Equipment (DME) and Supplies

The fiscal impact of the proposed 3-year minimum lifetime standard for DME is likely to be minimal because we believe that this standard is consistent with our current interpretation of durability for DME. It is difficult to predict how many different types of new devices will be introduced in the market in the future that may or may not meet the 3-year minimum lifetime standard. However, even absent the rule, it is likely that new products which do not meet the 3-year lifetime standard would not qualify as DME based upon our current interpretation of durability for DME. It is possible that with the clarification of the 3-year minimum lifetime standard, we would be limiting what can be covered as DME compared to what we would have covered as DME absent this regulatory clarification. To the extent the regulatory change is binding to some new products, there may be reduced program cost. Also, the revised regulation does not apply to items that were classified as DME before the effective date of the amended regulation, which tends to lessen the overall impact to the program. In general, we would expect that this proposed rule would have a small, if any, savings impact on the program.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 15 below, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

TABLE 15—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS ESRD PPS FOR CY 2012

Category	Transfers
Annualized Monetized Transfers	$160 million.
From Whom to Whom	Federal Government to ESRD providers.
Category	**Costs**
Increased Beneficiary Co-insurance Payments	$40 million.
ESRD QIP for PYs 2013 and 2014	
Category	**Transfers**
Annualized Monetized Transfers at the 7% Discount Rate	−$31.2 million.
Annualized Monetized Transfers at the 3% Discount Rate	−$30.9 million.
From Whom to Whom	Federal Government to ESRD providers.
Category	**Costs**
Annualized Monetized ESRD Provider Costs at the 7% Discount Rate	$11.7 million.
Annualized Monetized ESRD Provider Costs at the 7% Discount Rate	$11.9 million.
Ambulance Fee Schedule for CY 2011	
Category	**Transfers**
Annualized Monetized Transfers	$20 million.
From Whom to Whom	Federal Government to Medicare Ambulance Providers.
Durable Medical Equipment (DME) and Supplies	
Category	**Transfers**
Annualized Monetized Transfers	Impact of the 3 year RUL not estimated.
From Whom to Whom	Federal Government to DME suppliers.

VIII. 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 20 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's 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 and seventeen percent of dialysis facilities are nonprofit organizations. For more information on SBA's size standards, see the Small Business Administration's Web site at *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf* (Kidney Dialysis Centers are listed as 621492 with a size standard of $34.5 million).

The claims data utilized to estimate payments to ESRD facilities in this RFA and RIA do not identify which dialysis facilities are part of an large dialysis organizations (LDO), regional chain, or other type of ownership. Each individual dialysis facility has its own provider number and bills Medicare using this number. Therefore, in previous RFAs and RIAs presented in proposed and final rules that updated the basic case-mix adjusted composite payment system, we considered each ESRD to be a small entity for purposes of the RFA. However, we conducted a special analysis for this proposed 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, regardless of ownership, that would be considered small entities.

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations 50,000 or less and therefore, they are not enumerated or included in this estimated RFA. Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 20 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 the impact Table 15. Using the definitions in this ownership category, we consider the 624 facilities that are independent and

the 430 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 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) are not included as small entities.

For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by ownership type) is estimated to receive a 1.7 percent increase in payments for CY 2012. An independent facility (as defined by ownership type) is estimated to receive a 2.0 percent increase in payments for 2012.

Based on the proposed QIP payment reduction impacts to ESRD facilities for PY 2013, we estimate that of the 2,059 ESRD facilities expected to receive a payment reduction, 385 ESRD small entity facilities would experience a payment reduction (ranging from 0.5 percent up to 2.0 of total payments), as presented in Table 15 above. We anticipate the payment reductions to average approximately $22,934 per facility, with an average of $23,807 per small entity. Using our projections of provider/facility performance, we then estimated the impact of anticipated payment reductions on ESRD small entities, by comparing the total payment reductions for the 385 small entities expected to receive a payment reduction, with the aggregate ESRD payments to all small entities. For the entire group of 1,054 ESRD small entity facilities, a decrease of 0.57 percent in aggregate ESRD payments is observed.

Furthermore, based on the proposed QIP payment reduction impacts to ESRD facilities for PY 2014, we estimate that of the 737 ESRD entity facilities expected to receive a payment reduction, 132 small entities are expected to experience a payment reduction (ranging from 1.0 percent up to 2.0 of total payments), as presented in Table 15 above. We anticipate the payment reductions to average approximately $18,820 per facility, with an average of $20,436 per small entity facility. Using our projections of provider/facility performance, we then estimated the impact of anticipated payment reductions on small entities, by comparing the total payment reductions for the 132 small entities expected to receive a payment reduction, with the aggregate ESRD payments to all small entities. For the entire group of 1,054 small entity facilities, a decrease of 0.16 percent in aggregate ESRD payments is observed.

Therefore, the Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities. We solicit comment on the RFA analysis provided.

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 603 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 proposed rule would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 174 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 174 rural hospital-based dialysis facilities will experience an estimated 1.8 percent increase in payments. As a result, this proposed rule is estimated to not have a significant impact on small rural hospitals. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

IX. 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 2011, that threshold is approximately $136 million. This proposed rule does not include any mandates that would impose spending costs on State, local, or Tribal governments in the aggregate, or by the private sector, of $136 million.

X. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it would not have substantial direct effects on the rights, roles, and responsibilities of States, local or Tribal governments.

XI. Files Available to the Public via the Internet

This section lists the Addenda referred to in the preamble of this proposed 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 Lisa Hubbard at (410) 786–4533.

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Proposed Rule to revise the definition of durable medical equipment (DME) to incorporate a minimum lifetime standard of 3 years and further refine the meaning of the term durable.

For the reasons set forth in the preamble, the Center for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

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 continues 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), 1395(g), 1395I(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106–113 (133 stat. 1501A–332)

2. Section 413.232 is amended by revising paragraphs (b)(1), (b)(2), and (f) to read as follows:

§ 413.232 Low-Volume adjustment.

(a) * * *

(b) * * *

(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or

final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year; and

(2) Has not opened, closed, or had a change in ownership in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

* * * * *

(f) To receive the low-volume adjustment an ESRD facility must provide an attestation statement, prior to November 1st of each year, to its Medicare administrative contractor that the facility has met all the criteria established in paragraphs (a), (b), (c), and (d) of this section.

* * * * *

4. Section 413.237 is amended by adding paragraph (a)(1)(v) to read as follows:

§ 413.237 Outliers.

(a) * * *

(1) * * *

(v) As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

5. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

6. Section 414.202 is amended by revising the definition of durable medical equipment to read as follows:

§ 414.202 Definitions.

* * * * *

Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:

(1) Can withstand repeated use.

(2) Has an expected life of at least 3 years (This expected life requirement applies to items classified as DME after [EFFECTIVE DATE OF FINAL RULE]).

(3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

* * * * *

Subpart H—Fee Schedule for Ambulance Services

7. Section 414.610 is amended by revising paragraphs (c)(1) introductory text, (c)(1)(ii), (c)(5)(ii) and (h) to read as follows:

§ 414.610 Basis of payments.

* * * * *

(c) * * *

(1) *Ground ambulance service levels. The CF is multiplied* by the applicable RVUs for each level of service to produce a service-level base rate.

* * * * *

(ii) For services furnished during the period July 1, 2008 through December 31, 2011, ambulance services originating in—

* * * * *

(5) * * *

(ii) For services furnished during the period July 1, 2004 through December 31, 2011, the payment amount for the ground ambulance base rate is increased by 22.6 percent where the point of pickup is in a rural area determined to be in the lowest 25 percent of rural population arrayed by population density. The amount of this increase is based on CMS's estimate of the ratio of the average cost per trip for the rural areas in the lowest quartile of population compared to the average cost per trip for the rural areas in the highest quartile of population. In making this estimate, CMS may use data provided by the GAO.

* * * * *

(h) *Treatment of certain areas for payment for air ambulance services.* Any area that was designated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished on December 31, 2006, must be treated as a rural area for purposes of making payments under the ambulance fee schedule for air ambulance services furnished during the period July 1, 2008 through December 31, 2011.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 16, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 20, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–16874 Filed 7–1–11; 4:15 pm]

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Part IV

Department of Justice

Drug Enforcement Administration

21 CFR Chapter II

Denial of Petition To Initiate Proceedings To Reschedule Marijuana; Proposed Rule

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Chapter II

[Docket No. DEA–352N]

Denial of Petition To Initiate Proceedings To Reschedule Marijuana

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Denial of petition to initiate proceedings to reschedule marijuana.

SUMMARY: By letter dated June 21, 2011, the Drug Enforcement Administration (DEA) denied a petition to initiate rulemaking proceedings to reschedule marijuana.[1] Because DEA believes that this matter is of particular interest to members of the public, the agency is publishing below the letter sent to the petitioner (denying the petition), along with the supporting documentation that was attached to the letter.

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone (202) 307–7165.

SUPPLEMENTARY INFORMATION:

June 21, 2011.

Dear Mr. Kennedy:

On October 9, 2002, you petitioned the Drug Enforcement Administration (DEA) to initiate rulemaking proceedings under the rescheduling provisions of the Controlled Substances Act (CSA). Specifically, you petitioned DEA to have marijuana removed from schedule I of the CSA and rescheduled as cannabis in schedule III, IV or V.

You requested that DEA remove marijuana from schedule I based on your assertion that:

(1) Cannabis has an accepted medical use in the United States;

(2) Cannabis is safe for use under medical supervision;

(3) Cannabis has an abuse potential lower than schedule I or II drugs; and

(4) Cannabis has a dependence liability that is lower than schedule I or II drugs.

In accordance with the CSA rescheduling provisions, after gathering the necessary data, DEA requested a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services (DHHS). DHHS concluded that marijuana has a high potential for abuse, has no accepted medical use in the United States, and lacks an acceptable level of safety for use even under medical supervision. Therefore, DHHS recommended that marijuana remain in schedule I. The scientific and medical evaluation and scheduling recommendation that DHHS submitted to DEA is attached hereto.

Based on the DHHS evaluation and all other relevant data, DEA has concluded that there is no substantial evidence that marijuana should be removed from schedule I. A document prepared by DEA addressing these materials in detail also is attached hereto. In short, marijuana continues to meet the criteria for schedule I control under the CSA because:

(1) *Marijuana has a high potential for abuse.* The DHHS evaluation and the additional data gathered by DEA show that marijuana has a high potential for abuse.

(2) *Marijuana has no currently accepted medical use in treatment in the United States.* According to established case law, marijuana has no ''currently accepted medical use'' because: The drug's chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well-controlled studies proving efficacy; the drug is not accepted by qualified experts; and the scientific evidence is not widely available.

(3) *Marijuana lacks accepted safety for use under medical supervision.* At present, there are no U.S. Food and Drug Administration (FDA)-approved marijuana products, nor is marijuana under a New Drug Application (NDA) evaluation at the FDA for any indication. Marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. At this time, the known risks of marijuana use have not been shown to be outweighed by specific benefits in well-controlled clinical trials that scientifically evaluate safety and efficacy.

You also argued that cannabis has a dependence liability that is lower than schedule I or II drugs. Findings as to the physical or psychological dependence of a drug are only one of eight factors to be considered. As discussed further in the attached documents, DHHS states that long-term, regular use of marijuana can lead to physical dependence and withdrawal following discontinuation as well as psychic addiction or dependence.

The statutory mandate of 21 U.S.C. 812(b) is dispositive. Congress established only one schedule, schedule I, for drugs of abuse with ''no currently accepted medical use in treatment in the United States'' and ''lack of accepted safety for use under medical supervision.'' 21 U.S.C. 812(b).

Accordingly, and as set forth in detail in the accompanying DHHS and DEA documents, there is no statutory basis under the CSA for DEA to grant your petition to initiate rulemaking proceedings to reschedule marijuana. Your petition is, therefore, hereby denied.

Sincerely,

Michele M. Leonhart,
Administrator.

Attachments:

Marijuana. Scheduling Review Document: Eight Factor Analysis

Basis for the recommendation for maintaining marijuana in schedule I of the Controlled Substances Act

Date: June 30, 2011

Michele M. Leonhart
Administrator

Department of Health and Human Services,
Office of the Secretary Assistant Secretary for Health, Office of Public Health and Science Washington, D.C. 20201.

December 6, 2006.

The Honorable Karen P. Tandy
Administrator, Drug Enforcement Administration, U.S. Department of Justice, Washington, D.C. 20537

Dear Ms. Tandy:

This is in response to your request of July 2004, and pursuant to the Controlled Substances Act (CSA), 21 U.S.C. 811(b), (c), and (f), the Department of Health and Human Services (DHHS) recommends that marijuana continue to be subject to control under Schedule I of the CSA.

Marijuana is currently controlled under Schedule I of the CSA. Marijuana continues to meet the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(l). As discussed in the attached analysis, marijuana has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and has a lack of an accepted level of safety for use under medical supervision. Accordingly, HHS recommends that marijuana continue to be subject to control under Schedule I of the CSA. Enclosed is a document prepared by FDA's Controlled Substance Staff that is the basis for this recommendation.

Should you have any questions regarding this recommendation, please contact Corinne P. Moody, of the Controlled Substance Staff, Center for Drug Evaluation and Research. Ms. Moody can be reached at 301–827–1999.

Sincerely yours,
John O. Agwunobi,
Assistant Secretary for Health.

Enclosure:

[1] Note that ''marihuana'' is the spelling originally used in the Controlled Substances Act (CSA). This document uses the spelling that is more common in current usage, ''marijuana.''

Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act

BASIS FOR THE RECOMMENDATION FOR MAINTAINING MARIJUANA IN SCHEDULE I OF THE CONTROLLED SUBSTANCES ACT

On October 9, 2002, the Coalition for Rescheduling Cannabis (hereafter known as the Coalition) submitted a petition to the Drug Enforcement Administration (DEA) requesting that proceedings be initiated to repeal the rules and regulations that place marijuana in Schedule I of the Controlled Substances Act (CSA). The petition contends that cannabis has an accepted medical use in the United States, is safe for use under medical supervision, and has an abuse potential and a dependency liability that is lower than Schedule I or II drugs. The petition requests that marijuana be rescheduled as ''cannabis'' in either Schedule III, IV, or V of the CSA. In July 2004, the DEA Administrator requested that the Department of Health and Human Services (HHS) provide a scientific and medical evaluation of the available information and a scheduling recommendation for marijuana, in accordance with the provisions of 21 U.S.C. 811(b).

In accordance with 21 U.S.C. 811(b), DEA has gathered information related to the control of marijuana (*Cannabis sativa*)[2] under the CSA. Pursuant to 21 U.S.C. 811(b), the Secretary is required to consider in a scientific and medical evaluation eight factors determinative of control under the CSA. Following consideration of the eight factors, if it is appropriate, the Secretary must make three findings to recommend scheduling a substance in the CSA. The findings relate to a substance's abuse potential, legitimate medical use, and safety or dependence liability.

Administrative responsibilities for evaluating a substance for control under the CSA are performed by the Food and Drug Administration (FDA), with the concurrence of the National Institute on Drug Abuse (NIDA), as described in the Memorandum of Understanding (MOU) of March 8, 1985 (50 FR 9518–20).

In this document, FDA recommends the continued control of marijuana in Schedule I of the CSA. Pursuant to 21 U.S.C. 811(c), the eight factors pertaining to the scheduling of marijuana are considered below.

1. ITS ACTUAL OR RELATIVE POTENTIAL FOR ABUSE

The first factor the Secretary must consider is marijuana's actual or relative potential for abuse. The term ''abuse'' is not defined in the CSA. However, the legislative history of the CSA suggests the following in determining whether a particular drug or substance has a potential for abuse:

a. Individuals are taking the substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.

b. There is a significant diversion of the drug or substance from legitimate drug channels.

c. Individuals are taking the substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substances.

d. The substance is so related in its action to a substance already listed as having a potential for abuse to make it likely that it will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970) reprinted in U.S.C.C.A.N. 4566, 4603.

In considering these concepts in a variety of scheduling analyses over the last three decades, the Secretary has analyzed a range of factors when assessing the abuse liability of a substance. These factors have included the prevalence and frequency of use in the general public and in specific sub-populations, the amount of the material that is available for illicit use, the ease with which the substance may be obtained or manufactured, the reputation or status of the substance ''on the street,'' as well as evidence relevant to population groups that may be at particular risk.

Abuse liability is a complex determination with many dimensions. There is no single test or assessment procedure that, by itself, provides a full and complete characterization. Thus, no single measure of abuse liability is ideal. Scientifically, a comprehensive evaluation of the relative abuse potential of a drug substance can include consideration of the drug's receptor binding affinity, preclinical pharmacology, reinforcing effects, discriminative stimulus effects, dependence producing potential, pharmacokinetics and route of administration, toxicity, assessment of the clinical efficacy-safety database relative to actual abuse, clinical abuse liability studies, and the public health risks following introduction of the substance to the general population. It is important to note that abuse may exist independent of a state of tolerance or physical dependence, because drugs may be abused in doses or in patterns that do not induce these phenomena. Animal data, human data, and epidemiological data are all used in determining a substance's abuse liability. Epidemiological data can also be an important indicator of actual abuse. Finally, evidence of clandestine production and illicit trafficking of a substance are also important factors.

a. There is evidence that individuals are taking the substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.

Marijuana is a widely abused substance. The pharmacology of the psychoactive constituents of marijuana, including delta^9-tetrahydrocannabinol (delta^9-THC), the primary psychoactive ingredient in marijuana, has been studied extensively in animals and humans and is discussed in more detail below in Factor 2, ''Scientific Evidence of its Pharmacological Effects, if Known.'' Data on the extent of marijuana abuse are available from HHS through NIDA and the Substance Abuse and Mental Health Services Administration (SAMHSA). These data are discussed in detail under Factor 4, ''Its History and Current Pattern of Abuse;'' Factor 5, ''The Scope, Duration, and Significance of Abuse;'' and Factor 6, ''What, if any, Risk There is to the Public Health?''

According to SAMHSA's 2004 National Survey on Drug Use and Health (NSDUH; the database formerly known as the National Household Survey on Drug Abuse (NHSDA)), the latest year for which complete data are available, 14.6 million Americans have used marijuana in the past month. This is an increase of 3.4 million individuals since 1999, when 11.2 million individuals reported using marijuana monthly. (See the discussion of NSDUH data under Factor 4).

The Drug Abuse Warning Network (DAWN), sponsored by SAMHSA, is a national probability survey of U.S. hospitals with emergency departments (EDs) designed to obtain information on ED visits in which recent drug use is implicated; 2003 is the latest year for which complete data are available. Marijuana was involved in 79,663 ED visits (13 percent of drug-related visits). There are a number of risks resulting from both acute and chronic use of marijuana which are discussed in full below under Factors 2 and 6.

b. There is significant diversion of the substance from legitimate drug channels.

At present, cannabis is legally available through legitimate channels for research purposes only and thus has a limited potential for diversion. In addition, the lack of significant diversion of investigational supplies may result from the ready availability of illicit cannabis of equal or greater quality. The magnitude of the demand for illicit marijuana is evidenced by DEA/Office of National Drug Control Policy (ONDCP) seizure statistics. Data on marijuana seizures can often highlight trends in the overall trafficking patterns. DEA's Federal-Wide Drug Seizure System (FDSS) provides information on total federal drug seizures. FDSS reports total federal seizures of 2,700,282 pounds of marijuana in 2003, the latest year for which complete data are available (DEA, 2003). This represents nearly a doubling of marijuana seizures since 1995, when 1,381,107 pounds of marijuana were seized by federal agents.

c. Individuals are taking the substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substances.

[2] The CSA defines marijuana as the following:

all parts of the plant Cannabis Sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted there from), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination (21 U.S.C. 802(16)).

The 2004 NSDUH data show that 14.6 million American adults use marijuana on a monthly basis (SAMHSA, 2004), confirming that marijuana has reinforcing properties for many individuals. The FDA has not evaluated or approved a new drug application (NDA) for marijuana for any therapeutic indication, although several investigational new drug (IND) applications are currently active. Based on the large number of individuals who use marijuana, it can be concluded that the majority of individuals using cannabis do so on their own initiative, not on the basis of medical advice from a practitioner licensed to administer the drug in the course of professional practice.

d. The substance is so related in its action to a substance already listed as having a potential for abuse to make it likely that it will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

The primary psychoactive compound in botanical marijuana is delta^9-THC. Other cannabinoids also present in the marijuana plant likely contribute to the psychoactive effects.

There are two drug products containing cannabinoid compounds that are structurally related to the active components in marijuana. Both are controlled under the CSA. Marinol is a Schedule III drug product containing synthetic delta^9-THC, known generically as dronabinol, formulated in sesame oil in soft gelatin capsules. Dronabinol is listed in Schedule I. Marinol was approved by the FDA in 1985 for the treatment of two medical conditions: nausea and vomiting associated with cancer chemotherapy in patients that had failed to respond adequately to conventional anti-emetic treatments, and for the treatment of anorexia associated with weight loss in patients with acquired immunodeficiency syndrome or AIDS. Cesamet is a drug product containing the Schedule II substance, nabilone, that was approved for marketing by the FDA in 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy. All other structurally related cannabinoids in marijuana are already listed as Schedule I drugs under the CSA.

2. SCIENTIFIC EVIDENCE OF ITS PHARMACOLOGICAL EFFECTS, IF KNOWN

The second factor the Secretary must consider is scientific evidence of marijuana's pharmacological effects. There are abundant scientific data available on the neurochemistry, toxicology, and pharmacology of marijuana. This section includes a scientific evaluation of marijuana's neurochemistry, pharmacology, and human and animal behavioral, central nervous system, cognitive, cardiovascular, autonomic, endocrinological, and immunological system effects. The overview presented below relies upon the most current research literature on cannabinoids.

Neurochemistry and Pharmacology of Marijuana

Some 483 natural constituents have been identified in marijuana, including approximately 66 compounds that are classified as cannabinoids (Ross and El Sohly, 1995). Cannabinoids are not known to exist in plants other than marijuana, and most of the cannabinoid compounds that occur naturally have been identified chemically. Delta^9-THC is considered the major psychoactive cannabinoid constituent of marijuana (Wachtel et al., 2002). The structure and function of delta^9-THC was first described in 1964 by Gaoni and Mechoulam.

The site of action of delta^9-THC and other cannabinoids was verified with the cloning of cannabinoid receptors, first from rat brain tissue (Matsuda et al., 1990) and then from human brain tissue (Gerard et al., 1991). Two cannabinoid receptors, CB_1 and CB_2, have subsequently been characterized (Piomelli, 2005).

Autoradiographic studies have provided information on the distribution of cannabinoid receptors. CB_1 receptors are found in the basal ganglia, hippocampus, and cerebellum of the brain (Howlett et al., 2004) as well as in the immune system. It is believed that the localization of these receptors may explain cannabinoid interference with movement coordination and effects on memory and cognition. The concentration of CB_1 receptors is considerably lower in peripheral tissues than in the central nervous system (Henkerham et al., 1990 and 1992).

CB_2 receptors are found primarily in the immune system, predominantly in B lymphocytes and natural killer cells (Bouaboula et al., 1993). It is believed that the CB_2-type receptor is responsible for mediating the immunological effects of cannabinoids (Galiegue et al., 1995).

However, CB_2 receptors also have recently been localized in the brain, primarily in the cerebellum and hippocampus (Gong et al., 2006).

The cannabinoid receptors belong to the family of G-protein-coupled receptors and present a typical seven transmembrane-spanning domain structure. Many G-protein-coupled receptors are linked to adenylate cyclase either positively or negatively, depending on the receptor system. Cannabinoid receptors are linked to an inhibitory G-protein (Gi), so that when the receptor is activated, adenylate cyclase activity is inhibited, which prevents the conversion of adenosine triphosphate (ATP)to the second messenger cyclic adenosine monophosphate (cAMP). Examples of inhibitory-coupled receptors include: opioid, muscarinic cholinergic, alpha $_2$-adrenoreceptors, dopamine (D_2), and serotonin (5–HT_1).

It has been shown that CB_1, but not CB_2 receptors, inhibit N- and P/Q type calcium channels and activate inwardly rectifying potassium channels (Mackie et al., 1995; Twitchell et al., 1997). Inhibition of the N-type calcium channels decreases neurotransmitter release from several tissues and this may be the mechanism by which cannabinoids inhibit acetylcholine, norepinephrine, and glutamate release from specific areas of the brain. These effects might represent a potential cellular mechanism underlying the antinociceptive and psychoactive effects of cannabinoids (Ameri, 1999). When cannabinoids are given subacutely to rats, there is a down-regulation of CB_1 receptors, as well as a decrease in GTPgammaS binding, the second messenger system coupled to CB_1 receptors (Breivogel et al., 2001).

Delta^9-THC displays similar affinity for CB_1 and CB_2 receptors but behaves as a weak agonist for CB_2 receptors, based on inhibition of adenylate cyclase. The identification of synthetic cannabinoid ligands that selectively bind to CB_2 receptors but do not have the typical delta^9-THC-like psychoactive properties suggests that the psychotropic effects of cannabinoids are mediated through the activation of CB_1-receptors (Hanus et al., 1999). Naturally-occurring cannabinoid agonists, such as delta^9-THC, and the synthetic cannabinoid agonists such as WIN–55,212–2 and CP–55,940 produce hypothermia, analgesia, hypoactivity, and cataplexy in addition to their psychoactive effects.

In 2000, two endogenous cannabinoid receptor agonists, anandamide and arachidonyl glycerol (2–AG), were discovered. Anandamide is a low efficacy agonist (Breivogel and Childers, 2000), 2–AG is a highly efficacious agonist (Gonsiorek et al., 2000). Cannabinoid endogenous ligands are present in central as well as peripheral tissues. The action of the endogenous ligands is terminated by a combination of uptake and hydrolysis. The physiological role of endogenous cannabinoids is an active area of research (Martin et al., 1999).

Progress in cannabinoid pharmacology, including further characterization of the cannabinoid receptors, isolation of endogenous cannabinoid ligands, synthesis of agonists and antagonists with variable affinity, and selectivity for cannabinoid receptors, provide the foundation for the potential elucidation of cannabinoid-mediated effects and their relationship to psychomotor disorders, memory, cognitive functions, analgesia, anti-emesis, intraocular and systemic blood pressure modulation, bronchodilation, and inflammation.

Central Nervous System Effects

Human Physiological and Psychological Effects

Subjective Effects

The physiological, psychological, and behavioral effects of marijuana vary among individuals. Common responses to cannabinoids, as described by Adams and Martin (1996) and others (Hollister, 1986 and 1988; Institute of Medicine, 1982) are listed below:

1) Dizziness, nausea, tachycardia, facial flushing, dry mouth, and tremor initially

2) Merriment, happiness, and even exhilaration at high doses

3) Disinhibition, relaxation, increased sociability, and talkativeness

4) Enhanced sensory perception, giving rise to increased appreciation of music, art, and touch

5) Heightened imagination leading to a subjective sense of increased creativity

6) Time distortions

7) Illusions, delusions, and hallucinations, especially at high doses

8) Impaired judgment, reduced co-ordination and ataxia, which can impede driving ability or lead to an increase in risk-taking behavior

9) Emotional lability, incongruity of affect, dysphoria, disorganized thinking, inability to converse logically, agitation, paranoia, confusion, restlessness, anxiety, drowsiness, and panic attacks, especially in inexperienced users or in those who have taken a large dose

10) Increased appetite and short-term memory impairment

These subjective responses to marijuana are pleasurable to many humans and are associated with drug-seeking and drug-taking (Maldonado, 2002).

The short-term perceptual distortions and psychological alterations produced by marijuana have been characterized by some researchers as acute or transient psychosis (Favrat et al., 2005). However, the full response to cannabinoids is dissimilar to the DSM–IV–TR criteria for a diagnosis of one of the psychotic disorders (DSM–IV–TR, 2000).

As with many psychoactive drugs, an individual's response to marijuana can be influenced by that person's medical/psychiatric history and history with drugs. Frequent marijuana users (greater than 100 times) were better able to identify a drug effect from low dose delta^9-THC than infrequent users (less than 10 times) and were less likely to experience sedative effects from the drug (Kirk and deWit, 1999). Dose preferences have been demonstrated for marijuana in which higher doses (1.95 percent delta^9-THC) are preferred over lower doses (0.63 percent delta^9-THC) (Chait and Burke, 1994).

Behavioral Impairment

Acute administration of smoked marijuana impairs performance on tests of learning, associative processes, and psychomotor behavior (Block et al., 1992). These data demonstrate that the short-term effects of marijuana can interfere significantly with an individual's ability to learn in the classroom or to operate motor vehicles. Administration to human volunteers of 290 micrograms per kilogram (μg/kg) delta^9-THC in a smoked marijuana cigarette resulted in impaired perceptual motor speed and accuracy, two skills that are critical to driving ability (Kurzthaler et al., 1999). Similarly, administration of 3.95 percent delta^9-THC in a smoked marijuana cigarette increased disequilibrium measures, as well as the latency in a task of simulated vehicle braking, at a rate comparable to an increase in stopping distance of 5 feet at 60 mph (Liguori et al., 1998).

The effects of marijuana may not fully resolve until at least 1 day after the acute psychoactive effects have subsided, following repeated administration. Heishman et al. (1990) showed that impairment on memory tasks persists for 24 hours after smoking marijuana cigarettes containing 2.57 percent delta^9-THC. However, Fant et al. (1998) showed minimal residual alterations in subjective or performance measures the day after subjects were exposed to 1.8 percent or 3.6 percent smoked delta^9-THC.

The effects of chronic marijuana use have also been investigated. Marijuana did not appear to have residual effects on performance of a comprehensive neuropsychological battery when 54 monozygotic male twins (one of whom used marijuana, one of whom did not) were compared 1–20 years after cessation of marijuana use (Lyons et al., 2004). This conclusion is similar to the results from an earlier study of marijuana's effects on cognition in 1,318 participants over a 15-year period, where there was no evidence of long-term residual effects (Lyketsos et al., 1999). In contrast, Solowij et al. (2002) demonstrated that 51 long-term cannabis users did less well than 33 non-using controls or 51 short-term users on certain tasks of memory and attention, but users in this study were abstinent for only 17 hours at time of testing. A recent study noted that heavy, frequent cannabis users, abstinent for at least 24 hours, performed significantly worse than controls on verbal memory and psychomotor speed tests (Messinis et al, 2006).

Pope et al. (2003) reported that no differences were seen in neuropsychological performance in early- or late-onset users compared to non-using controls, after adjustment for intelligence quotient (IQ). In another cohort of chronic, heavy marijuana users, some deficits were observed on memory tests up to a week following supervised abstinence, but these effects disappeared by day 28 of abstinence (Harrison et al., 2002). The authors concluded that, ''cannabis-associated cognitive deficits are reversible and related to recent cannabis exposure, rather than irreversible and related to cumulative lifetime use.'' Other investigators have reported neuropsychological deficits in memory, executive functioning, psychomotor speed, and manual dexterity in heavy marijuana smokers who had been abstinent for 28 days (Bolla et al., 2002). A follow up study of heavy marijuana users noted decision-making deficits after 25 days of abstinence (Bolla et al., 2005). Finally, when IQ was contrasted in adolescents at 9–12 years and at 17–20 years, current heavy marijuana users showed a 4-point reduction in IQ in later adolescence compared to those who did not use marijuana (Fried et al., 2002).

Age of first use may be a critical factor in persistent impairment resulting from chronic marijuana use. Individuals with a history of marijuana-only use that began before the age of 16 were found to perform more poorly on a visual scanning task measuring attention than individuals who started using marijuana after age 16 (Ehrenreich et al., 1999). Kandel and Chen (2000) assert that the majority of early-onset marijuana users do not go on to become heavy users of marijuana, and those that do tend to associate with delinquent social groups.

Heavy marijuana users were contrasted with an age matched control group in a case-control design. The heavy users reported lower educational achievement and lower income than controls, a difference that persisted after confounding variables were taken into account. Additionally, the users also reported negative effects of marijuana use on cognition, memory, career, social life, and physical and mental health (Gruber et al., 2003).

Association with Psychosis

Extensive research has been conducted recently to investigate whether exposure to marijuana is associated with schizophrenia or other psychoses. While many studies are small and inferential, other studies in the literature utilize hundreds to thousands of subjects.

At present, the data do not suggest a causative link between marijuana use and the development of psychosis. Although some individuals who use marijuana have received a diagnosis of psychosis, most reports conclude that prodromal symptoms of schizophrenia appear prior to marijuana use (Schiffman et al., 2005). When psychiatric symptoms are assessed in individuals with chronic psychosis, the ''schizophrenic cluster'' of symptoms is significantly observed among individuals who do not have a history of marijuana use, while ''mood cluster'' symptoms are significantly observed in individuals who do have a history of marijuana use (Maremmani et al., 2004).

In the largest study evaluating the link between psychosis and drug use, 3 percent of 50,000 Swedish conscripts who used marijuana more than 50 times went on to develop schizophrenia (Andreasson et al., 1987). This was interpreted by the authors to suggest that marijuana use increased the risk for the disorder only among those individuals who were predisposed to develop psychosis. A similar conclusion was drawn when the prevalence of schizophrenia was modeled against marijuana use across birth cohorts in Australia between the years 1940 to 1979 (Degenhardt et al., 2003). Although marijuana use increased over time in adults born during the 4-decade period, there was not a corresponding increase in diagnoses for psychosis in these individuals. The authors conclude that marijuana may precipitate schizophrenic disorders only in those individuals who are vulnerable to developing psychosis. Thus, marijuana per se does not appear to induce schizophrenia in the majority of individuals who try or continue to use the drug.

However, as might be expected, the acute intoxication produced by marijuana does exacerbate the perceptual and cognitive deficits of psychosis in individuals who have been previously diagnosed with the condition (Schiffman et al., 2005; Hall et al., 2004; Mathers and Ghodse, 1992; Thornicroft, 1990). This is consistent with a 25-year longitudinal study of over 1,000 individuals who had a higher rate of experiencing some symptoms of psychosis (but who did not receive a diagnosis of psychosis) if they were daily marijuana users than if they were not (Fergusson et al., 2005). A shorter, 3-year longitudinal study with over 4,000 subjects similarly showed that psychotic symptoms, but not diagnoses, were more prevalent in subjects who used marijuana (van Os et al., 2002).

Additionally, schizophrenic individuals stabilized with antipsychotics do not respond differently to marijuana than healthy controls (D'Souza et al., 2005), suggesting that psychosis and/or antipsychotics do not biochemically alter cannabinoid systems in the brain.

Interestingly, cannabis use prior to a first psychotic episode appeared to spare neurocognitive deficits compared to patients who had not used marijuana (Stirling et al., 2005). Although adolescents diagnosed with a first psychotic episode used more marijuana than adults who had their first psychotic break, adolescents and adults had similar clinical outcomes 2 years later (Pencer et al., 2005).

Heavy marijuana users, though, do not perform differently than non-users on the Stroop task, a classic psychometric instrument that measures executive cognitive functioning. Since psychotic individuals do not perform the Stroop task well, alterations in executive functioning consistent with a psychotic profile were not apparent following chronic exposure to marijuana (Gruber and Yurgelun-Todd, 2005; Eldreth et al., 2004).

Alteration in Brain Structure

Although evidence suggests that some drugs of abuse can lead to changes in the density or structure of the brain in humans, there are currently no data showing that exposure to marijuana can induce such alterations. A recent comparison of long-term marijuana smokers to non-smoking control subjects using magnetic resonance imaging (MRI) did not reveal any differences in the volume of grey or white matter, in the hippocampus, or in cerebrospinal fluid volume, between the two groups (Tzilos et al., 2005).

Behavioral Effects of Prenatal Exposure

The impact of in utero marijuana exposure on performance in a series of cognitive tasks has been studied in children at different stages of development. However, since many marijuana users have abused other drugs, it is difficult to determine the specific impact of marijuana on prenatal exposure.

Differences in several cognitive domains distinguished the 4-year-old children of heavy marijuana users. In particular, memory and verbal measures are negatively associated with maternal marijuana use (Fried and Watkinson, 1987). Maternal marijuana use is predictive of poorer performance on abstract/visual reasoning tasks, although it is not associated with an overall lowered IQ in 3-year old children (Griffith et al., 1994). At 6 years of age, prenatal marijuana history is associated with an increase in omission errors on a vigilance task, possibly reflecting a deficit in sustained attention (Fried et al., 1992). When the effect of prenatal exposure in 9–12 year old children is analyzed, in utero marijuana exposure is negatively associated with executive function tasks that require impulse control, visual analysis, and hypothesis testing, and it is not associated with global intelligence (Fried et al., 1998).

Marijuana as a ''Gateway Drug''

The Institute of Medicine (IOM) reported that the widely held belief that marijuana is a ''gateway drug,'' leading to subsequent abuse of other illicit drugs, lacks conclusive evidence (Institute of Medicine, 1999). Recently, Fergusson et al. (2005) in a 25-year study of 1,256 New Zealand children concluded that use of marijuana correlates to an increased risk of abuse of other drugs, including cocaine and heroin. Other sources, however, do not support a direct causal relationship between regular marijuana and other illicit drug use. In general, such studies are selective in recruiting individuals who, in addition to having extensive histories of marijuana use, are influenced by myriad social, biological, and economic factors that contribute to extensive drug abuse (Hall and Lynskey, 2005). For most studies that test the hypothesis that marijuana causes abuse of harder drugs, the determinative measure of choice is any drug use, rather than DSM–IV–TR criteria for drug abuse or dependence (DSM–IV–TR, 2000).

According to Golub & Johnson (2001), the rate of progression to hard drug use by youth born in the 1970's, as opposed to youth born between World War II and the 1960's, is significantly decreased, although overall marijuana use among youth appears to be increasing. Nace et al. (1975) reported that even in the Vietnam-era soldiers who extensively abused marijuana and heroin, there was a lack of correlation of a causal relationship demonstrating marijuana use leading to heroin addiction. A recent longitudinal study of 708 adolescents demonstrated that early onset marijuana use did not lead to problematic drug use (Kandel and Chen, 2000). Similarly, among 2,446 adolescents followed longitudinally, cannabis dependence was uncommon but when it did occur, it was predicted primarily by parental death, deprived socio-economic status, and baseline use of illicit drugs other than marijuana (von Sydow et al., 2002).

Animal behavioral effects

Self-Administration

Self-administration is a method that assesses whether a drug produces rewarding effects that increase the likelihood of behavioral responses in order to obtain additional drug. Drugs that are self-administered by animals are likely to produce rewarding effects in humans, which is indicative of abuse liability. Generally, a good correlation exists between those drugs that are self-administered by rhesus monkeys and those that are abused by humans (Balster and Bigelow, 2003).

Interestingly, self-administration of hallucinogenic-like drugs, such as cannabinoids, lysergic acid diethylamide (LSD), and mescaline, has been difficult to demonstrate in animals (Yanagita, 1980). However, when it is known that humans voluntarily consume a particular drug (such as cannabis) for its pleasurable effects, the inability to establish self-administration with that drug in animals has no practical importance in the assessment of abuse potential. This is because the animal test is a predictor of human behavioral response in the absence of naturalistic data.

The experimental literature generally reports that naïve animals will not self-administer cannabinoids unless they have had previous experience with other drugs of abuse. However, when squirrel monkeys are first trained to self-administer intravenous cocaine, they will continue to bar-press at the same rate as when delta^9-THC is substituted for cocaine, at doses that are comparable to those used by humans who smoke marijuana (Tanda et al., 2000). This effect is blocked by the cannabinoid receptor antagonist, SR 141716. New studies show that monkeys without a history of any drug exposure can be successfully trained to self-administer delta^9-THC intravenously (Justinova et al., 2003). The maximal rate of responding is 4 μg/kg/injection, which is 2–3 times greater than that observed in previous studies using cocaine-experienced monkeys.

These data demonstrate that under specific pretreatment conditions, an animal model of reinforcement by cannabinoids now exists for future investigations. Rats will self-administer delta^9-THC when it is applied intracerebroventricularly (i.c.v.), but only at the lowest doses tested (0.01–0.02 μg/infusion) (Braida et al., 2004). This effect is antagonized by the cannabinoid antagonist SR141716 and by the opioid antagonist naloxone (Braida et al., 2004). Additionally, mice will self-administer WIN 55212, a CB_1 receptor agonist with a non-cannabinoid structure (Martellotta et al., 1998).

There may be a critical dose-dependent effect, though, since aversive effects, rather than reinforcing effects, have been described in rats that received high doses of WIN 55212 (Chaperon et al., 1998) or delta^9-THC (Sanudo-Pena et al., 1997). SR 141716 reversed these aversive effects in both studies.

Conditioned Place Preference

Conditioned place preference (CPP) is a less rigorous method than self-administration of determining whether drugs have rewarding properties. In this behavioral test, animals are given the opportunity to spend time in two distinct environments: one where they previously received a drug and one where they received a placebo. If the drug is reinforcing, animals will choose to spend more time in the environment paired with the drug than the one paired with the placebo, when both options are presented simultaneously.

Animals show CPP to delta^9-THC, but only at the lowest doses tested (0.075–0.75 mg/kg, i.p.) (Braida et al., 2004). This effect is antagonized by the cannabinoid antagonist, SR141716, as well as by the opioid antagonist, naloxone (Braida et al., 2004). However, SR141716 may be a partial agonist, rather than a full antagonist, since it is also able to induce CPP (Cheer et al., 2000). Interestingly, in knockout mice, animals without μ-opioid receptors do not develop CPP to delta^9-THC (Ghozland et al., 2002).

Drug Discrimination Studies

Drug discrimination is a method in which animals indicate whether a test drug produces physical or psychic perceptions similar to those produced by a known drug of abuse. In this test, an animal learns to press one bar when it receives the known drug of abuse and another bar when it receives placebo. A challenge session with the test drug determines which of the two

bars the animal presses more often, as an indicator of whether the test drug is like the known drug of abuse.

Animals, including monkeys and rats (Gold et al., 1992), as well as humans (Chait, 1988), can discriminate cannabinoids from other drugs or placebo. Discriminative stimulus effects of delta^9-THC are pharmacologically specific for marijuana-containing cannabinoids (Balster and Prescott, 1992; Barnett et al., 1985; Browne and Weissman, 1981; Wiley et al., 1993; Wiley et al., 1995). Additionally, the major active metabolite of delta^9-THC, 11-hydroxy-delta^9-THC, also generalizes to the stimulus cue elicited by delta^9-THC (Browne and Weissman, 1981). Twenty-two other cannabinoids found in marijuana also fully substitute for delta^9-THC.

The discriminative stimulus effects of the cannabinoid group appear to provide unique effects because stimulants, hallucinogens, opioids, benzodiazepines, barbiturates, NMDA antagonists, and antipsychotics do not fully substitute for delta^9-THC.

Tolerance and Physical Dependence

Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time (American Academy of Pain Medicine, American Pain Society and American Society of Addiction Medicine consensus document, 2001). Physical dependence is a state of adaptation manifested by a drug class-specific withdrawal syndrome produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist (*ibid*).

The presence of tolerance or physical dependence does not determine whether a drug has abuse potential, in the absence of other abuse indicators such as rewarding properties. Many medications that are not associated with abuse or addiction, such as antidepressants, beta-blockers, and centrally acting antihypertensive drugs, can produce physical dependence and withdrawal symptoms after chronic use.

Tolerance to the subjective and performance effects of marijuana has not been demonstrated in studies with humans. For example, reaction times are not altered by acute administration of marijuana in long term marijuana users (Block and Wittenborn, 1985). This may be related to recent electrophysiological data showing that the ability of delta^9-THC to increase neuronal firing in the ventral tegmental area (a region known to play a critical role in drug reinforcement and reward) is not reduced following chronic administration of the drug (Wu and French, 2000). On the other hand, tolerance can develop in humans to marijuana-induced cardiovascular and autonomic changes, decreased intraocular pressure, and sleep alterations (Jones et al., 1981). Down-regulation of cannabinoid receptors has been suggested as the mechanism underlying tolerance to the effects of marijuana (Rodriguez de Fonseca et al., 1994; Oviedo et al., 1993).

Acute administration of marijuana containing 2.1 percent delta^9-THC does not produce ''hangover effects'' (Chait et al., 1985). In chronic marijuana users, though, a marijuana withdrawal syndrome has been described that consists of restlessness, irritability, mild agitation, insomnia, sleep EEG disturbances, nausea, and cramping that resolves within a few days (Haney et al., 1999). However, the American Psychiatric Association's Diagnostic and Statistical Manual (DSM–IV–TR, 2000) does not include a listing for cannabis withdrawal syndrome because, ''symptoms of cannabis withdrawal . . . have been described . . . but their clinical significance is uncertain.'' A review of all current clinical studies on cannabis withdrawal led to the recommendation by Budney et al. (2004) that the DSM introduce a listing for cannabis withdrawal that includes such symptoms as sleep difficulties, strange dreams, decreased appetite, decreased weight, anger, irritability, and anxiety. Based on clinical descriptions, this syndrome appears to be mild compared to classical alcohol and barbiturate withdrawal syndromes, which can include more serious symptoms such as agitation, paranoia, and seizures. A recent study comparing marijuana and tobacco withdrawal symptoms in humans demonstrated that the magnitude and timecourse of the two withdrawal syndromes are similar (Vandrey et al., 2005).

The production of an overt withdrawal syndrome in animals following chronic delta^9-THC administration has been variably demonstrated under conditions of natural discontinuation. This may be the result of the slow release of cannabinoids from adipose storage, as well as the presence of the major psychoactive metabolite, 11-hydroxy-delta^9-THC. When investigators have shown such a withdrawal syndrome in monkeys following the termination of cannabinoid administration, the behaviors included transient aggression, anorexia, biting, irritability, scratching, and yawning (Budney et al., 2004). However, in rodents treated with a cannabinoid antagonist following subacute administration of delta^9-THC, pronounced withdrawal symptoms, including wet dog shakes, can be provoked (Breivogel et al., 2003).

Behavioral Sensitization

Sensitization to the effects of drugs is the opposite of tolerance: instead of a reduction in behavioral response upon repeated drug administration, animals that are sensitized demonstrate an increase in behavioral response. Cadoni et al. (2001) demonstrated that repeated exposure to delta^9-THC can induce sensitization to a variety of cannabinoids. These same animals also have a sensitized response to administration of opioids, an effect known as cross-sensitization. Conversely, when animals were sensitized to the effects of morphine, there was cross-sensitization to cannabinoids. Thus, the cannabinoid and opioids systems appear to operate symmetrically in terms of cross-sensitization.

Cardiovascular and Autonomic Effects

Single smoked or oral doses of delta^9-THC produce tachycardia and may increase blood pressure (Capriotti et al., 1988; Benowitz and Jones, 1975). However, prolonged delta^9-THC ingestion produces significant heart rate slowing and blood pressure lowering (Benowitz and Jones, 1975). Both plant-derived cannabinoids and endocannabinoids have been shown to elicit hypotension and bradycardia via activation of peripherally-located CB_1 receptors (Wagner et al., 1998). This study suggests that the mechanism of this effect is through presynaptic CB_1 receptor-mediated inhibition of norepinephrine release from peripheral sympathetic nerve terminals, with possible additional direct vasodilation via activation of vascular cannabinoid receptors.

The impaired circulatory responses following delta^9-THC administration to standing, exercise, Valsalva maneuver, and cold pressor testing suggest that cannabinoids induce a state of sympathetic insufficiency. In humans, tolerance can develop to the orthostatic hypotension (Jones, 2002; Sidney, 2002), possibly related to plasma volume expansion, but does not develop to the supine hypotensive effects (Benowitz and Jones, 1975). During chronic marijuana ingestion, nearly complete tolerance develops to tachycardia and psychological effects when subjects are challenged with smoked marijuana. Electrocardiographic changes are minimal even after large cumulative doses of delta^9-THC. (Benowitz and Jones, 1975).

It is notable that marijuana smoking by older patients, particularly those with some degree of coronary artery or cerebrovascular disease, poses risks related to increased cardiac work, increased catecholamines, carboxyhemoglobin, and postural hypotension (Benowitz and Jones, 1981; Hollister, 1988).

Respiratory Effects

Transient bronchodilation is the most typical effect following acute exposure to marijuana (Gong et al., 1984). Long-term use of marijuana can lead to an increased frequency of chronic bronchitis and pharyngitis, as well as chronic cough and increased sputum. Pulmonary function tests reveal that large-airway obstruction can occur with chronic marijuana smoking, as can cellular inflammatory histopathological abnormalities in bronchial epithelium (Adams and Martin, 1996; Hollister, 1986).

The evidence that marijuana may lead to cancer associated with respiratory effects is inconsistent, with some studies suggesting a positive correlation while others do not (Tashkin, 2005). Several cases of lung cancer have been reported in young marijuana users with no history of tobacco smoking or other significant risk factors (Fung et al., 1999). Marijuana use may dose-dependently interact with mutagenic sensitivity, cigarette smoking and alcohol use to increase the risk of head and neck cancer (Zhang et al., 1999). However, in the largest study to date with 1,650 subjects, no positive association was found between marijuana use and lung cancer (Tashkin et al., 2006). This finding held true regardless of extent of marijuana use, when tobacco use and other potential confounding factors were controlled.

The lack of evidence for carcinogenicity related to cannabis may be related to the fact that intoxication from marijuana does not require large amounts of smoked material.

This may be especially pertinent since marijuana is reportedly more potent today than a generation ago. Thus, individuals may consume much less marijuana than in previous decades to reach the desired subjective effects, exposing them to less potential carcinogens.

Endocrine System

The presence of in vitro delta^9-THC reduces binding of the corticosteroid, dexamethasone, in hippocampal tissue from adrenalectomized rats, suggesting an interaction with the glucocorticoid receptor (Eldridge et al., 1991). Acute delta^9-THC releases corticosterone, but tolerance develops to this effect with chronic administration (Eldridge et al., 1991).

Experimental administration of marijuana to humans does not consistently alter endocrine parameters. In an early study, male subjects who experimentally received smoked marijuana showed a significant depression in luteinizing hormone and a significant increase in cortisol were observed (Cone et al., 1986). However, two later studies showed no changes in hormones. Male subjects who were experimentally exposed to smoked delta^9-THC (18 mg/marijuana cigarette) or oral delta^9-THC (10 mg t.i.d. for 3 days and on the morning of the fourth day) showed no changes in plasma prolactin, ACTH, cortisol, luteinizing hormone, or testosterone levels (Dax et al., 1989). Similarly, a study with 93 men and 56 women showed that chronic marijuana use did not significantly alter concentrations of testosterone, luteinizing hormone, follicle stimulating hormone, prolactin, or cortisol (Block et al., 1991).

Relatively little research has been performed on the effects of experimentally administered marijuana on female reproductive system functioning. In monkeys, delta^9-THC administration suppressed ovulation (Asch et al., 1981) and reduced progesterone levels (Almirez et al., 1983). However, when women were studied following experimental exposure to smoked marijuana, no hormonal or menstrual cycle changes were observed (Mendelson and Mello, 1984). Brown and Dobs (2002) suggest that the discrepancy between animal and human hormonal response to cannabinoids may be attributed to the development of tolerance in humans.

Recent data suggest that cannabinoid agonists may have therapeutic value in the treatment of prostate cancer, a type of carcinoma in which growth is stimulated by androgens. Research with prostate cancer cells shows that the mixed CB_1/CB_2 agonist, WIN–55212–2, induces apoptosis in prostate cancer cell growth, as well as decreases in expression of androgen receptors and prostate-specific antigens (Sarfaraz et al., 2005).

Immune System

Immune functions are altered by cannabinoids, but there can be differences between the effects of synthetic, natural, and endogenous cannabinoids, often in an apparently biphasic manner depending on dose (Croxford and Yamamura, 2005).

Abrams et al. (2003) investigated the effect of marijuana on immunological functioning in 62 AIDS patients who were taking protease inhibitors. Subjects received one of the following three times a day: smoked marijuana cigarette containing 3.95 percent delta^9-THC; oral tablet containing delta^9-THC (2.5 mg oral dronabinol); or oral placebo. There were no changes in CD4+ and CD8+ cell counts or HIV RNA levels or protease inhibitor levels between groups, demonstrating no short-term adverse virologic effects from using cannabinoids in individuals with compromised immune systems.

These human data contrast with data generated in immunodeficient mice showing that exposure to delta^9-THC in vivo suppresses immune function, increases HIV co-receptor expression, and acts as a cofactor to enhance HIV replication (Roth et al., 2005).

3. THE STATE OF CURRENT SCIENTIFIC KNOWLEDGE REGARDING THE DRUG OR OTHER SUBSTANCE

The third factor the Secretary must consider is the state of current scientific knowledge regarding marijuana. Thus, this section discusses the chemistry, human pharmacokinetics, and medical uses of marijuana.

Chemistry

According to the DEA, Cannabis sativa is the primary species of cannabis currently marketed illegally in the United States of America. From this plant, three derivatives are sold as separate illicit drug products: marijuana, hashish, and hashish oil.

Each of these derivatives contains a complex mixture of chemicals. Among the components are the 21 carbon terpenes found in the plant as well as their carboxylic acids, analogues, and transformation products known as cannabinoids (Agurell et al., 1984 and 1986; Mechoulam, 1973). The cannabinoids appear to naturally occur only in the marijuana plant and most of the botanically-derived cannabinoids have been identified. Among the cannabinoids, delta^9-THC (alternate name delta^1-THC) and delta-8-tetrahydrocannabinol (delta^8-THC, alternate name delta^6-THC) are both found in marijuana and are able to produce the characteristic psychoactive effects of marijuana. Because delta^9-THC is more abundant than delta^8-THC, the activity of marijuana is largely attributed to the former. Delta^8-THC is found only in few varieties of the plant (Hively et al., 1966).

Delta^9-THC is an optically active resinous substance, insoluble in water, and extremely lipid soluble. Chemically delta^9-THC is (6aR-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo-[b,d]pyran-1-ol or (-)-delta^9-(trans)-tetrahydrocannabinol. The (-)-trans isomer of delta^9-THC is pharmacologically 6 to 100 times more potent than the (+)-trans isomer (Dewey et al., 1984).

Other cannabinoids, such as cannabidiol (CBD) and cannabinol (CBN), have been characterized. CBD is not considered to have cannabinol-like psychoactivity, but is thought to have significant anticonvulsant, sedative, and anxiolytic activity (Adams and Martin, 1996; Agurell et al., 1984 and 1986; Hollister, 1986).

Marijuana is a mixture of the dried flowering tops and leaves from the plant and is variable in content and potency (Agurell et al., 1984 and 1986; Graham, 1976; Mechoulam, 1973). Marijuana is usually smoked in the form of rolled cigarettes while hashish and hash oil are smoked in pipes. Potency of marijuana, as indicated by cannabinoid content, has been reported to average from as low as 1 to 2 percent to as high as 17 percent.

The concentration of delta^9-THC and other cannabinoids in marijuana varies with growing conditions and processing after harvest. Other variables that can influence the strength, quality, and purity of marijuana are genetic differences among the cannabis plant species and which parts of the plant are collected (flowers, leaves, stems, etc.) (Adams and Martin, 1996; Agurell et al., 1984; Mechoulam, 1973). In the usual mixture of leaves and stems distributed as marijuana, the concentration of delta^9-THC ranges widely from 0.3 to 4.0 percent by weight. However, specially grown and selected marijuana can contain even 15 percent or greater delta^9-THC. Thus, a 1 gm marijuana cigarette might contain as little as 3 mg or as much as 150 mg or more of delta^9-THC.

Hashish consists of the cannabinoid-rich resinous material of the cannabis plant, which is dried and compressed into a variety of forms (balls, cakes, etc.). Pieces are then broken off, placed into a pipe and smoked. DEA reports that cannabinoid content in hashish averages 6 percent.

Hash oil is produced by solvent extraction of the cannabinoids from plant material. Color and odor of the extract vary, depending on the type of solvent used. Hash oil is a viscous brown or amber-colored liquid that contains approximately 15 percent cannabinoids. One or two drops of the liquid placed on a cigarette purportedly produce the equivalent of a single marijuana cigarette (DEA, 2005).

The lack of a consistent concentration of delta^9-THC in botanical marijuana from diverse sources complicates the interpretation of clinical data using marijuana. If marijuana is to be investigated more widely for medical use, information and data regarding the chemistry, manufacturing, and specifications of marijuana must be developed.

Human Pharmacokinetics

Marijuana is generally smoked as a cigarette (weighing between 0.5 and 1.0 gm), or in a pipe. It can also be taken orally in foods or as extracts of plant material in ethanol or other solvents.

The absorption, metabolism, and pharmacokinetic profile of delta^9-THC (and other cannabinoids) in marijuana or other drug products containing delta^9-THC vary with route of administration and formulation (Adams and Martin, 1996; Agurell et al., 1984 and 1986). When marijuana is administered by smoking, delta^9-THC in the form of an aerosol is absorbed within seconds. The psychoactive effects of marijuana occur immediately following absorption, with mental and behavioral effects measurable up to 6 hours (Grotenhermen, 2003; Hollister,

1986 and 1988). Delta9-THC is delivered to the brain rapidly and efficiently as would be expected of a very lipid-soluble drug.

The bioavailability of the delta9-THC from marijuana in a cigarette or pipe can range from 1 to 24 percent with the fraction absorbed rarely exceeding 10 to 20 percent (Agurell et al., 1986; Hollister, 1988). The relatively low and variable bioavailability results from the following: significant loss of delta9-THC in side-stream smoke, variation in individual smoking behaviors, cannabinoid pyrolysis, incomplete absorption of inhaled smoke, and metabolism in the lungs. A individual's experience and technique with smoking marijuana is an important determinant of the dose that is absorbed (Herning et al., 1986; Johansson et al., 1989).

After smoking, venous levels of delta9-THC decline precipitously within minutes, and within an hour are about 5 to 10 percent of the peak level (Agurell et al., 1986; Huestis et al., 1992a and 1992b). Plasma clearance of delta9-THC is approximately 950 ml/min or greater, thus approximating hepatic blood flow. The rapid disappearance of delta9-THC from blood is largely due to redistribution to other tissues in the body, rather than to metabolism (Agurell et al., 1984 and 1986). Metabolism in most tissues is relatively slow or absent. Slow release of delta9-THC and other cannabinoids from tissues and subsequent metabolism results in a long elimination half-life. The terminal half-life of delta9-THC is estimated to range from approximately 20 hours to as long as 10 to 13 days (Hunt and Jones, 1980), though reported estimates vary as expected with any slowly cleared substance and the use of assays of variable sensitivities. Lemberger et al. (1970) determined the half-life of delta9-THC to range from 23 to 28 hours in heavy marijuana users to 60 to 70 hours in naïve users.

Characterization of the pharmacokinetics of delta9-THC and other cannabinoids from smoked marijuana is difficult (Agurell et al., 1986; Herning et al., 1986; Huestis et al., 1992a), in part because a subject's smoking behavior during an experiment is variable. Each puff delivers a discrete dose of delta9-THC. An experienced marijuana smoker can titrate and regulate the dose to obtain the desired acute psychological effects and to avoid overdose and/or minimize undesired effects. For example, under naturalistic conditions, users will hold marijuana smoke in the lungs for an extended period of time, in order to prolong absorption and increase psychoactive effects. The effect of experience in the psychological response may explain why venous blood levels of delta9-THC correlate poorly with intensity of effects and level of intoxication (Agurell et al., 1986; Barnett et al., 1985; Huestis et al., 1992a).

Additionally, puff and inhalation volume changes with phase of smoking, tending to be highest at the beginning and lowest at the end of smoking a cigarette. Some studies found frequent users to have higher puff volumes than less frequent marijuana users. During smoking, as the cigarette length shortens, the concentration of delta9-THC in the remaining marijuana increases; thus, each successive puff contains an increasing concentration of delta9-THC.

In contrast to smoking, the onset of effects after oral administration of delta9-THC or marijuana is 30 to 90 min, which peaks after 2 to 3 hours and continues for 4 to 12 hours (Grotenhermen, 2003; Adams and Martin, 1996; Agurell et al., 1984 and 1986). Oral bioavailability of delta9-THC, whether pure or in marijuana, is low and extremely variable, ranging between 5 and 20 percent (Agurell et al., 1984 and 1986). Following oral administration of radioactive-labeled delta9-THC, delta9-THC plasma levels are low relative to those levels after smoking or intravenous administration. There is inter- and intra-subject variability, even when repeated dosing occurs under controlled conditions. The low and variable oral bioavailability of delta9-THC is a consequence of its first-pass hepatic elimination from blood and erratic absorption from stomach and bowel. It is more difficult for a user to titrate the oral delta9-THC dose than marijuana smoking because of the delay in onset of effects after an oral dose (typically 1 to 2 hours).

Cannabinoid metabolism is extensive. Delta9-THC is metabolized via microsomal hydroxylation to both active and inactive metabolites (Lemberger et al., 1970, 1972a, and 1972b; Agurell et al., 1986; Hollister, 1988) of which the primary active metabolite was 11-hydroxy-delta9-THC. This metabolite is approximately equipotent to delta9-THC in producing marijuana-like subjective effects (Agurell et al., 1986; Lemberger and Rubin, 1975). After oral administration, metabolite levels may exceed that of delta9-THC and thus contribute greatly to the pharmacological effects of oral delta9-THC or marijuana. In addition to 11-hydroxy-delta9-THC, some inactive carboxy metabolites have terminal half-lives of 50 hours to 6 days or more. The latter substances serve as long-term markers of earlier marijuana use in urine tests. The majority of the absorbed delta9-THC dose is eliminated in feces, and about 33 percent in urine. Delta9-THC enters enterohepatic circulation and undergoes hydroxylation and oxidation to 11-nor-9-carboxy-delta9-THC. The glucuronide is excreted as the major urine metabolite along with about 18 nonconjugated metabolites. Frequent and infrequent marijuana users are similar in the way they metabolize delta9-THC (Agurell et al., 1986).

Medical Uses for Marijuana

A NDA for marijuana/cannabis has not been submitted to the FDA for any indication and thus no medicinal product containing botanical cannabis has been approved for marketing. However, small clinical studies published in the current medical literature demonstrate that research with marijuana is being conducted in humans in the United States under FDA-authorized investigational new drug (IND) applications.

HHS states in a published guidance that it is committed to providing ''research-grade marijuana for studies that are the most likely to yield usable, essential data'' (HHS, 1999). The opportunity for scientists to conduct clinical research with botanical marijuana has increased due to changes in the process for obtaining botanical marijuana from NIDA, the only legitimate source of the drug for research in the United States. In May 1999, HHS provided guidance on the procedures for providing research-grade marijuana to scientists who intend to study marijuana in scientifically valid investigations and well-controlled clinical trials (DHHS, 1999). This action was prompted by the increasing interest in determining whether cannabinoids have medical use through scientifically valid investigations.

In February 1997, a National Institutes of Health (NIH)-sponsored workshop analyzed available scientific information and concluded that ''in order to evaluate various hypotheses concerning the potential utility of marijuana in various therapeutic areas, more and better studies would be needed'' (NIH, 1997). In addition, in March 1999, the Institute of Medicine (IOM) issued a detailed report that supported the need for evidence-based research into the effects of marijuana and cannabinoid components of marijuana, for patients with specific disease conditions. The IOM report also emphasized that smoked marijuana is a crude drug delivery system that exposes individuals to a significant number of harmful substances and that ''if there is any future for marijuana as a medicine, it lies in its isolated components, the cannabinoids and their synthetic derivatives.'' As such, the IOM recommended that clinical trials should be conducted with the goal of developing safe delivery systems (Institute of Medicine, 1999). Additionally, state-level public initiatives, including referenda in support of the medical use of marijuana, have generated interest in the medical community for high quality clinical investigation and comprehensive safety and effectiveness data.

For example, in 2000, the state of California established the Center for Medicinal Cannabis Research (CMCR) (*www.cmcr.ucsd.edu*) ''in response to scientific evidence for therapeutic possibilities of cannabis and local legislative initiatives in favor of compassionate use'' (Grant, 2005). State legislation establishing the CMCR called for high quality medical research that will ''enhance understanding of the efficacy and adverse effects of marijuana as a pharmacological agent,'' but stressed that the project ''should not be construed as encouraging or sanctioning the social or recreational use of marijuana.'' CMCR has thus far funded studies on the potential use of cannabinoids for the treatment of multiple sclerosis, neuropathic pain, appetite suppression and cachexia, and severe pain and nausea related to cancer or its treatment by chemotherapy. To date, though, no NDAs utilizing marijuana for these indications have been submitted to the FDA.

However, FDA approval of an NDA is not the sole means through which a drug can be determined to have a ''currently accepted medical use'' under the CSA. According to established case law, a drug has a ''currently accepted medical use'' if all of the following five elements have been satisfied:

a. the drug's chemistry is known and reproducible;

b. there are adequate safety studies;

c. there are adequate and well-controlled studies proving efficacy;

d. the drug is accepted by qualified experts; and

e. the scientific evidence is widely available.

[*Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994)]

Although the structures of many cannabinoids found in marijuana have been characterized, a complete scientific analysis of all the chemical components found in marijuana has not been conducted. Safety studies for acute or subchronic administration of marijuana have been carried out through a limited number of Phase 1 clinical investigations approved by the FDA, but there have been no NDA-quality studies that have scientifically assessed the efficacy and full safety profile of marijuana for any medical condition. A material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts. At this time, it is clear that there is not a consensus of medical opinion concerning medical applications of marijuana. Finally, the scientific evidence regarding the safety or efficacy of marijuana is typically available only in summarized form, such as in a paper published in the medical literature, rather than in a raw data format. As such, there is no opportunity for adequate scientific scrutiny of whether the data demonstrate safety or efficacy.

Alternately, a drug can be considered to have ''a currently accepted medical use with severe restrictions'' (21 U.S.C. 812(b)(2)(B)), as allowed under the stipulations for a Schedule II drug. However, as stated above, a material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts, even under conditions where its use is severely restricted. Thus, to date, research on the medical use of marijuana has not progressed to the point that marijuana can be considered to have a ''currently accepted medical use'' or a ''currently accepted medical use with severe restrictions.''

4. ITS HISTORY AND CURRENT PATTERN OF ABUSE

The fourth factor the Secretary must consider is the history and current pattern of abuse of marijuana. A variety of sources provide data necessary to assess abuse patterns and trends of marijuana. The data indicators of marijuana use include NSDUH, Monitoring the Future (MTF), DAWN, and Treatment Episode Data Set (TEDS), which are described below:

National Survey on Drug Use and Health

The National Survey on Drug Use and Health (NSDUH, 2004; *http://oas.samhsa.gov/nsduh.htm*) is conducted annually by SAMHSA, an agency of HHS. NSDUH provides estimates of the prevalence and incidence of illicit drug, alcohol, and tobacco use in the United States. This database was known until 2001 as the National Household Survey on Drug Abuse. The survey is based on a nationally representative sample of the civilian, non-institutionalized population 12 years of age and older. The survey identifies whether an individual used a drug during a certain period, but not the amount of the drug used on each occasion. Excluded groups include homeless people, active military personnel, and residents of institutions, such as jails.

According to the 2004 NSDUH, 19.1 million individuals (7.9 percent of the U.S. population) illicitly used drugs other than alcohol and nicotine on a monthly basis, compared to 14.8 million (6.7 percent of the U.S. population) users in 1999. This is an increase from 1999 of 4.3 million (2.0 percent of the U.S. population). The most frequently used illicit drug was marijuana, with 14.6 million individuals (6.1 percent of the U.S. population) using it monthly. Thus, regular illicit drug use, and more specifically marijuana use, for rewarding responses is increasing. The 2004 NSDUH estimated that 96.8 million individuals (40.2 percent of the U.S. population) have tried marijuana at least once during their lifetime. Thus, 15 percent of those who have tried marijuana on one occasion go on to use it monthly, but 85 percent of them do not.

Monitoring the Future

MTF (2005, *http://www.monitoringthefuture.org*) is a NIDA-sponsored annual national survey that tracks drug use trends among adolescents in the United States. The MTF surveys 8th, 10th, and 12th graders every spring in randomly selected U.S. schools. The MTF survey has been conducted since 1975 for 12th graders and since 1991 for 8th and 10th graders by the Institute for Social Research at the University of Michigan under a grant from NIDA. The 2005 sample sizes were 17,300—8th graders; 16,700—10th graders; and 15,400—12th graders. In all, a total of 49,300 students in 402 schools participated.

Since 1999, illicit drug use among teens decreased and held steady through 2005 in all three grades (Table 1). Marijuana remained the most widely used illicit drug, though its use has steadily decreased since 1999. For 2005, the annual prevalence rates for marijuana use in grades 8, 10, and 12 were, respectively, 12.2 percent, 26.6 percent, and 33.6 percent. Current monthly prevalence rates for marijuana use were 6.6 percent, 15.2 percent, and 19.8 percent. (See Table 1). According to Gruber and Pope (2002), when adolescents who used marijuana reach their late 20's, the vast majority of these individuals will have stopped using marijuana.

TABLE 1—TRENDS IN ANNUAL AND MONTHLY PREVALENCE OF USE OF VARIOUS DRUGS FOR EIGHTH, TENTH, AND TWELFTH GRADERS, FROM MONITORING THE FUTURE. PERCENTAGES REPRESENT STUDENTS IN SURVEY RESPONDING THAT THEY HAD USED A DRUG EITHER IN THE PAST YEAR OR IN THE PAST 30 DAYS

	Annual			30-Day		
	2003	2004	2005	2003	2004	2005
Any illicit drug (a):						
8th Grade	16.1	15.2	15.5	9.7	8.4	8.5
10th Grade	32.0	31.1	29.8	19.5	18.3	17.3
12th Grade	39.3	38.8	38.4	24.1	23.4	23.1
Any illicit drug other than cannabis (a):						
8th Grade	8.8	7.9	8.1	4.7	4.1	4.1
10th Grade	13.8	13.5	12.9	6.9	6.9	6.4
12th Grade	19.8	20.5	19.7	10.4	10.8	10.3
Marijuana/hashish:						
8th Grade	12.8	11.8	12.2	7.5	6.4	6.6
10th Grade	28.2	27.5	26.6	17.0	15.9	15.2
12th Grade	34.9	34.3	33.6	21.2	19.9	19.8

SOURCE: The Monitoring the Future Study, the University of Michigan.

a. For 12th graders only, ''any illicit drug'' includes any use of marijuana, LSD, other hallucinogens, crack, other cocaine, or heroin, or any use of other opiates, stimulants, barbiturates, or tranquilizers not under a doctor's orders. For 8th and 10th graders, the use of other opiates and barbiturates was excluded.

Drug Abuse Warning Network

DAWN (2006, *http://dawninfo.samhsa.gov/*) is a national probability survey of U.S. hospitals with EDs designed to obtain information on ED visits in which recent drug use is implicated. The ED data from a representative sample of hospital emergency departments are weighted to produce national estimates. It is critical to note that DAWN data and estimates for 2004 are not comparable to those for any prior years because of vast

changes in the methodology used to collect the data. Further, estimates for 2004 are the first to be based on a new, redesigned sample of hospitals. Thus, the most recent estimates available are for 2004.

Many factors can influence the estimates of ED visits, including trends in the ED usage in general. Some drug users may have visited EDs for a variety of reasons, some of which may have been life-threatening, whereas others may have sought care at the ED for detoxification because they needed certification before entering treatment. DAWN data do not distinguish the drug responsible for the ED visit from others used concomitantly. As stated in a recent DAWN report, ''Since marijuana/hashish is frequently present in combination with other drugs, the reason for the ED contact may be more relevant to the other drug(s) involved in the episode.''

For 2004, DAWN estimates a total of 1,997,993 (95 percent confidence interval [CI]: 1,708,205 to 2,287,781) drug-related ED visits for the entire United States. During this period, DAWN estimates 940,953 (CI: 773,124 to 1,108,782) drug-related ED visits involved a major drug of abuse. Thus, nearly half of all drug-related visits involved alcohol or an illicit drug. Overall, drug-related ED visits averaged 1.6 drugs per visit, including illicit drugs, alcohol, prescription and over-the-counter (OTC) pharmaceuticals, dietary supplements, and non-pharmaceutical inhalants.

Marijuana was involved in 215,665 (CI: 175,930 to 255,400) ED visits, while cocaine was involved in 383,350 (CI: 284,170 to 482,530) ED visits, heroin was involved in 162,137 (CI: 122,414 to 201,860) ED visits, and stimulants, including amphetamine and methamphetamine, were involved in 102,843 (CI: 61,520 to 144,166) ED visits. Other illicit drugs, such as PCP, MDMA, and GHB, were much less frequently associated with ED visits.

Approximately 18 percent of ED visits involving marijuana were for patients under the age of 18, whereas this age group accounts for less than 1 percent of the ED visits involving heroin/morphine and approximately 3 percent of the visits involving cocaine. Since the size of the population differs across age groups, a measure standardized for population size is useful to make comparisons. For marijuana, the rates of ED visits per 100,000 population were highest for patients aged 18 to 20 (225 ED visits per 100,000) and for patients aged 21 to 24 (190 ED visits per 100,000).

Treatment Episode Data Set

TEDS (TEDS, 2003; *http://oas.samhsa.gov/dasis.htm#teds2*) system is part of SAMHSA's Drug and Alcohol Services Information System (Office of Applied Science, SAMHSA). TEDS comprises data on treatment admissions that are routinely collected by States in monitoring their substance abuse treatment systems. The TEDS report provides information on the demographic and substance use characteristics of the 1.8 million annual admissions to treatment for abuse of alcohol and drugs in facilities that report to individual State administrative data systems.

TEDS is an admission-based system, and TEDS admissions do not represent individuals. Thus, a given individual admitted to treatment twice within a given year would be counted as two admissions. Additionally, TEDS does not include all admissions to substance abuse treatment. TEDS includes facilities that are licensed or certified by the States to provide substance abuse treatment and that are required by the States to provide TEDS client-level data. Facilities that report TEDS data are those that receive State alcohol and/or drug agency funds for the provision of alcohol and/or drug treatment services. The primary goal for TEDS is to monitor the characteristics of treatment episodes for substance abusers.

Primary marijuana abuse accounted for 15.5 percent of TEDS admissions in 2003, the latest year for which data are available. Three-quarters of the individuals admitted for marijuana were male and 55 percent of the admitted individuals were white. The average age at admission was 23 years. The largest proportion (84 percent) of admissions to ambulatory treatment was for primary marijuana abuse. More than half (57 percent) of marijuana treatment admissions were referred through the criminal justice system.

Between 1993 and 2003, the percentage of admissions for primary marijuana use increased from 6.9 percent to 15.5 percent, comparable to the increase for primary opioid use from 13 percent in 1993 to 17.6 percent in 2003. In contrast, the percentage of admissions for primary cocaine use declined from 12.6 percent in 1993 to 9.8 percent in 2003, and for primary alcohol use from 56.9 percent in 1993 to 41.7 percent in 2003.

Twenty-six percent of those individuals who were admitted for primary use of marijuana reported its daily use, although 34.6 percent did not use marijuana in the past month. Nearly all (96.2 percent) of primary marijuana users utilized the drug by smoking it. Over 90 percent of primary marijuana admissions used marijuana for the first time before the age of 18.

5. THE SCOPE, DURATION, AND SIGNIFICANCE OF ABUSE

The fifth factor the Secretary must consider is the scope, duration, and significance of marijuana abuse. According to 2004 data from NSDUH and MTF, marijuana remains the most extensively used illegal drug in the United States, with 40.6 percent of U.S. individuals over age 12 (96.6 million) and 44.8 percent of 12th graders having used marijuana at least once in their lifetime. While the majority of individuals over age 12 (85 percent) who have used marijuana do not use the drug monthly, 14.6 million individuals (6.1 percent of the U.S. population) report that they used marijuana within the past 30 days. An examination of use among various age cohorts in NSDUH demonstrates that monthly use occurs primarily among college age individuals, with use dropping off sharply after age 25.

DAWN data show that marijuana was involved in 79,663 ED visits, which amounts to 13 percent of all drug-related ED visits. Minors accounted for 15 percent of these marijuana-related visits, making marijuana the drug most frequently associated with ED visits for individuals under the age of 18 years.

Data from TEDS show that 15.5 percent of all admissions were for primary marijuana abuse. Approximately 90 percent of these primary marijuana admissions were for individuals under the age of 18 years.

6. WHAT, IF ANY, RISK THERE IS TO THE PUBLIC

The sixth factor the Secretary must consider is the risk marijuana poses to the public health. The risk to the public health as measured by emergency room episodes, marijuana-related deaths, and drug treatment admissions is discussed in full under Factors 1, 4, and 5, above. Accordingly, Factor 6 focuses on the health risks to the individual user.

All drugs, both medicinal and illicit, have a broad range of effects on the individual user that are dependent on dose and duration of use among others. FDA-approved drug products can produce adverse events (or ''side effects'') in some individuals even at doses in the therapeutic range. When determining whether a drug product is safe and effective for any indication, FDA performs an extensive risk-benefit analysis to determine whether the risks posed by the drug product's potential or actual side effects are outweighed by the drug product's potential benefits. As marijuana is not FDA-approved for any medicinal use, any potential benefits attributed to marijuana use have not been found to be outweighed by the risks. However, cannabinoids are generally potent psychoactive substances and are pharmacologically active on multiple organ systems.

The discussion of marijuana's central nervous system, cognitive, cardiovascular, autonomic, respiratory, and immune system effects are fully discussed under Factor 2. Consequences of marijuana use and abuse are discussed below in terms of the risk from acute and chronic use of the drug to the individual user (Institute of Medicine, 1999).

Risks from acute use of marijuana

Acute use of marijuana impairs psychomotor performance, including performance of complex tasks, which makes it inadvisable to operate motor vehicles or heavy equipment after using marijuana (Ramaekers et al., 2004). Dysphoria and psychological distress, including prolonged anxiety reactions, are potential responses in a minority of individuals who use marijuana (Haney et al., 1999).

Risks from chronic use of marijuana

Chronic exposure to marijuana smoke is considered to be comparable to tobacco smoke with respect to increased risk of cancer, lung damage, and poor pregnancy outcome. Although a distinctive marijuana withdrawal syndrome has been identified, indicating that marijuana produces physical dependence, this phenomenon is mild and short-lived (Budney et al., 2004), as described above under Factor 2.

The Diagnostic and Statistical Manual (DSM–IV–TR, 2000) of the American Psychiatric Association states that the

consequences of cannabis abuse are as follows:

[P]eriodic cannabis use and intoxication can interfere with performance at work or school and may be physically hazardous in situations such as driving a car. Legal problems may occur as a consequence of arrests for cannabis possession. There may be arguments with spouses or parents over the possession of cannabis in the home or its use in the presence of children. When psychological or physical problems are associated with cannabis in the context of compulsive use, a diagnosis of Cannabis Dependence, rather than Cannabis Abuse, should be considered.

Individuals with Cannabis Dependence have compulsive use and associated problems. Tolerance to most of the effects of cannabis has been reported in individuals who use cannabis chronically. There have also been some reports of withdrawal symptoms, but their clinical significance is uncertain. There is some evidence that a majority of chronic users of cannabinoids report histories of tolerance or withdrawal and that these individuals evidence more severe drug-related problems overall. Individuals with Cannabis Dependence may use very potent cannabis throughout the day over a period of months or years, and they may spend several hours a day acquiring and using the substance. This often interferes with family, school, work, or recreational activities. Individuals with Cannabis Dependence may also persist in their use despite knowledge of physical problems (e.g., chronic cough related to smoking) or psychological problems (e.g., excessive sedation and a decrease in goal-oriented activities resulting from repeated use of high doses).

7. ITS PSYCHIC OR PHYSIOLOGIC DEPENDENCE LIABILITY

The seventh factor the Secretary must consider is marijuana's psychic or physiologic dependence liability. Physical dependence is a state of adaptation manifested by a drug class-specific withdrawal syndrome produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist (American Academy of Pain Medicine, American Pain Society and American Society of Addiction Medicine consensus document, 2001). Long-term, regular use of marijuana can lead to physical dependence and withdrawal following discontinuation as well as psychic addiction or dependence. The marijuana withdrawal syndrome consists of symptoms such as restlessness, mild agitation, insomnia, nausea, and cramping that may resolve after 4 days, and may require in-hospital treatment. It is distinct from the withdrawal syndromes associated with alcohol and heroin use (Budney et al., 1999; Haney et al., 1999). Lane and Phillips-Bute (1998) describes milder cases of dependence including symptoms that are comparable to those from caffeine withdrawal, including decreased vigor, increased fatigue, sleepiness, headache, and reduced ability to work. The marijuana withdrawal syndrome has been reported in adolescents who were admitted for substance abuse treatment or in individuals who had been given marijuana on a daily basis during research conditions. Withdrawal symptoms can also be induced in animals following administration of a cannabinoid antagonist after chronic delta^{9}-THC administration (Breivogel et al., 2003).

Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time (American Academy of Pain Medicine, American Pain Society and American Society of Addiction Medicine consensus document, 2001). Tolerance can develop to marijuana-induced cardiovascular and autonomic changes, decreased intraocular pressure, sleep and sleep EEG, and mood and behavioral changes (Jones et al., 1981). Down-regulation of cannabinoid receptors has been suggested as the mechanism underlying tolerance to the effects of marijuana (Rodriguez de Fonseca et al., 1994). Pharmacological tolerance does not indicate the physical dependence liability of a drug.

8. WHETHER THE SUBSTANCE IS AN IMMEDIATE PRECURSOR OF A SUBSTANCE ALREADY CONTROLLED UNDER THIS ARTICLE

The eighth factor the Secretary must consider is whether marijuana is an immediate precursor of a controlled substance. Marijuana is not an immediate precursor of another controlled substance.

RECOMMENDATION

After consideration of the eight factors discussed above, HHS recommends that marijuana remain in Schedule I of the CSA. Marijuana meets the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(1):

1) Marijuana has a high potential for abuse:

The large number of individuals using marijuana on a regular basis, its widespread use, and the vast amount of marijuana that is available for illicit use are indicative of the high abuse potential for marijuana. Approximately 14.6 million individuals in the United States (6.1 percent of the U.S. population) used marijuana monthly in 2003. A 2003 survey indicates that by 12th grade, 33.6 percent of students report having used marijuana in the past year, and 19.8 percent report using it monthly. In Q3 to Q4 2003, 79,663 ED visits were marijuana-related, representing 13 percent of all drug-related episodes. Primary marijuana use accounted for 15.5 percent of admissions to drug treatment programs in 2003. Marijuana has dose-dependent reinforcing effects, as demonstrated by data that humans prefer higher doses of marijuana to lower doses. In addition, there is evidence that marijuana use can result in psychological dependence in at risk individuals.

2) Marijuana has no currently accepted medical use in treatment in the United States:

The FDA has not yet approved an NDA for marijuana. The opportunity for scientists to conduct clinical research with marijuana exists under the HHS policy supporting clinical research with botanical marijuana. While there are INDs for marijuana active at the FDA, marijuana does not have a currently accepted medical use for treatment in the United States, nor does it have an accepted medical use with severe restrictions.

A drug has a ''currently accepted medical use'' if all of the following five elements have been satisfied:

a. The drug's chemistry is known and reproducible;

b. There are adequate safety studies;

c. There are adequate and well-controlled studies proving efficacy;

d. The drug is accepted by qualified experts; and

e. The scientific evidence is widely available.

[*Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994)]

Although the structures of many cannabinoids found in marijuana have been characterized, a complete scientific analysis of all the chemical components found in marijuana has not been conducted. Safety studies for acute or subchronic administration of marijuana have been carried out through a limited number of Phase 1 clinical investigations approved by the FDA, but there have been no NDA-quality studies that have scientifically assessed the efficacy of marijuana for any medical condition. A material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts. At this time, it is clear that there is not a consensus of medical opinion concerning medical applications of marijuana. Finally, the scientific evidence regarding the safety or efficacy of marijuana is typically available only in summarized form, such as in a paper published in the medical literature, rather than in a raw data format. As such, there is no opportunity for adequate scientific scrutiny of whether the data demonstrate safety or efficacy.

Alternately, a drug can be considered to have ''a currently accepted medical use with severe restrictions'' (21 U.S.C. 812(b)(2)(B)), as allowed under the stipulations for a Schedule II drug. However, as stated above, a material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts, even under conditions where its use is severely restricted. To date, research on the medical use of marijuana has not progressed to the point that marijuana can be considered to have a ''currently accepted medical use'' or a ''currently accepted medical use with severe restrictions.''

3) There is a lack of accepted safety for use of marijuana under medical supervision.

At present, there are no FDA-approved marijuana products, nor is marijuana under NDA evaluation at the FDA for any indication. Marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. The Center for Medicinal Cannabis Research in California, among others, is conducting research with marijuana at the IND level, but these studies have not yet progressed to the stage of submitting an NDA. Thus, at this time, the known risks of marijuana use have

not been shown to be outweighed by specific benefits in well-controlled clinical trials that scientifically evaluate safety and efficacy.

In addition, the agency cannot conclude that marijuana has an acceptable level of safety without assurance of a consistent and predictable potency and without proof that the substance is free of contamination. If marijuana is to be investigated more widely for medical use, information and data regarding the chemistry, manufacturing, and specifications of marijuana must be developed. Therefore, HHS concludes that, even under medical supervision, marijuana has not been shown at present to have an acceptable level of safety.

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Marijuana

Scheduling Review Document: Eight Factor Analysis

Drug and Chemical Evaluation Section
Office of Diversion Control
Drug Enforcement Administration, April 2011

INTRODUCTION

On October 9, 2002, the Coalition for Rescheduling Cannabis submitted a petition to the Drug Enforcement Administration (DEA) to initiate proceedings for a repeal of the rules or regulations that place marijuana [3] in schedule I of the Controlled Substances Act (CSA). The petition requests that marijuana be rescheduled as ''cannabis'' in either schedule III, IV, or V of the CSA. The petitioner claims that:

1. Cannabis has an accepted medical use in the United States;
2. Cannabis is safe for use under medical supervision;
3. Cannabis has an abuse potential lower than schedule I or II drugs; and
4. Cannabis has a dependence liability that is lower than schedule I or II drugs.

The DEA accepted this petition for filing on April 3, 2003. In accordance with 21 U.S.C. 811(b), after gathering the necessary data, the DEA requested a medical and scientific evaluation and scheduling recommendation for cannabis from the Department of Health and Human Services (DHHS) on July 12, 2004. On December 6, 2006, the DHHS provided its scientific and medical evaluation titled *Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act* and recommended that marijuana continue to be controlled in schedule I of the CSA.

The CSA requires DEA to determine whether the DHHS scientific and medical evaluation and scheduling recommendation and ''all other relevant data'' constitute substantial evidence that the drug should be rescheduled as proposed in the petition. 21 U.S.C. 811(b). This document is prepared accordingly.

The Attorney General ''may by rule'' transfer a drug or other substance between schedules if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by subsection (b) of Section 812 for the schedule in which such drug is to be placed. 21 U.S.C. 811(a)(1). In order for a substance to be placed in schedule I, the Attorney General must find that:

A. The drug or other substance has a high potential for abuse.

B. The drug or other substance has no currently accepted medical use in treatment in the United States.

C. There is a lack of accepted safety for use of the drug or other substance under medical supervision.

21 U.S.C. 812(b)(1)(A)–(C). To be classified in one of the other schedules (II through V), a drug of abuse must have either a ''currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.'' 21 U.S.C. 812(b)(2)–(5). If a controlled substance has no such currently accepted medical use, it must be placed in schedule I. *See* Notice of Denial of Petition, 66 FR 20038, 20038 (Apr. 18, 2001) (''Congress established only one schedule—schedule I—for drugs of abuse with 'no currently accepted medical use in treatment in the United States' and 'lack of accepted safety for use . . . under medical supervision.'''').

In deciding whether to grant a petition to initiate rulemaking proceedings with respect to a particular drug, DEA must determine whether there is sufficient evidence to conclude that the drug meets the criteria for placement in another schedule based on the criteria set forth in 21 U.S.C. 812(b). To do so, the CSA requires that DEA and DHHS consider eight factors as specified in 21 U.S.C. 811(c). This document is organized according to these eight factors.

With specific regard to the issue of whether the drug has a currently accepted medical use in treatment in the United States, DHHS states that the FDA has not evaluated nor approved a new drug application (NDA) for marijuana. The long-established factors applied by the DEA for determining whether a drug has a ''currently accepted medical use'' under the CSA are:

[3] The Controlled Substances Act (CSA) defines marijuana as the following:

All parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted there from), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination. 21 U.S.C. 802(16).

Note that ''marihuana'' is the spelling originally used in the CSA. This document uses the spelling that is more common in current usage, ''marijuana.''

1. The drug's chemistry must be known and reproducible;
2. There must be adequate safety studies;
3. There must be adequate and well-controlled studies proving efficacy;
4. The drug must be accepted by qualified experts; and
5. The scientific evidence must be widely available.

57 FR 10,499, 10,506 (1992); *Alliance for Cannabis Therapeutics v. DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994) (*ACT*) (upholding these factors as valid criteria for determining ''accepted medical use''). A drug will be deemed to have a currently accepted medical use for CSA purposes only if all five of the foregoing elements are demonstrated. This test is considered here under the third factor.

Accordingly, as the eight factor analysis sets forth in detail below, the evidence shows:

1. *Actual or relative potential for abuse.* Marijuana has a high abuse potential. It is the most widely used illicit substance in the United States. Preclinical and clinical data show that it has reinforcing effects characteristic of drugs of abuse. National databases on actual abuse show marijuana is the most widely abused drug, including significant numbers of substance abuse treatment admissions. Data on marijuana seizures show widespread availability and trafficking.

2. *Scientific evidence of its pharmacological effect.* The scientific understanding of marijuana, cannabinoid receptors, and the endocannabinoid system has improved. Marijuana produces various pharmacological effects, including subjective (e.g., euphoria, dizziness, disinhibition), cardiovascular, acute and chronic respiratory, immune system, cognitive impairment, and prenatal exposure effects as well as possible increased risk of schizophrenia among those predisposed to psychosis.

3. *Current scientific knowledge.* There is no currently accepted medical use for marijuana in the United States. Under the five-part test for currently accepted medical use approved in *ACT,* 15 F.3d at 1135, there is no complete scientific analysis of marijuana's chemical components; there are no adequate safety studies; there are no adequate and well-controlled efficacy studies; there is not a consensus of medical opinion concerning medical applications of marijuana; and the scientific evidence regarding marijuana's safety and efficacy is not widely available. While a number of states have passed voter referenda or legislative actions authorizing the use of marijuana for medical purposes, this does not establish a currently accepted medical use under federal law. To date, scientific and medical research has not progressed to the point that marijuana has a currently accepted medical use, even under conditions where its use is severely restricted.

4. *History and current pattern of abuse.* Marijuana use has been relatively stable from 2002 to 2009, and it continues to be the most widely used illicit drug. In 2009, there were 16.7 million current users. There were also 2.4 million new users, most of whom were less than 18 years of age. During the same period, marijuana was the most frequently identified drug exhibit in federal, state, and local laboratories. High consumption of marijuana is fueled by increasing amounts of both domestically grown and illegally smuggled foreign source marijuana, and an increasing percentage of seizures involve high potency marijuana.

5. *Scope, duration, and significance of abuse.* Abuse of marijuana is widespread and significant. In 2008, for example, an estimated 3.9 million people aged 12 or older used marijuana on a daily or almost daily basis over a 12-month period. In addition, a significant proportion of all admissions for treatment for substance abuse are for primary marijuana abuse: in 2007, 16 percent of all admissions were for primary marijuana abuse, representing 287,933 individuals. Of individuals under the age of 19 admitted to substance abuse treatment, more than half were treated for primary marijuana abuse.

6. *Risk, if any, to public health.* Together with the health risks outlined in terms of pharmacological effects above, public health risks from acute use of marijuana include impaired psychomotor performance, including impaired driving, and impaired performance on tests of learning and associative processes. Public health risks from chronic use of marijuana include respiratory effects, physical dependence, and psychological problems.

7. *Psychic or physiological dependence liability.* Long-term, regular use of marijuana can lead to physical dependence and withdrawal following discontinuation, as well as psychic addiction or dependence.

8. *Immediate precursor.* Marijuana is not an immediate precursor of any controlled substance.

This review shows, in particular, that the evidence is insufficient with respect to the specific issue of whether marijuana has a currently accepted medical use under the five-part test. The evidence was insufficient in this regard on the prior two occasions when DEA considered petitions to reschedule marijuana in 1992 (57 FR 10499)[4] and in 2001 (66 FR 20038).[5] Little has changed since then with respect to the lack of clinical evidence necessary to establish that marijuana has a currently accepted medical use: only a limited number of FDA-approved Phase 1 clinical investigations have been carried out, and there have been no studies that have scientifically assessed the efficacy and full safety profile of marijuana for any medical condition.[6] The limited existing clinical evidence is not adequate to warrant rescheduling of marijuana under the CSA.

To the contrary, the data in this Scheduling Review document show that marijuana continues to meet the criteria for schedule I control under the CSA for the following reasons:

1. Marijuana has a high potential for abuse.
2. Marijuana has no currently accepted medical use in treatment in the United States.
3. Marijuana lacks accepted safety for use under medical supervision.

FACTOR 1: THE DRUG'S ACTUAL OR RELATIVE POTENTIAL FOR ABUSE

Marijuana is the most commonly abused illegal drug in the United States. It is also the most commonly used illicit drug by American high-schoolers. Marijuana is the most frequently identified drug in state, local and federal forensic laboratories, with increasing amounts both of domestically grown and of illicitly smuggled marijuana. Marijuana's main psychoactive ingredient, Δ^9-THC, is an effective reinforcer in laboratory animals, including primates and rodents. These animal studies both predict and support the observations that Δ^9-THC, whether smoked as marijuana or administered by other routes, produces reinforcing effects in humans. Such reinforcing effects can account for the repeated abuse of marijuana.

A. Indicators of Abuse Potential

DHHS has concluded in its document, ''Basis for the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act'', that marijuana has a high potential for abuse. The finding of ''abuse potential'' is critical for control under the Controlled Substances Act (CSA). Although the term is not defined in the CSA, guidance in determining abuse potential is provided in the legislative history of the Act (Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–144, 91st Cong., Sess.1 (1970), reprinted in 1970 U.S.C.C.A.N. 4566, 4603). Accordingly, the following items are indicators that a drug or other substance has potential for abuse:

- There is evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or
- There is significant diversion of the drug or other substance from legitimate drug channels; or
- Individuals are taking the drug or substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs; or
- The drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug substance will have the same potential for abuse as such drugs, thus

[4] *Petition for review dismissed, Alliance for Cannabis Therapeutics v. DEA,* 15 F.3d 1131 (D.C. Cir. 1994).

[5] *Petition for review dismissed, Gettman v. DEA,* 290 F.3d 430 (D.C. Cir. 2002).

[6] Clinical trials generally proceed in three phases. *See* 21 CFR 312.21 (2010). Phase I trials encompass initial testing in human subjects, generally involving 20 to 80 patients. Id. They are designed primarily to assess initial safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary studies of potential therapeutic benefit. 62 FR 66113, 1997. Phase II and Phase III studies involve successively larger groups of patients: usually no more than several hundred subjects in Phase II, and usually from several hundred to several thousand in Phase III. 21 CFR 312.21. These studies are designed primarily to explore (Phase II) and to demonstrate or confirm (Phase III) therapeutic efficacy and benefit in patients. 62 FR 66113, 1997. *See also Riegel v. Medtronic, Inc.,* 128 S.Ct. 999, 1018–19 n.15 (2008) (Ginsburg, J., dissenting).

making it reasonable to assume that there may be significant diversion from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community. Of course, evidence of actual abuse of a substance is indicative that a drug has a potential for abuse.

After considering the above items, DHHS has found that marijuana has a high potential for abuse.

1. There is evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.

Marijuana is the most highly used illicit substance in the United States. Smoked marijuana exerts a number of cardiovascular and respiratory effects, both acutely and chronically and can cause chronic bronchitis and inflammatory abnormalities of the lung tissue. Marijuana's main psychoactive ingredient Δ^9-THC alters immune function and decreases resistance to microbial infections. The cognitive impairments caused by marijuana use that persist beyond behaviorally detectable intoxication may have significant consequences on workplace performance and safety, academic achievement, and automotive safety, and adolescents may be particularly vulnerable to marijuana's cognitive effects. Prenatal exposure to marijuana was linked to children's poorer performance in a number of cognitive tests. Data on the extent and scope of marijuana abuse are presented under factors 4 and 5 of this analysis. DHHS's discussion of the harmful health effects of marijuana and additional information gathered by DEA are presented under factor 2, and the assessment of risk to the public health posed by acute and chronic marijuana abuse is presented under factor 6 of this analysis.

2. There is significant diversion of the drug or other substance from legitimate drug channels.

DHHS states that at present, marijuana is legally available through legitimate channels for research only and thus has a limited potential for diversion. (DEA notes that while a number of states have passed voter referenda or legislative actions authorizing the use of marijuana for medical purposes, this does not establish a currently accepted medical use under federal law.) In addition, the lack of significant diversion of investigational supplies may result from the ready availability of illicit cannabis of equal or greater quality.

DEA notes that the magnitude of the demand for illicit marijuana is evidenced by information from a number of databases presented under factor 4. Briefly, marijuana is the most commonly abused illegal drug in the United States. It is also the most commonly used illicit drug by American high-schoolers. Marijuana is the most frequently identified drug in state, local, and federal forensic laboratories, with increasing amounts both of domestically grown and of illicitly smuggled marijuana. An observed increase in the potency of seized marijuana also raises concerns.

3. Individuals are taking the drug or substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs.

16.7 million adults over the age of 12 reported having used marijuana in the past month, according to the 2009 National Survey on Drug Use and Health (NSDUH), as further described later in this factor. DHHS states in its 2006 analysis of the petition that the FDA has not evaluated or approved a new drug application (NDA) for marijuana for any therapeutic indication, although several investigational new drug (IND) applications are currently active. Based on the large number of individuals who use marijuana, DHHS concludes that the majority of individuals using cannabis do so on their own initiative, not on the basis of medical advice from a practitioner licensed to administer the drug in the course of professional practice.

4. The drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug substance will have the same potential for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community. Of course, evidence of actual abuse of a substance is indicative that a drug has a potential for abuse.

Marijuana is not a new drug. Marijuana's primary psychoactive ingredient delta-9-tetrahydrocannabinol (Δ^9-THC) is controlled in schedule I of the CSA. DHHS states that there are two drug products containing cannabinoid compounds that are structurally related to the active components in marijuana. Both are controlled under the CSA. Marinol is a schedule III drug product containing synthetic Δ^9-THC, known generically as dronabinol, formulated in sesame oil in soft gelatin capsules. Marinol was approved by the FDA in 1985 for the treatment of two medical conditions: nausea and vomiting associated with cancer chemotherapy in patients that had failed to respond adequately to conventional anti-emetic treatments, and for the treatment of anorexia associated with weight loss in patients with acquired immunodeficiency syndrome (AIDS). Cesamet is a drug product containing the schedule II substance, nabilone, that was approved for marketing by the FDA in 1985 for the treatment of nausea and vomiting associated with cancer chemotherapy. All other structurally related cannabinoids in marijuana are already listed as Schedule I drugs under the CSA.

In addition, DEA notes that marijuana and its active ingredient Δ^9-THC are related in their action to other controlled drugs of abuse when tested in preclinical and clinical tests of abuse potential. Data showing that marijuana and Δ^9-THC exhibit properties common to other controlled drugs of abuse in those tests are described below in this factor.

In summary, examination of the indicators set forth in the legislative history of the CSA demonstrates that marijuana has a high potential for abuse. Indeed, marijuana is abused in amounts sufficient to create hazards to public health and safety; there is significant trafficking of the substance; individuals are using marijuana on their own initiative, for the vast majority, rather than on the basis of medical advice; and finally, marijuana exhibits several properties common to those of drugs already listed as having abuse potential.

The petitioner states that, ''widespread use of cannabis is not an indication of its abuse potential [...] .'' (Exh. C, Section IV(15), pg. 87).

To the contrary, according to the indicators set forth in the legislative history of the CSA as described above, the fact that ''Individuals are taking the drug or substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs'' is indeed one of several indicators that a drug has high potential for abuse.

B. Abuse Liability Studies

In addition to the indicators suggested by the CSA's legislative history, data as to preclinical and clinical abuse liability studies, as well as actual abuse, including clandestine manufacture, trafficking, and diversion from legitimate sources, are considered in this factor.

Abuse liability evaluations are obtained from studies in the scientific and medical literature. There are many preclinical measures of a drug's effects that when taken together provide an accurate prediction of the human abuse liability. Clinical studies of the subjective and reinforcing effects in humans and epidemiological studies provide quantitative data on abuse liability in humans and some indication of actual abuse trends. Both preclinical and clinical studies have clearly demonstrated that marijuana and Δ^9-THC possess the attributes associated with drugs of abuse: they function as a positive reinforcer to maintain drug-seeking behavior, they function as a discriminative stimulus, and they have dependence potential.

Preclinical and most clinical abuse liability studies have been conducted with the psychoactive constituents of marijuana, primarily Δ^9-THC and its metabolite, 11-OH-Δ^9-THC. Δ^9-THC's subjective effects are considered to be the basis for marijuana's abuse liability. The following studies provide a summary of that data.

1. Preclinical Studies

Delta-9-THC is an effective reinforcer in laboratory animals, including primates and rodents, as these animals will self-administer Δ^9-THC. These animal studies both predict and support the observations that Δ^9-THC, whether smoked as marijuana or administered by other routes, produces reinforcing effects in humans. Such reinforcing effects can account for the repeated abuse of marijuana.

a. Discriminative Stimulus Effects

The drug discrimination paradigm is used as an animal model of human subjective effects (Solinas *et al.*, 2006). This procedure provides a direct measure of stimulus

specificity of a test drug in comparison with a known standard drug or a neutral stimulus (e.g., injection of saline water). The light-headedness and warmth associated with drinking alcohol or the jitteriness and increased heart rate associated with drinking coffee are examples of substance-specific stimulus effects. The drug discrimination paradigm is based on the ability of nonhuman and human subjects to learn to identify the presence or absence of these stimuli and to differentiate among the constellation of stimuli produced by different pharmacological classes. In drug discrimination studies, the drug stimuli function as cues to guide behavioral choice, which is subsequently reinforced with other rewards. Repeated pairing of the reinforcer with only drug-appropriate responses can engender reliable discrimination between drug and no-drug or amongst several drugs. Because some interoceptive stimuli are believed to be associated with the reinforcing effects of drugs, the drug discrimination paradigm is used to evaluate the abuse potential of new substances.

DHHS states that in the drug discrimination test, animals are trained to respond by pressing one bar when they receive the known drug of abuse and another bar when they receive placebo.

DHHS states that cannabinoids appear to provide unique discriminative stimulus effects because stimulants, non-cannabinoid hallucinogens, opioids, benzodiazepines, barbiturates, NMDA antagonists and antipsychotics do not fully substitute for Δ^9-THC (Browne and Weissman, 1981; Balster and Prescott, 1992, Gold *et al.*, 1992; Barrett *et al.*, 1995; Wiley *et al.*, 1995). Animals, including monkeys and rats (Gold et al., 1992), as well as humans (Chait *et al.*, 1988), can discriminate cannabinoids from other drugs or placebo.

DEA notes several studies that show that the discriminative stimulus effects of Δ^9-THC are mediated via a cannabinoid receptor, specifically, the CB_1 receptor subtype, and that the CB_1 antagonist rimonabant (SR 141716A) antagonizes the discriminative stimulus effects of Δ^9-THC in several species (Pério *et al.*, 1996; Mansbach *et al.*, 1996; Järbe *et al.*, 2001). The subjective effects of marijuana and Δ^9-THC are, therefore, mediated by a neurotransmitter system in the brain that is specific to Δ^9-THC and cannabinoids.

b. Self-Administration Studies

Self-administration is a behavioral assay that measures the rewarding effects of a drug that increase the likelihood of continued drug-taking behavior. Drugs that are self-administered by animals are likely to produce rewarding effects in humans. A strong correlation exists between drugs and other substances that are abused by humans and those that maintain self-injection in laboratory animals (Schuster and Thompson, 1969; Griffiths *et al.*, 1980). As a result, intravenous self-injection of psychoactive substances in laboratory animals is considered to be useful for the prediction of human abuse liability of these compounds (Johanson and Balster, 1978; Collins et al., 1984).

DHHS states that self-administration of hallucinogenic-like drugs, such as cannabinoids, lysergic acid diethylamide (LSD), and mescaline, has been difficult to demonstrate in animals (Yanagita, 1980). DHHS further states that an inability to establish self-administration has no practical importance in the assessment of abuse potential, because it is known that humans voluntarily consume a particular drug (such as cannabis) for its pleasurable effects.

DHHS states that the experimental literature generally reports that naïve animals will not self-administer cannabinoids unless they have had previous experience with other drugs of abuse, however, animal research in the past decade has provided several animal models of reinforcement by cannabinoids to allow for pre-clinical research into cannabinoids' reinforcing effects. Squirrel monkeys trained to self-administer intravenous cocaine will continue to respond at the same rate as when Δ^9-THC is substituted for cocaine, at doses that are comparable to those used by humans who smoke marijuana (Tanda *et al.*, 2000). This effect is blocked by the cannabinoid receptor antagonist, SR 141716. Squirrel monkeys without a history of any drug exposure can be successfully trained to self-administer Δ^9-THC intravenously (Justinova *et al.*, 2003). The maximal rate of responding is 4 μg/kg/injection, which is 2–3 times greater than that observed in previous studies using cocaine-experienced monkeys. Rats will self-administer Δ^9-THC when it is applied intracerebroventricularly (i.c.v.), but only at the lowest doses tested (0.01:–0.02/μg/infusion) (Braida *et al.*, 2004). This effect is antagonized by the cannabinoid antagonist SR141716 and by the opioid antagonist naloxone (Braida et al., 2004). Additionally, mice will self-administer WIN 55212, a synthetic CB_1 receptor agonist with a non-cannabinoid structure (Martellotta *et al.*, 1998).

DEA notes a study showing that the opioid antagonist naltrexone reduces the self-administration responding for Δ^9-THC in squirrel monkeys (Justinova *et al.*, 2004). These investigators, using second-order schedules of drug-seeking procedures, also showed that pre-session administration of Δ^9-THC and other cannabinoid agonists, or morphine, but not cocaine, reinstates the Δ^9-THC seeking behavior following a period of abstinence (Justinova *et al.*, 2008). Furthermore, the endogenous cannabinoid anandamide and its synthetic analog methanandamide are self-administered by squirrel monkeys, and CB_1 receptor antagonism blocks the reinforcing effect of both substances (Justinova *et al.*, 2005).

c. Place Conditioning Studies

Conditioned place preference (CPP) is another behavioral assay used to determine if a drug has rewarding properties. In this test, animals in a drug-free state are given the opportunity to spend time in two distinct environments: one where they previously received a drug and one where they received a placebo. If the drug is reinforcing, animals in a drug-free state will choose to spend more time in the environment paired with the drug when both environments are presented simultaneously.

DHHS states that animals exhibit CPP to Δ^9-THC, but only at the lowest doses tested (0.075–0.75 mg/kg, i.p.) (Braida *et al.*, 2004). The effect is antagonized by the cannabinoid antagonist, rimonabant, as well as the opioid antagonist, naloxone. The effect of naloxone on CPP to Δ^9-THC raises the possibility that the opioid system may be involved in the rewarding properties of Δ^9-THC and marijuana. DEA notes a recent review (Murray and Bevins, 2010) that further explores the currently available knowledge on Δ^9-THC's ability to induce CPP and conditioned place aversion (CPA), and further supports that low doses of Δ^9-THC appear to have conditioned rewarding effects, whereas higher doses have aversive effects.

2. Clinical Studies

DHHS states that the physiological, psychological, and behavioral effects of marijuana vary among individuals and presents a list of common responses to cannabinoids, as described in the scientific literature (Adams and Martin, 1996; Hollister, 1986, 1988; Institute of Medicine, 1982):

1. Dizziness, nausea, tachycardia, facial flushing, dry mouth and tremor initially
2. Merriment, happiness and even exhilaration at high doses
3. Disinhibition, relaxation, increased sociability, and talkativeness
4. Enhanced sensory perception, giving rise to increased appreciation of music, art and touch
5. Heightened imagination leading to a subjective sense of increased creativity
6. Time distortions
7. Illusions, delusions and hallucinations are rare except at high doses
8. Impaired judgment, reduced coordination and ataxia, which can impede driving ability or lead to an increase in risk-taking behavior
9. Emotional lability, incongruity of affect, dysphoria, disorganized thinking, inability to converse logically, agitation, paranoia, confusion, restlessness, anxiety, drowsiness and panic attacks may occur, especially in inexperienced users or in those who have taken a large dose
10. Increased appetite and short-term memory impairment are common

These subjective responses to marijuana are pleasurable to many humans and are associated with drug-seeking and drug-taking (Maldonado, 2002). DHHS states that, as with most psychoactive drugs, an individual's response to marijuana can be influenced by a person's medical/psychiatric history as well as their experience with drugs. Frequent marijuana users (used more than 100 times) were better able to identify a drug effect from low-dose Δ^9-THC than infrequent users (used less than 10 times) and were less likely to experience sedative effects from the drug (Kirk and de Wit, 1999). However, dose preferences have been demonstrated for marijuana in which higher doses (1.95 percent Δ^9-THC) are preferred over lower doses (0.63 percent Δ^9-THC) (Chait and Burke, 1994).

DEA notes that an extensive review of the reinforcing effects of marijuana in humans was included in DEA/DHHS's prior review of

marijuana (Notice of Denial of Petition, 66 FR 20038, 2001). While additional studies have been published on the reinforcing effects of marijuana in humans (e.g., see review by Cooper and Haney, 2009), they are consistent with the information provided in DEA/DHHS's prior review of this matter. Excerpts are provided below, with some citations omitted.

Both marijuana and THC can serve as positive reinforcers in humans. Marijuana and Δ^9-THC produced profiles of behavioral and subjective effects that were similar regardless of whether the marijuana was smoked or taken orally, as marijuana in brownies, or orally as THC-containing capsules, although the time course of effects differed substantially. There is a large clinical literature documenting the subjective, reinforcing, discriminative stimulus, and physiological effects of marijuana and THC and relating these effects to the abuse potential of marijuana and THC (e.g., Chait *et al.*, 1988; Lukas *et al.*, 1995; Kamien et al., 1994; Chait and Burke, 1994; Chait and Pierri, 1992; Foltin *et al.*, 1990; Azorlosa *et al.*, 1992; Kelly et al., 1993, 1994; Chait and Zacny, 1992; Cone *et al.*, 1988; Mendelson and Mello, 1984).

These listed studies represent a fraction of the studies performed to evaluate the abuse potential of marijuana and THC. In general, these studies demonstrate that marijuana and THC dose-dependently increases heart rate and ratings of ''high'' and ''drug liking'', and alters behavioral performance measures (e.g., Azorlosa *et al.*, 1992; Kelly et al., 1993, 1994; Chait and Zacny, 1992; Kamien *et al.*, 1994; Chait and Burke, 1994; Chait and Pierri, 1992; Foltin *et al.*, 1990; Cone *et al.*, 1988; Mendelson and Mello, 1984). Marijuana also serves as a discriminative stimulus in humans and produces euphoria and alterations in mood. These subjective changes were used by the subjects as the basis for the discrimination from placebo (Chait *et al.*, 1988).

In addition, smoked marijuana administration resulted in multiple brief episodes of euphoria that were paralleled by rapid transient increases in EEG alpha power (Lukas *et al.*, 1995); these EEG changes are thought to be related to CNS processes of reinforcement (Mello, 1983).

To help elucidate the relationship between the rise and fall of plasma THC and the self-reported psychotropic effects, Harder and Rietbrock (1997) measured both the plasma levels of THC and the psychological ''high'' obtained from smoking a marijuana cigarette containing 1% THC. As can be seen from these data, a rise in plasma THC concentrations results in a corresponding increase in the subjectively reported feelings of being ''high''. However, as THC levels drop the subjectively reported feelings of ''high'' remain elevated. The subjective effects seem to lag behind plasma THC levels. Similarly, Harder and Rietbrock compared lower doses of 0.3% THC-containing and 0.1% THC-containing cigarettes in human subjects.

As can be clearly seen from these data, even low doses of marijuana, containing 1%, 0.3% and even 0.1% THC, typically referred to as ''non-active'', are capable of producing subjective reports and physiological markers of being ''high'.

THC and its major metabolite, 11-OH-THC, have similar psychoactive and pharmacokinetic profiles in man (Wall *et al.*, 1976; DiMarzo *et al.*, 1998; Lemberger *et al.*, 1972). Perez-Reyes *et al.* (1972) reported that THC and 11-OH-THC were equipotent in generating a ''high'' in human volunteers. However, the metabolite, 11-OH-THC, crosses the blood-brain barrier faster than the parent THC compound (Ho *et al.*, 1973; Perez-Reyes et al., 1976). Therefore, the changes in THC plasma concentrations in humans may not be the best predictive marker for the subjective and physiological effects of marijuana in humans. Cocchetto *et al.* (1981) have used hysteresis plots to clearly demonstrate that plasma THC concentration is a poor predictor of simultaneous occurring physiological (heart rate) and psychological (''high'') pharmacological effects. Cocchetto *et al.* demonstrated that the time course of tachycardia and psychological responses lagged behind the plasma THC concentration-time profile. As recently summarized by Martin and Hall (1997, 1998)

''There is no linear relationship between blood [THC] levels and pharmacological effects with respect to time, a situation that hampers the prediction of cannabis-induced impairment based on THC blood levels (p90)''.

Drug craving is an urge or desire to re-experience the drug's effects and is considered to be one component of drug dependence, in part responsible for continued drug use and relapse after treatment or during periods of drug abstinence. DEA notes that Budney and colleagues (1999) reported that 93 percent of marijuana-dependent adults seeking treatment reported experiencing mild craving for marijuana, and 44 percent rated their past craving as severe. Heishman and colleagues developed in 2001 a Marijuana Craving Questionnaire (MCQ). When they administered their MCQ to 217 current marijuana smokers who were not attempting to quit or reduce their marijuana use, they found that marijuana craving can be measured in current smokers that are not seeking treatment. Most subjects (83 percent) reported craving marijuana 1–5 times per day, and 82 percent reported that each craving episode lasted 30 minutes or less. Furthermore, they determined that craving for marijuana can be characterized by four components: (1) compulsivity, an inability to control marijuana use; (2) emotionality, use of marijuana in anticipation of relief from withdrawal or negative mood; (3) expectancy, anticipation of positive outcomes from smoking marijuana; and (4) purposefulness, intention and planning to use marijuana for positive outcomes.

C. Actual Abuse of Marijuana—National Databases Related to Marijuana Abuse and Trafficking

Marijuana use has been relatively stable from 2002 to 2008, and it continues to be the most widely used illicit drug. Evidence of actual abuse can be defined by episodes/mentions in databases indicative of abuse/dependence. DHHS provided in its 2006 documents data relevant to actual abuse of marijuana including data from the National Survey on Drug Use and Health (NSDUH; formally known as the National Household Survey on Drug Abuse), the Drug Abuse Warning Network (DAWN), Monitoring the Future (MTF) survey, and the Treatment Episode Data Set (TEDS). These data collection and reporting systems provide quantitative data on many factors related to abuse of a particular substance, including incidence, pattern, consequence and profile of the abuser of specific substances. DEA provides here updates to these databases as well as additional data on trafficking and illicit availability of marijuana using information from databases it produces, such as the National Forensic Laboratory Information System (NFLIS), the System to Retrieve Information from Drug Evidence (STRIDE) and the Federal-wide Drug Seizure System (FDSS), as well as other sources of data specific to marijuana, including the Potency Monitoring Project and the Domestic Cannabis Eradication and Suppression Program (DCE/SP).

1. National Survey on Drug Use and Health (NSDUH)

The National Survey on Drug Use and Health, formerly known as the National Household Survey on Drug Abuse (NHSDA), is conducted annually by the Department of Health and Human Service's Substance Abuse and Mental Health Services Administration (SAMHSA). It is the primary source of estimates of the prevalence and incidence of pharmaceutical drugs, illicit drugs, alcohol, and tobacco use in the United States. The survey is based on a nationally representative sample of the civilian, non-institutionalized population 12 years of age and older. The survey excludes homeless people who do not use shelters, active military personnel, and residents of institutional group quarters such as jails and hospitals.

According to the 2009 NSDUH report, marijuana was the most commonly used illicit drug (16.7 million past month users) in the United States. (Note that NSDUH figures on marijuana use include hashish use; the relative proportion of hashish use to marijuana use is very low). Marijuana was also the most widely abused drug. The 2009 NSDUH report stated that 4.3 million persons were classified with substance dependence or abuse of marijuana in the past year based on criteria specified in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM–IV). Among persons aged 12 or older, the past month marijuana use in 2009 (6.6 percent) was statistically significantly higher than in 2008 (6.1 percent). In 2008, among adults aged 18 or older who first tried marijuana at age 14 or younger, 13.5 percent were classified with illicit drug dependence or abuse, higher than the 2.2 percent of adults who had first used marijuana at age 18 or older.

In 2008, among past year marijuana users aged 12 or older, 15.0 percent used marijuana on 300 or more days within the previous 12 months. This translates into 3.9 million people using marijuana on a daily or almost

daily basis over a 12-month period, higher than the estimate of 3.6 million (14.2 percent of past year users) in 2007. Among past month marijuana users, 35.7 percent (5.4 million) used the drug on 20 or more days in the past month.

2. Monitoring the Future

Monitoring the Future (MTF) is a national survey conducted by the Institute for Social Research at the University of Michigan under a grant from the National Institute on Drug Abuse (NIDA) that tracks drug use trends among American adolescents in the 8th, 10th, and 12th grades. Marijuana was the most commonly used illicit drug reported in the 2010 MTF report. Approximately 8.0 percent of 8th graders, 16.7 percent of the 10th graders, and 21.4 percent of 12th graders surveyed in 2010 reported marijuana use during the past month prior to the survey. Monitoring the Future participants reported a statistically significant increase of daily use in the past month in 2010, compared to 2009, 1.2 percent, 3.3 percent, and 6.1 percent of eighth, tenth and twelfth graders, respectively.

3. DAWN ED (Emergency Department)

The Drug Abuse Warning Network (DAWN) is a public health surveillance system that monitors drug-related hospital emergency department (ED) visits to track the impact of drug use, misuse, and abuse in the United States. DAWN provides a picture of the impact of drug use, misuse, and abuse on metropolitan areas and across the nation. DAWN gathers data on drug abuse-related ED visits from a representative sample of hospitals in the coterminous United States. DAWN ED gathers data on emergency department visits relating to substance use including, but not limited to, alcohol, illicit drugs, and other substances categorized as psychotherapeutic, central nervous system, respiratory, cardiovascular, alternative medication, anti-infective, hormone, nutritional product and gastrointestinal agents. For the purposes of DAWN, the term ''drug abuse'' applies if the following conditions are met: (1) the case involved at least one of the following: use of an illegal drug; use of a legal drug contrary to directions; or inhalation of a non-pharmaceutical substance and (2) the substance was used for one of the following reasons: because of drug dependence; to commit suicide (or attempt to commit suicide); for recreational purposes; or to achieve other psychic effects.

In 2009, marijuana was involved in 376,467 ED visits, out of 1,948,312 drug-related ED visits, as estimated by DAWN ED for the entire United States. This compares to a higher number of ED visits involving cocaine (422,896), and lower numbers of ED visits involving heroin (213,118) and stimulants (amphetamine, methamphetamine) (93,562). Visits involving the other major illicit drugs, such as MDMA, GHB, LSD and other hallucinogens, PCP, and inhalants, were much less frequent, comparatively.

In young patients, marijuana is the illicit drug most frequently involved in ED visits according to DAWN estimates, with 182.2 per 100,000 population aged 12 to 17, 484.8 per 100,000 population aged 18 to 20, and 360.2 per 100,000 population aged 21 to 24.

4. Treatment Episode Data Set (TEDS) System

Users can become dependent on marijuana to the point that they seek treatment to stop abusing it or are referred to a drug abuse treatment program. The TEDS system is part of the SAMHSA Drug and Alcohol Services Information System. TEDS comprises data on treatment admissions that are routinely collected by states in monitoring their substance abuse treatment systems. The primary goal of the TEDS is to monitor the characteristics of treatment episodes for substances abusers. The TEDS report provides information on both the demographic and substance use characteristics of admissions to treatment for abuse of alcohol and drugs in facilities that report to individual state administrative data systems. TEDS does not include all admissions to substance abuse treatment. It includes admissions to facilities that are licensed or certified by the state substance abuse agency to provide substance abuse treatment (or are administratively tracked by the agency for other reasons). In general, facilities reporting to TEDS are those that receive state alcohol and/or drug agency funds (including federal block grant funds) for the provision of alcohol and/or drug treatment services. The primary substances reported by TEDS are alcohol, cocaine, marijuana (marijuana is considered together with hashish), heroin, other opiates, PCP, hallucinogens, amphetamines, other stimulants, tranquilizers, sedatives, inhalants and other/unknown. TEDS defines Primary Substance of Abuse as the main substance of abuse reported at the time of admission. TEDS also allows for the recording of two other substances of abuse (secondary and tertiary). A client may be abusing more than three substances at the time of admission, but only three are recorded in TEDS.

Admissions for primary abuse of marijuana/hashish accounted for 16 percent of all treatment admissions reported to the TEDS system in 2006 and 2007. In 2006, 2007 and 2008, 1,933,206, 1,920,401 and 2,016,256 people were admitted to drug and alcohol treatment in the United States, respectively. The marijuana/hashish admissions represented 16 percent (308,670), 16 percent (307,123) and 17.2 percent (346,679) of the total drug/alcohol treatment admissions in 2006, 2007 and 2008, respectively. In 2008, 65.8 percent of the individuals admitted for marijuana were aged 12–17, 18–20 and 21–25 (30.5 percent, 15.3 percent and 20.0 percent, respectively). Among the marijuana/hashish admissions in 2007 in which age of first use was reported (286,194), 25.1 percent began using marijuana at age 12 or younger.

5. Forensic Laboratory Data

Marijuana is widely available in the United States, fueled by increasing marijuana production at domestic grow sites as well as increasing production in Mexico and Canada. Data on marijuana seizures from federal, state, and local law enforcement laboratories have indicated that there is significant trafficking of marijuana. The National Forensic Laboratory Information System (NFLIS) is a program sponsored by the Drug Enforcement Administration's Office of Diversion Control. NFLIS compiles information on exhibits analyzed in state and local law enforcement laboratories. The System to Retrieve Information from Drug Evidence (STRIDE) is a DEA database which compiles information on exhibits analyzed in DEA laboratories. NFLIS and STRIDE together capture data for all substances reported by forensic laboratory analyses. More than 1,700 unique substances are reported to these two databases.

NFLIS showed that marijuana was the most frequently identified drug in state and local laboratories from January 2001 through December 2010. Marijuana accounted for between 34 percent and 38 percent of all drug exhibits analyzed during that time frame. Similar to NFLIS, STRIDE data showed that marijuana was the most frequently identified drug in DEA laboratories for the same reporting period. From January 2001 through December 2010, a range of between 17 percent and 21 percent of all exhibits analyzed in DEA laboratories were identified as marijuana (Table 1).

TABLE 1—MARIJUANA (OTHER THAN HASHISH) (EXHIBITS AND CASES) REPORTED BY NFLIS AND STRIDE, 2001–2010, FORENSIC LABORATORY DATA

	NFLIS		STRIDE	
	Exhibits (percent total exhibits)	Cases	Exhibits (percent total exhibits)	Cases
2001	314,002 (37.9%)	261,191	16,523 (20.7%)	13,256
2002	373,497 (36.6%)	312,161	14,010 (19.4%)	11,306
2003	407,046 (36.7%)	339,995	13,946 (19.9%)	10,910
2004	440,964 (35.5%)	371,841	13,657 (18.4%)	10,569
2005	469,186 (33.5%)	394,557	14,004 (18.3%)	10,661

TABLE 1—MARIJUANA (OTHER THAN HASHISH) (EXHIBITS AND CASES) REPORTED BY NFLIS AND STRIDE, 2001–2010, FORENSIC LABORATORY DATA—Continued

	NFLIS		STRIDE	
	Exhibits (percent total exhibits)	Cases	Exhibits (percent total exhibits)	Cases
2006	506,472 (33.6%)	421,943	13,597 (18.5%)	10,277
2007	512,082 (34.7%)	423,787	13,504 (19.2%)	10,413
2008	513,644 (35.1%)	421,782	12,828 (18.8%)	10,109
2009	524,827 (35.6%)	414,006	12,749 (17.7%)	10,531
2010	464,059 (36.3%)	362,739	11,293 (16.7%)	7,158

Data queried 03–04–2011.

TABLE 2—HASHISH (EXHIBITS AND CASES) REPORTED BY NFLIS AND STRIDE, 2001–2010, FORENSIC LABORATORY DATA

	NFLIS		STRIDE	
	Exhibits	Cases	Exhibits	Cases
2001	1,689	1,671	53	50
2002	2,278	2,254	40	38
2003	2,533	2,503	48	42
2004	2,867	2,829	63	51
2005	2,674	2,639	122	90
2006	2,836	2,802	102	76
2007	3,224	3,194	168	122
2008	2,988	2,920	124	102
2009	2,952	2,843	119	96
2010	2,473	2,392	141	84

Data queried 03–04–2011.

Since 2001, the total number of exhibits and cases of marijuana and the amount of marijuana seized federally has remained high and the number of marijuana plants eradicated has considerably increased (see data from Federal-wide Drug Seizure System and Domestic Cannabis Eradication and Suppression Program below).

6. Federal-wide Drug Seizure System

The Federal-wide Drug Seizure System (FDSS) contains information about drug seizures made by the Drug Enforcement Administration, the Federal Bureau of Investigation, United States Customs and Border Protection, and United States Immigration and Customs Enforcement, within the jurisdiction of the United States. It also records maritime seizures made by the United States Coast Guard. Drug seizures made by other Federal agencies are included in the FDSS database when drug evidence custody is transferred to one of the agencies identified above. FDSS is now incorporated into the National Seizure System (NSS), which is a repository for information on clandestine laboratory, contraband (chemicals and precursors, currency, drugs, equipment and weapons). FDSS reports total federal drug seizures (kg) of substances such as cocaine, heroin, MDMA, methamphetamine, and cannabis (marijuana and hashish). The yearly volume of cannabis seized (Table 3), consistently exceeding a thousand metric tons per year, shows that cannabis is very widely trafficked in the United States.

TABLE 3—TOTAL FEDERAL SEIZURES OF CANNABIS

[Expressed in kg]

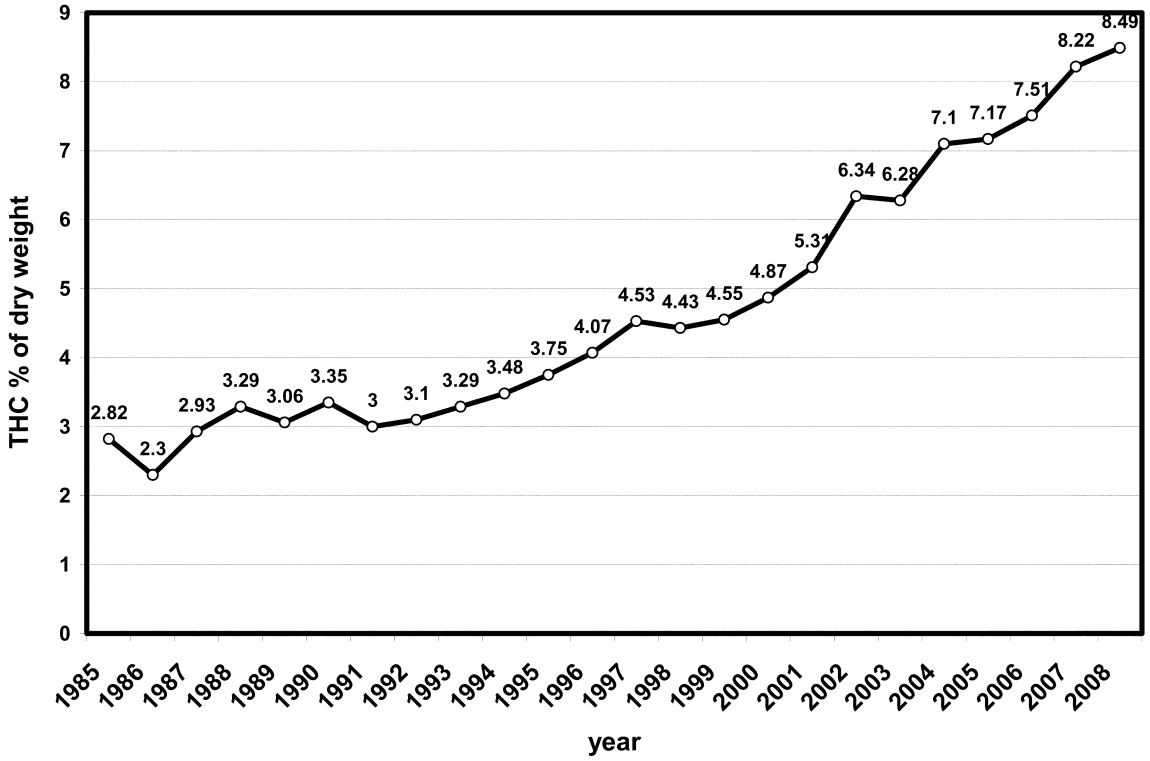
	2002	2003	2004	2005	2006	2007	2008	2009	2009
Cannabis	1,103,173	1,232,711	1,179,230	1,116,977	1,141,915	1,459,220	1,590,793	1,911,758	1,858,808
Marijuana	1,102,556	1,232,556	1,179,064	1,116,589	1,141,737	1,458,883	1,590,505	1,910,775	1,858,422
Hashish	618	155	166	388	178	338	289	983	386

7. Potency Monitoring Project

Rising availability of high potency (i.e., with high Δ^9-THC concentrations) marijuana has pushed the average marijuana potency to its highest recorded level. The University of Mississippi's Potency Monitoring Project (PMP), through a contract with the National Institute on Drug Abuse (NIDA), analyzes and compiles data on the Δ^9-THC concentrations of cannabis, hashish and hash oil samples provided by DEA regional laboratories and by state and local police agencies.

DEA notes studies showing that when given the choice between low- and high-potency marijuana, subjects chose the high-potency marijuana significantly more often than the low-potency marijuana (Chait and Burke, 1994), supporting the hypothesis that the reinforcing effects of marijuana, and possibly its abuse liability, are positively related to THC content.

Figure 1. Average Percentage of Δ^9-THC in Samples of Seized Marijuana (1985 –2008) (Source: The University of Mississippi Potency Monitoring Project)



8. The Domestic Cannabis Eradication and Suppression Program

The Domestic Cannabis Eradication and Suppression Program (DCE/SP) was established in 1979 to reduce the supply of domestically cultivated marijuana in the United States. The program was designed to serve as a partnership between federal, state, and local agencies. Only California and Hawaii were active participants in the program at its inception. However, by 1982 the program had expanded to 25 states and by 1985 all fifty states were participants. Cannabis is cultivated in remote locations and frequently on public lands. Data provided by the DCE/SP (Table 4) shows that in 2009, there were 9,980,038 plants eradicated in outdoor cannabis cultivation areas in the United States. Marijuana is illicitly grown in all states. Major domestic outdoor cannabis cultivation areas were found in California, Kentucky, Tennessee and Hawaii. Significant quantities of marijuana were also eradicated from indoor cultivation operations. There were 414,604 indoor plants eradicated in 2009 compared to 217,105 eradicated in 2000. As indoor cultivation is generally associated with plants that have higher concentrations of Δ^9-THC, the larger numbers of indoor grow facilities may be impacting the higher average Δ^9-THC concentrations of seized materials.

TABLE 4—DOMESTIC CANNABIS ERADICATION, OUTDOOR AND INDOOR PLANTS SEIZED, 2000–2009

[Source: Domestic Cannabis Eradication/Suppression Program]

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Outdoor	2,597,798	3,068,632	3,128,800	3,427,923	2,996,144	3,938,151	4,830,766	6,599,599	7,562,322	9,980,038
Indoor	217,105	236,128	213,040	223,183	203,896	270,935	400,892	434,728	450,986	414,604
Total	2,814,903	3,304,760	3,341,840	3,651,106	3,200,040	4,209,086	5,231,658	7,034,327	8,013,308	10,394,642

The recent statistics from these various surveys and databases show that marijuana continues to be the most commonly used illicit drug, with considerable rates of heavy abuse and dependence. They also show that marijuana is the most readily available illicit drug in the United States.

The petitioner states that, ''The abuse potential of cannabis is insufficient to justify the prohibition of medical use.'' The petitioner also states that, ''[s]everal studies demonstrate that abuse rates for cannabis are lower than rates for other common drugs.'' (Exh. C, Section IV(16), pg. 92).

DHHS states, to the contrary, ''the large number of individuals using marijuana on a regular basis, its widespread use, and the vast amount of marijuana that is available for illicit use are indicative of the high abuse potential for marijuana.'' Indeed, the data presented in this section shows that marijuana has a high potential for abuse as determined using the indicators identified in the CSA's legislative history. Both clinical and preclinical studies have demonstrated that marijuana and its principal psychoactive constituent Δ^9-THC possess the attributes associated with drugs of abuse. They function as positive reinforcers and as discriminative stimuli to maintain drug-seeking behavior.

In addition, marijuana is the most highly abused and trafficked illicit substance in the United States. Chronic abuse has resulted in a considerable number of individuals seeking substance abuse treatment according to national databases such as TEDS. Abuse of marijuana is associated with significant public health and safety risks that are described under factors 2, 6 and 7.

The issue of whether marijuana has a currently accepted medical use is discussed under Factor 3.

The petitioner claims that, ''[…]widespread use of marijuana without dependency supports the argument that marijuana is safe for use under medical supervision.'' (Exh. C, Section IV(15), pg. 87).

Petitioner's claim of widespread use without dependency is not supported by abuse-related data. In particular, this claim disregards the high numbers of admissions to treatment facilities for marijuana abuse. Indeed, TEDS admissions for primary abuse of marijuana/hashish accounted for roughly 17 percent of all treatment admissions in 2008. In 2008, 2,016,256 people were admitted to drug and alcohol treatment in the United States and 346,679 of those admissions were for marijuana/hashish abuse. These drug treatment numbers are not consistent with this claim. Marijuana is not safe for use under medical supervision, and this point is addressed further in Factor 3.

The petitioner also claims that, ''Data on both drug treatment and emergency room admissions also distinguishes the abuse potential of marijuana from that of other drugs and establishes its relative abuse potential as lower than schedule I drugs such as heroin and schedule II drugs such as cocaine.'' (Exh. C, Section IV(17), pg. 99). The petitioner then presents data from TEDS in 1998, in which a larger proportion of all marijuana treatment admissions are referred to by the criminal justice system (54 percent), compared to much smaller percentages for heroin and cocaine. The petitioner argues that the abuse potential of these other drugs is more severe such that addicts seek treatment on their own or through persuasion of their associates, and claims that this difference establishes marijuana's relative abuse potential as lower than the other drugs.

Petitioner's claim is not supported by an examination of the absolute numbers of admissions for treatment for each drug discussed. Regardless of proportions of referrals from the criminal justice systems, the absolute numbers of admissions for treatment for marijuana, heroin, or cocaine dependence are very high. Furthermore, data from TEDS in 2007 (SAMHSA, 2009) show that both primary marijuana and methamphetamine/amphetamine admissions had the largest proportion of admissions referred through the criminal justice system (57 percent each), followed by PCP (54 percent). Both methamphetamine/amphetamine and PCP have very high potential for abuse (Lile, 2006; Crider, 1986). Accordingly, this illustrates that it is not possible to establish or predict relative abuse potentials from the ranking of proportions of treatment admissions referred by the criminal justice system.

FACTOR 2: SCIENTIFIC EVIDENCE OF THE DRUG'S PHARMACOLOGICAL EFFECTS, IF KNOWN

DHHS states that there are abundant scientific data available on the neurochemistry, toxicology, and pharmacology of marijuana. Following is a summary of the current scientific understanding of the endogenous cannabinoid system and of marijuana's pharmacological effects, including its effects on the cardiovascular, respiratory, and immune systems, as well as its effects on mental health and cognitive function and the effect of prenatal exposure to marijuana.

Neurochemistry of the Psychoactive Constituents of Marijuana

DHHS states that of 483 natural constituents identified in marijuana, 66 are classified as cannabinoids (Ross and El Sohly, 1995). Cannabinoids are not known to exist in plants other than marijuana and most of the cannabinoid compounds have been identified chemically. The activity of marijuana is largely attributed to Δ^9-THC (Wachtel *et al.,* 2002).

DEA notes that Δ^9-THC and delta-8-tetrahydrocannabinol (Δ^8-THC) are the only known compounds in the cannabis plant which show all the psychoactive effects of marijuana. Δ^9-THC is more abundant than Δ^8-THC and Δ^9-THC concentrations vary within portions of the cannabis plant (Hanus and Subivá, 1989; Hanus *et al.,* 1975). The pharmacological activity of Δ^9-THC is stereospecific: the (-)-trans isomer is 6–100 times more potent than the (+)-trans isomer (Dewey *et al.,* 1984).

The mechanism of action of Δ^9-THC was verified with the cloning of cannabinoid receptors, first from rat brain tissue (Matsuda *et al.,* 1990) and then from human brain tissue (Gerard *et al.,* 1991). Two cannabinoid receptors have been identified and characterized, CB_1 and CB_2 (Piomelli, 2005). Autoradiographic studies have provided information on the distribution of CB_1 and CB_2 receptors. High densities of CB_1 receptors are found in the basal ganglia, hippocampus, and cerebellum of the brain (Howlett *et al.,* 2004; Herkenham *et al.,* 1990; Herkenham, 1992). These brain regions are associated with movement coordination and cognition and the location of CB_1 receptors in these areas may explain cannabinoid interference with these functions. Although CB_1 receptors are predominantly expressed in the brain, they have also been detected in the immune system (Bouaboula *et al.,* 1993). CB_2 receptors are primarily located in B lymphocytes and natural killer cells of the immune system and it is believed that this receptor is responsible for mediating immunological effects of cannabinoids (Galiegue *et al.,* 1995). Recently, however, CB_2 receptors have been localized in the brain, primarily in the cerebellum and hippocampus (Gong *et al.,* 2006).

Cannabinoid receptors are linked to an inhibitory G-protein (Breivogel and Childers, 2000). When the receptor is activated, adenylate cyclase activity is inhibited, preventing the conversion of adenosine triphosphate (ATP) to the second messenger cyclic adenosine monophosphate (cAMP). Other examples of inhibitory-coupled receptors include opioid, muscarinic cholinergic, alpha$_2$-adrenoreceptors, dopamine and serotonin receptors. However, several studies also suggest a link to stimulatory G-proteins, through which activation of CB_1 stimulates adenylate cyclase activity (Glass and Felder, 1997; Maneuf and Brotchie, 1997; Felder *et al.,* 1998).

Activation of CB_1 receptors inhibits N-and P/Q-type calcium channels and activate inwardly rectifying potassium channels (Mackie *et al.,* 1995; Twitchell *et al.,* 1997). Inhibition of N-type calcium channels decreases neurotransmitter release from a number of tissues and may be the mechanism by which cannabinoids inhibit acetylcholine, norepinephrine, and glutamate release from specific areas of the brain. These effects on G protein-mediated pathways and on calcium and potassium channels may represent potential cellular mechanisms underlying the antinociceptive and psychoactive effects of cannabinoids (Ameri, 1999).

Delta^9-THC displays similar affinity for both cannabinoid receptors but behaves as a weak agonist at CB_2 receptors, based on inhibition of adenylate cyclase. The identification of synthetic cannabinoid ligands that selectively bind to CB_2 receptors but do not have the typical Δ^9-THC-like psychoactive properties, along with the respective anatomical distribution of the two receptor subtypes suggests that the psychoactive effects of cannabinoids are mediated through the activation of CB_1 receptors (Hanus *et al.,* 1999). Naturally occurring cannabinoids and synthetic cannabinoid agonists (such as WIN-55,212-2 and CP-55,940) produce hypothermia, analgesia, hypoactivity, and catalepsy in addition to their psychoactive effects.

In 2000, two endogenous cannabinoid receptor agonists were discovered, anandamide and arachidonyl glycerol (2-AG). Anandamide is a low efficacy agonist (Breivogel and Childers, 2000) and 2-AG is a highly efficacious agonist (Gonsiorek *et al.,* 2000). These endogenous ligands are present in both central and peripheral tissues. The physiological role of these endogenous ligands is an active area of research (Martin *et al.,* 1999).

In summary, two receptors have been cloned, CB_1 (found in the central nervous system) and CB2 (predominantly found in the periphery), that bind Δ^9-THC and other cannabinoids. Activation of these inhibitory G-protein-coupled receptors inhibits calcium channels and adenylate cyclase. Endogenous cannabinoid agonists have been identified, anandamide and arachidonyl glycerol (2-AG).

Pharmacological Effects of Marijuana

Marijuana produces a number of central nervous system effects. Many of these effects are directly related to the abuse potential of marijuana, and are discussed in Factor 1. Other effects are discussed herein.

Cardiovascular and Autonomic Effects

DHHS states that acute use of marijuana causes an increase in heart rate (tachycardia) and may cause a modest increase in blood pressure as well (Capriotti *et al.,* 1988; Benowitz and Jones, 1975). Conversely, chronic exposure to marijuana will produce a decrease in heart rate (bradycardia) and decrease of blood pressure. In heavy smokers of marijuana, the degree of increased heart rate is diminished due to the development of tolerance (Jones, 2002 and Sidney, 2002). These effects are thought to be mediated through peripherally located, presynaptic CB_1 receptor inhibition of norepinephrine release with possible direct activation of vascular cannabinoid receptors (Wagner *et al.,* 1998).

DHHS cites a review (Jones, 2002) of studies showing that smoked marijuana causes orthostatic hypotension (sympathetic insufficiency, a sudden drop in blood pressure upon standing up) often accompanied by dizziness. DHHS states that tolerance can develop to this effect.

Marijuana smoking by older patients, particularly those with some degree of coronary artery or cerebrovascular disease, poses risks related to increased cardiac work, increased catecholamines, carboxyhemoglobin, and postural hypotension (Benowitz and Jones, 1981; Hollister, 1988).

DEA further notes studies in which marijuana has been administered under controlled conditions to marijuana-experienced users that showed that marijuana causes a substantial increase, compared to placebo, in heart rate (tachycardia) ranging from 20 percent to 100 percent above baseline. This effect was seen as usually greatest starting during the 10 minutes or so it takes to smoke a marijuana cigarette and lasting 2 to 3 hours (reviewed in Jones *et al.,* 2002).

DEA also notes a randomized, double-blind, placebo-controlled study by Mathew and colleagues (2003) that examined pulse rate, blood pressure (BP), and plasma Δ^9-THC levels during reclining and standing for 10 minutes before and after smoking one marijuana cigarette (3.55 percent Δ^9-THC) by twenty-nine volunteers. Marijuana induced postural dizziness, with 28 percent of subjects reporting severe symptoms. Intoxication and dizziness peaked immediately after drug intake. The severe dizziness group showed the most marked postural drop in blood pressure and showed a drop in pulse rate after an initial increase during standing.

Respiratory Effects

Both acute and chronic respiratory effects are associated with marijuana smoking.

DHHS states that acute exposure to marijuana produces transient bronchodilation (Gong *et al.,* 1984). DHHS states that long-term use of smoked marijuana can lead to increased frequency of chronic cough, increased sputum, large airway obstruction, as well as cellular inflammatory histopathological abnormalities in bronchial epithelium (Adams and Martin, 1996; Hollister, 1986).

DEA notes a study showing that both smoked marijuana and oral Δ^9-THC increases specific airway conductance in asthmatic subjects (Tashkin *et al.,* 1974). In addition, other studies have suggested that chronic marijuana smoking is also associated with increased incidence of emphysema and asthma (Tashkin *et al.,* 1987).

DHHS states that the evidence that marijuana may lead to cancer is inconsistent, with some studies suggesting a positive correlation while others do not. DHHS cited a large clinical study with 1,650 subjects in which no positive correlation was found between marijuana use and lung cancer (Tashkin *et al.,* 2006). This finding held true regardless of the extent of marijuana use when both tobacco use and other potential confounding factors were controlled. DHHS also cites other studies reporting lung cancer occurrences in young marijuana users with no history of tobacco smoking (Fung *et al.,* 1999), and suggesting a dose-dependent effect of marijuana on the risk of head and neck cancer (Zhang *et al.,* 1999).

DEA notes the publication of a more recent case–control study of lung cancer in adults under 55 years of age, conducted in New Zealand by Aldington and colleagues (2008). Interviewer-administered questionnaires were used to assess possible risk factors, including cannabis use. In total, 79 cases of lung cancer and 324 controls were included in the study. The risk of lung cancer increased 8 percent (95 percent confidence interval (CI) 2–15) for each joint-year of cannabis smoking (one joint-year being equivalent to one joint per day for a year), after adjustment for confounding variables including cigarette smoking; it went up 7 percent (95 percent CI 5–9) for each pack-year of cigarette smoking (one pack-year being equivalent to one pack per day for a year), after adjustment for confounding variables including cannabis smoking. Thus, a major differential risk between cannabis and cigarette smoking was observed, with one joint of cannabis being similar to 20 cigarettes for risk of lung cancer. Users reporting over 10.5 joint-years of exposure had a significantly increased risk of developing lung cancer (relative risk 5.7 (95 percent CI 1.5–21.6)) after adjustment for confounding variables including cigarette smoking. DEA notes that the authors of this study concluded from their results that long-term cannabis use increases the risk of lung cancer in young adults.

Some studies discuss marijuana smoke and tobacco smoke. DHHS states that chronic exposure to marijuana smoke is considered to be comparable to tobacco smoke with respect to increased risk of cancer and lung damage. DEA notes studies showing that marijuana smoke contains several of the same carcinogens and co-carcinogens as tobacco smoke and suggesting that pre-cancerous lesions in bronchial epithelium also seem to be caused by long-term marijuana smoking (Roth *et al.,* 1998).

In summary, studies are still needed to clarify the impact of marijuana on the risk of developing lung cancer as well as head and neck cancer. DHHS states that the evidence that marijuana may lead to cancer is inconsistent, with some studies suggesting a positive correlation while others do not.

Endocrine Effects

DHHS states that Δ^9-THC reduces binding of the corticosteroid dexamethasone in hippocampal tissue from adrenalectomized rats and acute Δ^9-THC releases corticosterone, with tolerance developing to this effect with chronic administration (Eldridge *et al.,* 1991). These data suggest that Δ^9-THC may interact with the glucocorticoid receptor system.

DHHS states that experimental administration of marijuana to humans does not consistently alter the endocrine system. In an early study, four male subjects administered smoked marijuana showed a significant depression in luteinizing hormone and a significant increase in cortisol (Cone *et al.,* 1986). However, later studies in male subjects receiving smoked Δ^9-THC (18 mg/marijuana cigarette) or oral Δ^9-THC (10 mg t.i.d. for 3 days) showed no changes in plasma prolactin, ACTH, cortisol, luteinizing hormone or testosterone levels (Dax *et al.,* 1989). Similarly, a study with 93 males and 56 female subjects showed that chronic marijuana use did not significantly alter concentrations of testosterone, luteinizing hormone, follicle stimulating hormone, prolactin or cortisol (Block *et al.,* 1991).

DHHS cites a study (Sarfaraz *et al.,* 2005) which showed that the cannabinoid agonist WIN 55,212-2 induces apoptosis in prostate cancer cells growth and decreases expression of androgen receptors. DHHS states that this data suggests a potential therapeutic value for cannabinoid agonists in the treatment of prostate cancer, an androgen-stimulated type of carcinoma.

In summary, while animal studies have suggested that cannabinoids can alter multiple hormonal systems, the effects in humans, in particular the consequences of long-term marijuana abuse, remain unclear.

Immune System Effects

DHHS states that cannabinoids alter immune function but that there can be differences between the effects of synthetic, natural, and endogenous cannabinoids (Croxford and Yamamura, 2005).

DHHS cites a study by Roth *et al.* (2005) that examined the effect of Δ^9-THC exposure on immune function and response to HIV infection in immunodeficient mice that were implanted with human blood cells infected with HIV. The study shows that exposure to Δ^9-THC *in vivo* suppresses immune function, increases HIV co-receptor expression and acts as a cofactor to enhance HIV replication. DEA notes that the authors of this study state that their results suggest a dynamic interaction between Δ^9-THC, immunity, and the pathogenesis of HIV and support epidemiologic studies that have identified marijuana use as a risk factor for HIV infection and the progression of AIDS. However, DHHS discusses a recent study by Abrams *et al.* (2003) that investigated the effect of marijuana on immunological functioning in 67 AIDS patients who were taking protease inhibitors. Subjects received one of three treatments, three times a day: smoked marijuana cigarette containing 3.95 percent Δ^9-THC; oral tablet containing Δ^9-THC (2.5 mg oral dronabinol); or oral placebo. There were no changes in HIV-RNA levels between groups, demonstrating no short-term adverse virologic effects from using cannabinoids.

DEA notes a review suggesting that Δ^9-THC and cannabinoids decrease resistance to microbial infections in experimental animal models and *in vitro* (see review by Cabral and Staab, 2005). Various studies have been conducted in drug-abusing human subjects, experimental animals exposed to marijuana smoke or injected with cannabinoids, and in *in vitro* models using immune cell cultures treated with various cannabinoids. DEA notes that for the most part, these studies suggest that cannabinoids modulate the function of various cells of the human immune system, including T- and B-

lymphocytes as well as natural killer (NK) cells and macrophages. Macrophages engulf and destroy foreign matter, NK cells target cells (e.g., cancerous cells) and destroy them, B-lymphocytes produce antibodies against infective organisms, and T-lymphocytes kill cells or trigger the activity of other cells of the immune system.

In addition to studies examining cannabinoid effects on immune cell function, DEA also notes other reports which have documented that cannabinoids modulate resistance to various infectious agents. Viruses such as herpes simplex virus and murine retrovirus have been studied as well as bacterial agents such as members of the genera Staphylococcus, Listeria, Treponema, and Legionella. These studies suggest that cannabinoids modulate host resistance, especially the secondary immune response (reviewed in Cabral and Dove-Pettit, 1998).

Finally, DEA notes a review suggesting that cannabinoids modulate the production and function of cytokines as well as modulate the activity of network cells such as macrophages and T helper cells. Cytokines are the chemicals produced by cells of the immune system in order to communicate and orchestrate the attack. Binding to specific receptors on target cells, cytokines recruit many other cells and substances to the field of action. Cytokines also encourage cell growth, promote cell activation, direct cellular traffic, and destroy target cells (see review by Klein *et al.*, 2000).

In summary, as DHHS states, cannabinoids alter immune function, but there can be differences between the effects of synthetic, natural, and endogenous cannabinoids. While there is a large body of evidence to suggest that Δ^9-THC alters immune function, research is still needed to clarify the effects of cannabinoids and marijuana on the immune system in humans, in particular the risks posed by smoked marijuana in immunocompromized individuals.

Association with Psychosis

The term psychosis is generally used in research as a generic description of severe mental illnesses characterized by the presence of delusions, hallucinations and other associated cognitive and behavioral impairments. Psychosis is measured either by using standardized diagnostic criteria for psychotic conditions such as schizophrenia or by using validated scales that rank the level of psychotic symptoms from none to severe (Fergusson *et al.*, 2006).

DHHS states that extensive research has been conducted recently to investigate whether exposure to marijuana is associated with schizophrenia or other psychoses. DHHS states that, at the time of their review, the data does not suggest a causative link between marijuana use and the development of psychosis.

DHHS discusses an early epidemiological study conducted by Andreasson and colleagues (1987), which examined the link between psychosis and marijuana use. In this study, 45,000 18- and 19-year-old male Swedish subjects provided detailed information on their drug-taking history. The incidence of schizophrenia was then recorded over the next 15 years. Those individuals who claimed, on admission, to have taken marijuana on more than 50 occasions were six times more likely to be diagnosed with schizophrenia in the following 15 years than those who had never consumed the drug. When confounding factors were taken into account, the risk of developing schizophrenia remained statistically significant. The authors concluded that marijuana users who are vulnerable to developing psychoses are at the greatest risk for schizophrenia. DHHS states that therefore marijuana per se does not appear to induce schizophrenia in the majority of individuals who try or continue to use the drug.

DHHS discusses another large longitudinal study in which the prevalence of schizophrenia was modeled against marijuana use across birth cohorts in Australia from 1940 to 1979 (Degenhardt *et al.*, 2003). The authors found that marijuana use may precipitate disorders in vulnerable individuals and worsen the course of the disorder among those that have already developed it. They did not find any causal relationship between marijuana use and increased incidence of schizophrenia.

DEA notes that Degenhardt and colleagues (2003) acknowledged that several environmental risk factors for schizophrenia had been reduced (i.e., poor maternal nutrition, infectious disease and poor antenatal and prenatal care) and that the diagnostic criteria for schizophrenia had changed over the span of this study making the classification of schizophrenia more rigorous. These confounders could reduce the reported prevalence of schizophrenia.

DHHS also discusses several longitudinal studies that found a dose-response relationship between marijuana use and an increasing risk of psychosis among those who are vulnerable to developing psychosis (Fergusson *et al.*, 2005; van Os *et al.*, 2002).

DEA notes several longitudinal studies (Arseneault *et al.*, 2002, Caspi *et al.*, 2005; Henquet *et al.*, 2005) that found increased rates of psychosis or psychotic symptoms in people using cannabis. Finally, DEA notes some studies that observe that individuals with psychotic disorders have higher rates of cannabis use compared to the general population (Regier *et al.*, 1990; Green *et al.*, 2005).

DEA also notes that, more recently, Moore and colleagues (2007) performed a meta-analysis of the longitudinal studies on the link between cannabis use and subsequent psychotic symptoms. Authors observed that there was an increased risk of any psychotic outcome in individuals who had ever used cannabis (pooled adjusted odds ratio=1.41, 95 percent CI 1.20–1.65). Furthermore, findings were consistent with a dose-response effect, with greater risk in people who used cannabis most frequently (2.09, 1.54–2.84). The authors concluded that their results support the view that cannabis increases risk of psychotic outcomes independently of confounding and transient intoxication effects.

DEA also notes another more recent study examining the association between marijuana use and psychosis-related outcome in pairs of young adult siblings in Brisbane, Australia (McGrath *et al.*, 2010). This study found a dose-response relationship where the longer the duration of time since the first cannabis use, the higher the risk of psychosis-related outcome. Those patients with early-onset psychotic symptoms were also likely to report early marijuana use. Authors suggest that their results support the hypothesis that early cannabis use is a risk-modifying factor for psychosis-related outcomes in young adults.

Cognitive Effects

DHHS states that acute administration of smoked marijuana impairs performance on tests of learning, associative processes, and psychomotor behavior (Block *et al.*, 1992; Heishman *et al.*, 1990). Marijuana may therefore considerably interfere with an individual's ability to learn in a classroom or to operate motor vehicles. DHHS cites a study conducted by Kurzthalar and colleagues (1999) with human volunteers, in which the administration of 290 μg/kg of Δ^9-THC in a smoked cigarette resulted in impaired perceptual motor speed and accuracy, skills of paramount importance for safe driving. Similarly, administration of 3.95 percent Δ^9-THC in a smoked cigarette increased disequilibrium measures, as well as the latency in a task of simulated vehicle braking (Liguori *et al.*, 1998).

DHHS states that the effects of marijuana may not be fully resolved until at least one day after the acute psychoactive effects have subsided, following repeated administration. Heishman and colleagues (1988) showed that impairment on memory tasks persists for 24 hours after smoking marijuana cigarettes containing 2.57 percent Δ^9-THC. However, Fant and colleagues (1998) showed minimal residual alterations in subjective or performance measures the day after subjects were exposed to 1.8 percent or 3.6 percent smoked Δ^9-THC.

DHHS discussed a study by Lyons and colleagues (2004) on the neuropsychological consequences of regular marijuana use in fifty-four monozygotic male twin pairs, with one subject being a regular user and its co-twin a non-user, and neither twin having used any other illicit drug regularly. Marijuana-using twins significantly differed from their non-using co-twins on the general intelligence domain. However, only one significant difference was noted between marijuana-using twins and their non-using co-twins on measures of cognitive functioning. Authors of the study proposed that the results indicate an absence of any marked long-term residual effects of marijuana use on cognitive abilities. This conclusion is similar to the results found by Lyketsos and colleagues (1999), who investigated the possible adverse effects of cannabis use on cognitive decline after 12 years in persons under 65 years of age. There were no significant differences in cognitive decline between heavy users, light users, and nonusers of cannabis. The authors conclude that over long time periods, in persons under age 65 years, cognitive decline occurs in all age groups. This decline is closely associated with aging and educational level but does not appear to be associated with cannabis use.

DEA notes that while Lyketsos and colleagues (1999) propose that their results

provide strong evidence of the absence of a long term residual effect of cannabis use on cognition, they also acknowledge a number of limitations to their study. Notably, authors remark that it is possible that some cannabis users in the study may have used cannabis on the day the test was administered. Given the acute effects on cannabis on cognition, this would have tended to reduce their test score on that day. This may have adversely affected accurate measurement of test score changes over time in cannabis users. The authors also noted, as another important limitation, that the test used is not intended for the purpose for which it was used in this study and is not a very sensitive measure of cognitive decline, even though it specifically tests memory and attention. Thus, small or subtle effects of cannabis use on cognition or psychomotor speed may have been missed.

DHHS also discussed a study by Solowij and colleagues (2002) which examined the effects of duration of cannabis use on specific areas of cognitive functioning among users seeking treatment for cannabis dependence. They compared 102 near-daily cannabis users (51 long-term users: mean, 23.9 years of use; 51 shorter-term users: mean, 10.2 years of use) with 33 nonuser controls. They collected measures from nine standard neuropsychological tests that assessed attention, memory, and executive functioning, and that were administered prior to entry to a treatment program and following a median 17-hour abstinence. Authors found that long-term cannabis users performed significantly less well than shorter-term users and controls on tests of memory and attention. Long-term users showed impaired learning, retention, and retrieval compared with controls. Both user groups performed poorly on a time estimation task. Performance measures often correlated significantly with the duration of cannabis use, being worse with increasing years of use, but were unrelated to withdrawal symptoms and persisted after controlling for recent cannabis use and other drug use. Authors of this study state that their results support the hypothesis that long-term heavy cannabis users show impairments in memory and attention that endure beyond the period of intoxication and worsen with increasing years of regular cannabis use.

DHHS cited a study by Messinis and colleagues (2006) which examined neurophysiological functioning for heavy, frequent cannabis users. The study compared 20 long-term (LT) and 20 shorter-term (ST) heavy, frequent cannabis users after abstinence for at least 24 hours prior to testing with 24 non-using controls. LT users performed significantly worse on verbal memory and psychomotor speed. LT and ST users had a higher proportion of deficits on verbal fluency, verbal memory, attention and psychomotor speed. Authors conclude from their study that specific cognitive domains appear to deteriorate with increasing years of heavy frequent cannabis use.

DHHS discussed a study by Pope and colleagues (2003) which reported no differences in neuropsychological performance in early- or late-onset users compared to non-using controls, after adjustment for intelligence quotient (IQ). In another cohort of chronic, heavy marijuana users, some deficits were observed on memory tests up to a week following supervised abstinence but these effects disappeared by day 28 of abstinence (Pope *et al.*, 2002). The authors concluded that ''cannabis-associated cognitive deficits are reversible and related to recent cannabis exposure rather than irreversible and related to cumulative lifetime use.'' Conversely, DHHS notes that other investigators have reported persistent neuropsychological deficits in memory, executive functioning, psychomotor speed, and manual dexterity in heavy marijuana smokers who had been abstinent for 28 days (Bolla *et al.*, 2002). Furthermore, when dividing the group into light, middle, and heavy user groups, Bolla and colleagues (2002) found that the heavy user group performed significantly below the light user group on 5 of 35 measures. A follow-up study of heavy marijuana users noted decision-making deficits after 25 days of abstinence (Bolla *et al.*, 2005). When IQ was contrasted in adolescents 9–12 years of age and at 17–20 years of age, current heavy marijuana users showed a 4-point reduction in IQ in later adolescence compared to those who did not use marijuana (Fried *et al.*, 2002).

DHHS states that age of first use may be a critical factor in persistent impairment from chronic marijuana use. Individuals with a history of marijuana-only use that began before the age of 16 were found to perform more poorly on a visual scanning task measuring attention than individuals who started using marijuana after 16 (Ehrenreich *et al.*, 1999). DHHS's document noted that Kandel and Chen (2000) assert that the majority of early-onset marijuana users do not go on to become heavy users of marijuana, and those that do tend to associate with delinquent social groups.

DEA notes an additional recent study that indicates that because neuromaturation continues through adolescence, results on the long-lasting cognitive effects of marijuana use in adults cannot necessarily generalize to adolescent marijuana users. Medina and colleagues (2007) examined neuropsychological functioning in 31 adolescent abstinent marijuana users, after a period of abstinence from marijuana of 23 to 28 days, and in 34 demographically similar control adolescents, all 16–18 years of age. After controlling for lifetime alcohol use and depressive symptoms, adolescent marijuana users demonstrated slower psychomotor speed (p .05), and poorer complex attention (p .04), story memory (p .04), and planning and sequencing ability (p .001) compared with nonusers. The number of lifetime marijuana use episodes was associated with poorer cognitive function, even after controlling for lifetime alcohol use. The general pattern of results suggested that, even after a month of monitored abstinence, adolescent marijuana users demonstrate subtle neuropsychological deficits compared with nonusers. The authors of this study suggest that frequent marijuana use during adolescence may negatively influence neuromaturation and cognitive development.

In summary, acute administration of marijuana impairs performance on tests of learning, associative processes, and psychomotor behavior. The effects of chronic marijuana use have also been studied. While a few studies did not observe strong persistent neurocognitive consequences of long-term cannabis use (Lyketsos *et al.*, 1999; Lyons *et al.*, 2004), others provide support for the existence of persistent consequences (Bolla *et al.*, 2002, 2005). The cognitive impairments that are observed 12 hours to seven days after marijuana use (Messinis *et al.*, 2006; Solowij *et al.*, 2002; Harrison *et al.*, 2002), and that persist beyond behaviorally detectable intoxication, are noteworthy and may have significant consequences on workplace performance and safety, academic achievement, and automotive safety. In addition, adolescents may be particularly vulnerable to the long-lasting deleterious effects of marijuana on cognition. The overall significant effect on general intelligence as measured by IQ should also not be overlooked.

Behavioral Effects of Prenatal Exposure

The impact of *in utero* marijuana exposure on performance in a series of cognitive tasks has been studied in children of various ages. DHHS concludes in its analysis of the presently examined petition that since many marijuana users have abused other drugs, it is difficult to determine the specific impact of marijuana on prenatal exposure. Fried and Watkinson (1990) found that four year old children of heavy marijuana users have deficits in memory and verbal measures. Maternal marijuana use is predictive of poorer performance on abstract/visual reasoning tasks of three year old children (Griffith *et al.*, 1994) and an increase in omission errors on a vigilance task of six year olds (Fried *et al.*, 1992). When the effect of prenatal exposure in nine to 12 year old children is analyzed, in utero exposure to marijuana is negatively associated with executive function tasks that require impulse control, visual analysis, and hypothesis testing (Fried *et al.*, 1998).

DEA notes studies showing that Δ^9-THC passes the placental barrier (Idanpaan-Heikkila *et al.*, 1969) and that fetal blood concentrations are at least equal to those found in the mother's blood (Grotenhermen, 2003).

In summary, smoked marijuana exerts a number of cardiovascular and respiratory effects, both acutely and chronically. Marijuana's main psychoactive ingredient Δ^9-THC alters immune function. The cognitive impairments caused by marijuana use that persist beyond behaviorally detectable intoxication may have significant consequences on workplace performance and safety, academic achievement, and automotive safety, and adolescents may be particularly vulnerable to marijuana's cognitive effects. Prenatal exposure to marijuana was linked to children's poorer performance in a number of cognitive tests.

FACTOR 3: THE STATE OF THE CURRENT SCIENTIFIC KNOWLEDGE REGARDING THE DRUG OR SUBSTANCE

DHHS states that marijuana is a mixture of the dried leaves and flowering tops of the cannabis plant (Agurell *et al.*, 1984; Graham,

1976; Mechoulam, 1973). These portions of the plant have the highest levels of Δ^9-THC, the primary psychoactive ingredient in marijuana. The most potent product (i.e., that having the highest percentage of Δ^9-THC) of dried material is sinsemilla, derived from the unpollinated flowering tops of the female cannabis plant. Generally, this potent marijuana product is associated with indoor grow sites and may have a Δ^9-THC content of 15 to 20 percent or more. Other, less common forms of marijuana found on the illicit market are hashish and hashish oil. Hashish is a Δ^9-THC-rich resinous material of the cannabis plant which is dried and compressed into a variety of forms (balls, cakes or sticks). Dried pieces are generally broken off and smoked. Δ^9-THC content is usually about five percent. The Middle East, North Africa and Pakistan/Afghanistan are the main sources of hashish. Hashish oil is produced by extracting the cannabinoids from plant material with a solvent. Hashish oil is a light to dark brown viscous liquid with a Δ^9-THC content of about 15 percent. The oil is often sprinkled on cigarettes, allowed to dry, and then smoked.

Chemistry

DHHS states that some 483 natural constituents have been identified in marijuana, including 66 compounds that are classified as cannabinoids (Ross and El Sohly, 1995). Cannabinoids are not known to exist in plants other than marijuana, and most naturally occurring cannabinoids have been identified chemically. The psychoactive properties of cannabis are attributed to one or two of the major cannabinoid substances, namely delta-9- tetrahydrocannabinol (Δ^9-THC) and delta-8-tetrahydrocannabinol (Δ^8-THC). Other natural cannabinoids, such as cannabidiol (CBD) and cannabinol (CBN), have been characterized. CBD does not possess Δ^9-THC-like psychoactivity. Its pharmacological properties appear to include anticonvulsant, anxiolytic and sedative properties (Agurell *et al.*, 1984, 1986; Hollister, 1986).

DHHS states that Δ^9-THC is an optically active resinous substance, extremely lipid soluble, and insoluble in water. Chemically, Δ^9-THC is known as (6aR-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo-[b,d]pyran-1-ol or (-)Δ^9-(trans)-tetrahydrocannabinol. The pharmacological activity of Δ^9-THC is stereospecific: the (-)-trans isomer is 6–100 times more potent than the (+)-trans isomer (Dewey *et al.*, 1984).

DEA notes a review of the contaminants and adulterants that can be found in marijuana (McPartland, 2002). In particular, DEA notes that many studies have reported contamination of both illicit and NIDA-grown marijuana with microbial contaminants, bacterial or fungal (McLaren *et al.*, 2008; McPartland, 1994, 2002; Ungerleider *et al.*, 1982; Taylor *et al.*, 1982; Kurup *et al.*, 1983). Other microbial contaminants include Klebsiella pneumoniae, salmonella enteritidis, and group D Streptococcus (Ungerlerder *et al.*, 1982; Kagen *et al.*, 1983; Taylor *et al.*, 1982). DEA notes that a review by McLaren and colleagues (2008) discusses studies showing that heavy metals present in soil may also contaminate cannabis, and states that these contaminants have the potential to harm the user without harming the plant. Other sources of contaminants discussed by McLaren and colleagues (2008) include growth enhancers and pest control products related to marijuana cultivation and storage.

Human Pharmacokinetics

DHHS states that marijuana is generally smoked as a cigarette (weighing between 0.5 and 1.0 gm; Jones, 1980) or in a pipe. It can also be taken orally in foods or as extracts of plant material in ethanol or other solvents. The absorption, metabolism, and pharmacokinetic profile of Δ^9-THC (and other cannabinoids) in marijuana or other drug products containing Δ^9-THC vary with route of administration and formulation (Adams and Martin, 1996; Agurell *et al.*, 1984, 1986). When marijuana is administered by smoking, Δ^9-THC in the form of an aerosol is absorbed within seconds. The psychoactive effects of marijuana occur immediately following absorption, with mental and behavioral effects measurable up for to six hours after absorption (Grotenhermen, 2003; Hollister, 1986, 1988). Δ^9-THC is delivered to the brain rapidly and efficiently as would be expected of a highly lipid-soluble drug.

The petitioner provided a discussion of new, or less common, routes and methods of administration being currently explored (pg. 57, line 1). These include vaporization for the inhalation route, as well as rectal, sublingual, and transdermal routes.

DEA notes that respiratory effects are only part of the harmful health effects of prolonged marijuana exposure, as described further under factor 2 of this document. DEA also notes that at this time, the majority of studies exploring the potential therapeutic uses of marijuana use smoked marijuana, and the pharmacokinetics and bioavailability from routes of administration other than smoked and oral are not well-known.

The pharmacokinetics of smoked and orally ingested marijuana are thoroughly reviewed in DHHS's review document.

Medical Utility

The petition filed by the Coalition to Reschedule Cannabis (Marijuana) aims to repeal the rule placing marijuana in schedule I of the CSA, based in part on the proposition that marijuana has an accepted medical use in the United States. However DHHS has concluded in its 2006 analysis that marijuana has no accepted medical use in treatment in the United States. Following is a discussion of the petitioner's specific points and a presentation of DHHS's evaluation and recommendation on the question of accepted medical use for marijuana.

The petitioner states (pg. 48, line 2), ''Results from clinical research demonstrated that both dronabinol and whole plant cannabis can offer a safe and effective treatment for the following illnesses: muscle spasm in multiple sclerosis, Tourette syndrome, chronic pain, nausea and vomiting in HIV/AIDS and cancer chemotherapy, loss of appetite from cancer, hyperactivity of the bladder in patients with multiple sclerosis and spinal cord injury, and dyskinesia caused by levodopa in Parkinson's disease.''

To support its claim that marijuana has an accepted medical use in the United States, the petitioner listed supporting evidence that included the following:

- Evidence from clinical research and reviews of earlier clinical research (Exh. C, Section I (4, 6), pg. 29)
- Acceptance of the medical use of marijuana by eight states since 1996 and state officials in these states establishing that marijuana has an accepted medical use in the United States (Exh. C, Section I (1), pg. 13)
- Increased recognition by health care professionals and the medical community, including the Institute of Medicine (IOM) (Exh. C, Section I (2), pg. 15)
- Patients' experience in which they reported benefits from smoking marijuana (Exh. C, Section I (3), pg. 22)
- *Evidence from clinical research (Exh. C, Section I (4, 6), pg. 29)*

DHHS states that a new drug application (NDA) for marijuana has not been submitted to the FDA for any indication and thus no medicinal product containing botanical cannabis has been approved for marketing. Only small clinical studies published in the current medical literature demonstrate that research with marijuana is being conducted in humans in the United States under FDA-authorized investigational new drug (IND) applications.

There are ongoing clinical studies of the potential utility of marijuana in medical applications. DHHS states that in 2000, the state of California established the Center for Medicinal Cannabis Research (CMCR) which has funded studies on the potential use of cannabinoids for the treatment of multiple sclerosis, neuropathic pain, appetite suppression and cachexia, and severe pain and nausea related to cancer or its treatment by chemotherapy. To date, though, no NDAs utilizing marijuana for these indications have been submitted to the FDA.

To establish accepted medical use, among other criteria, the effectiveness of a drug must be established in well-controlled scientific studies performed in a large number of patients. To date, such studies have not been performed for marijuana. Small clinical trial studies with limited patients and short duration such as those cited by the petitioner are not sufficient to establish medical utility. Larger studies of longer duration are needed to fully characterize the drug's efficacy and safety profile. Anecdotal reports, patients' self-reported effects, and isolated case reports are not adequate evidence to support an accepted medical use of marijuana (57 FR 10499, 1992).

In addition to demonstrating efficacy, adequate safety studies must be performed to show that the drug is safe for treating the targeted disease. DHHS states that safety studies for acute or subchronic administration of marijuana have been carried out through a limited number of Phase 1 clinical investigations approved by the FDA, but there have been no NDA-quality studies that have scientifically assessed the efficacy and full safety profile of marijuana for any medical condition.

DEA further notes that a number of clinical studies from CMCR have been discontinued. Most of these discontinuations were due to

recruitment difficulties (*http://www.cmcr.ucsd.edu/geninfo/research.htm* (last retrieved 07/07/2010) (listing 6 discontinued studies, 5 of which were discontinued because of recruitment issues)).

The petitioner states that the pharmacological effects are well established for marijuana and Δ^9-THC, using the argument that Marinol (containing synthetic Δ^9-THC, known generically as dronabinol) and Cesamet (containing nabilone, a synthetic cannabinoid not found in marijuana) are approved for several therapeutic indications. The approvals of Marinol and Cesamet were based on well-controlled clinical studies that established the efficacy and safety of these drugs as a medicine. Smoked marijuana has not been demonstrated to be safe and effective in treating these medical conditions. Marijuana is a drug substance composed of numerous cannabinoids and other constituents; hence the safety and efficacy of marijuana cannot be evaluated solely on the effects of Δ^9-THC. Adequate and well-controlled studies must be performed with smoked marijuana to establish efficacy and safety. DHHS states that there is a lack of accepted safety for the use of marijuana under medical supervision.

The petitioner has not submitted any new data meeting the requisite scientific standards to support the claim that marijuana has an accepted medical use in the United States. Hence, the new information provided by the petitioner does not change the federal government's evaluation of marijuana's medical use in the United States.

- Petitioner's claim of acceptance of the medical use of marijuana by eight states since 1996 and state officials in these states establishing that marijuana has an accepted medical use in the United States

Petitioner argues that, ''[t]he acceptance of cannabis's medical use by eight states since 1996 and the experiences of patients, doctors, and state officials in these states establish marijuana's accepted medical use in the United States.'' Petition at 10, 13. This argument is contrary to the CSA's statutory scheme. The CSA does not assign to the states the authority to make findings relevant to CSA scheduling determinations. Rather, the CSA expressly delegates the task of making such findings—including whether a substance has any currently accepted medical use in treatment in the United States—to the Attorney General. 21 U.S.C. 811(a). The CSA also expressly tasks the Secretary of DHHS to provide a scientific and medical evaluation and scheduling recommendations to inform the Attorney General's findings. 21 U.S.C. 811(b); *see also* 21 C.F.R. 308.43. That Congress explicitly provided scheduling authority to these two federal entities in this comprehensive and exclusive statutory scheme precludes the argument that state legislative action can establish accepted medical use under the CSA.

The CSA explicitly provides that in making a scheduling determination, the Attorney General shall consider the following eight factors:

1. The drug's actual or relative potential for abuse
2. Scientific evidence of its pharmacological effect, if known;
3. The state of current scientific knowledge regarding the drug;
4. Its history and current pattern of abuse;
5. The scope, duration, and significance of abuse;
6. What, if any, risk there is to the public health;
7. The drug's psychic or physiological dependence liability; and
8. Whether the substance is an immediate precursor of a substance already controlled under the CSA.

21 U.S.C. 811(c). These factors embody Congress's view of the specialized agency expertise required for drug rescheduling decisions. The CSA's statutory text thus further evidences that Congress did not envision such a role for state law in establishing the schedules of controlled substances under the CSA. *See Krumm v. Holder,* 2009 WL 1563381, at *16 (D.N.M. 2009) (''The CSA does not contemplate that state legislatures' determinations about the use of a controlled substance can be used to bypass the CSA's rescheduling process.'').

The long-established factors applied by DEA for determining whether a drug has a ''currently accepted medical use'' under the CSA are:

1. The drug's chemistry must be known and reproducible;
2. There must be adequate safety studies;
3. There must be adequate and well-controlled studies proving efficacy;
4. The drug must be accepted by qualified experts; and
5. The scientific evidence must be widely available.

57 FR 10,499, 10,506 (1992), *ACT,* 15 F.3d at 1135 (upholding these factors as valid criteria for determining ''currently accepted medical use''). A drug will be deemed to have a currently accepted medical use for CSA purposes only if all five of the foregoing elements are demonstrated. The following is a summary of information as it relates to each of these five elements.

1. The drug's chemistry must be known and reproducible

DHHS states that although the structures of many cannabinoids found in marijuana have been characterized, a complete scientific analysis of all the chemical components found in marijuana has not been conducted.

DEA notes that in addition to changes due to its own genetic plasticity, marijuana and its chemistry have been throughout the ages, and continue to be, modified by environmental factors and human manipulation (Paris and Nahas, 1984).

2. There must be adequate safety studies

DHHS states that safety studies for acute or subchronic administration of marijuana have been carried out only through a limited number of Phase 1 clinical investigations approved by the FDA. There have been no NDA-quality studies that have scientifically assessed the safety profile of marijuana for any medical condition. DHHS also states that at this time, the known risks of marijuana use have not been shown to be outweighed by specific benefits in well-controlled clinical trials that scientifically evaluate safety and efficacy.

DHHS further states that it cannot conclude that marijuana has an acceptable level of safety without assurance of a consistent and predictable potency and without proof that the substance is free of contamination.

As discussed in Factors 1 and 2, current data suggest that marijuana use produces adverse effects on the respiratory system, memory and learning. Marijuana use is associated with dependence and addiction. In addition, large epidemiological studies indicate that marijuana use may exacerbate symptoms in individuals with schizophrenia.

Therefore DHHS concludes that, even under medical supervision, marijuana has not been shown to have an accepted level of safety. Furthermore, if marijuana is to be investigated more widely for medical use, information and data regarding the chemistry, manufacturing, and specifications of marijuana must be developed.

3. There must be adequate and well-controlled studies proving efficacy

DHHS states that no studies have been conducted with marijuana showing efficacy for any indication in controlled, large scale, clinical trials.

To establish accepted medical use, the effectiveness of a drug must be established in well-controlled, well-designed, well-conducted, and well-documented scientific studies, including studies performed in a large number of patients (57 FR 10499, 1992). To date, such studies have not been performed. The small clinical trial studies with limited patients and short duration are not sufficient to establish medical utility. Studies of longer duration are needed to fully characterize the drug's efficacy and safety profile. Scientific reliability must be established in multiple clinical studies. Furthermore, anecdotal reports and isolated case reports are not adequate evidence to support an accepted medical use of marijuana (57 FR 10499, 1992). The evidence from clinical research and reviews of earlier clinical research does not meet this standard.

As noted, DHHS states that a limited number of Phase I investigations have been conducted as approved by the FDA. Clinical trials, however, generally proceed in three phases. *See* 21 C.F.R. 312.21 (2010). Phase I trials encompass initial testing in human subjects, generally involving 20 to 80 patients. *Id.* They are designed primarily to assess initial safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary studies of potential therapeutic benefit. (62 FR 66113, 1997). Phase II and Phase III studies involve successively larger groups of patients: usually no more than several hundred subjects in Phase II and usually from several hundred to several thousand in Phase III. 21 C.F.R. 312.21. These studies are designed primarily to explore (Phase II) and to demonstrate or confirm (Phase III) therapeutic efficacy and benefit in patients. (62 FR 66113, 1997). No Phase II or Phase III studies of marijuana have been conducted. Even in 2001, DHHS acknowledged that there is ''suggestive evidence that marijuana may have beneficial

therapeutic effects in relieving spasticity associated with multiple sclerosis, as an analgesic, as an antiemetic, as an appetite stimulant and as a bronchodilator.'' (66 FR 20038, 2001). But there is still no data from adequate and well-controlled clinical trials that meets the requisite standard to warrant rescheduling.

DHHS states in a published guidance that it is committed to providing ''research-grade marijuana for studies that are the most likely to yield usable, essential data'' (DHHS, 1999). DHHS states that the opportunity for scientists to conduct clinical research with botanical marijuana has increased due to changes in the process for obtaining botanical marijuana from NIDA, the only legitimate source of the drug for research in the United States. It further states that in May 1999, DHHS provided guidance on the procedures for providing research-grade marijuana to scientists who intend to study marijuana in scientifically valid investigations and well-controlled clinical trials (DHHS, 1999).

4. The drug must be accepted by qualified experts

A material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts (57 FR 10499, 1992). DHHS states that, at this time, it is clear that there is not a consensus of medical opinion concerning medical applications of marijuana, even under conditions where its use is severely restricted. DHHS also concludes that, to date, research on the medical use of marijuana has not progressed to the point that marijuana can be considered to have a ''currently accepted medical use'' or a ''currently accepted medical use with severe restrictions.''

5. The scientific evidence must be widely available

DHHS states that the scientific evidence regarding the safety or efficacy of marijuana is typically available only in summarized form, such as in a paper published in the medical literature, rather than in a raw data format. As such, there is no opportunity for adequate scientific scrutiny of whether the data demonstrate safety or efficacy. Furthermore, as stated before, there have only been a limited number of small clinical trials and no controlled, large-scale clinical trials have been conducted with marijuana on its efficacy for any indications or its safety.

In summary, from DHHS's statements on the five cited elements required to make a determination of ''currently accepted medical use'' for marijuana, DEA has determined that none has been fulfilled. A complete scientific analysis of all the chemical components found in marijuana is still missing. There has been no NDA-quality study that has assessed the efficacy and full safety profile of marijuana for any medical use. At this time, it is clear that there is not a consensus of medical opinion concerning medical applications of marijuana. To date, research on the medical use of marijuana has not progressed to the point that marijuana can be considered to have a ''currently accepted medical use'' or even a ''currently accepted medical use with severe restrictions.'' 21 U.S.C. 812(b)(2)(B)). Additionally, scientific evidence as to the safety or efficacy of marijuana is not widely available.

• *Petitioner's claim of increased recognition by health care professionals and the medical community, including the Institute of Medicine (IOM)*

The petitioner states (pg. 15 line 2), ''Cannabis's accepted medical use in the United States is increasingly recognized by healthcare professionals and the medical community, including the Institute of Medicine.''

DHHS describes that in February 1997, a National Institutes of Health (NIH)-sponsored workshop analyzed available scientific evidence on the potential utility of marijuana. In March 1999, the Institute of Medicine (IOM) issued a detailed report on the potential medical utility of marijuana. Both reports concluded that there need to be more and better studies to determine potential medical applications of marijuana. The IOM report also recommended that clinical trials should be conducted with the goal of developing safe delivery systems (NIH, 1997; IOM, 1999).

DEA notes that in its recommendations, the 1999 IOM report states,

If there is any future for marijuana as a medicine, it lies in its isolated components, the cannabinoids and their synthetic derivatives. Isolated cannabinoids will provide more reliable effects than crude plant mixtures. Therefore, the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug but rather to serve as a first step toward the development of nonsmoked rapid-onset cannabinoid delivery systems.

Thus, while the IOM report did support further research into therapeutic uses of cannabinoids, the IOM report did not *''recognize marijuana's accepted medical use''* but rather the potential therapeutic utility of cannabinoids.

DEA notes that the lists presented by the petitioner (pg. 16–18) of ''Organizations Supporting *Access* to Therapeutic Cannabis'' (emphasis added) and ''[Organizations Supporting] No Criminal Penalty'' contain a majority of organizations that do not specifically represent medical professionals. By contrast, the petitioner also provides a list of ''Organizations Supporting Research on the Therapeutic Use of Cannabis'' (emphasis added), which does contain a majority of organizations specifically representing medical professionals.

The petitioner discusses (pg. 20, line 11) the results of a United States survey presented at the annual meeting of the American Society of Addiction Medicine, and states that the study's results,

indicate that physicians are divided on the medical use of cannabis (Reuters of 23 April 2001). Researchers at Rhode Island Hospital in Providence asked 960 doctors about their attitude towards the statement, ''Doctors should be able to legally prescribe marijuana as medical therapy.'' 36 percent of the responders agreed, 38 percent disagreed and 26 percent were neutral.

DEA notes that the results of the study, later published in full (Charuvastra et al., 2005) show that a slight majority of medical doctors polled were opposed to the legalization of medical prescription of marijuana. This supports the finding that there is a material conflict of opinion among medical professionals.

• *Patients' experience in which they reported benefits from smoking marijuana (Exh. C, Section I(3), pg. 22);*

Under the petition's section C. I. 3., the petitioner proposes both anecdotal self-reported effects by patients and clinical studies. The petitioner states (pg. 22, line 2),

[. . .] an increasing number of patients have collected experience with cannabis. Many reported benefits from its use. Some of this experience has been confirmed in reports and clinical investigations or stimulated clinical research that confirmed these patients' experience on other patients suffering from the same disease.

Anecdotal self-reported effects by patients are not adequate evidence for the determination of a drug's accepted medical use. DEA previously ruled in its final order denying the petition of the National Organization for Reform of Marijuana Laws (NORML) to reschedule marijuana from Schedule I to Schedule II of the Controlled Substances Act (57 FR 10499, 1992) that,

Lay testimonials, impressions of physicians, isolated case studies, random clinical experience, reports so lacking in details they cannot be scientifically evaluated, and all other forms of anecdotal proof are entirely irrelevant.

DEA further explained in the same ruling that,

Scientists call [stories by marijuana users who claim to have been helped by the drug] anecdotes. They do not accept them as reliable proofs. The FDA's regulations, for example, provide that in deciding whether a new drug is a safe and effective medicine, ''isolated case reports will not be considered.'' 21 CFR 314.126(e). Why do scientists consider stories from patients and their doctors to be unreliable?

First, sick people are not objective scientific observers, especially when it comes to their own health. [. . .] Second, most of the stories come from people who took marijuana at the same time they took prescription drugs for their symptoms. [. . .] Third, any mind-altering drug that produces euphoria can make a sick person think he feels better. [. . .] Fourth, long-time abusers of marijuana are not immune to illness.

[. . .] Thanks to scientific advances and to the passage of the Federal Food, Drug and Cosmetic Act (FDCA) in 1906, 21 U.S.C. 301 et seq., we now rely on rigorous scientific proof to assure the safety and effectiveness of new drugs. Mere stories are not considered an acceptable way to judge whether dangerous drugs should be used as medicines.

Thus, patients' anecdotal experiences with marijuana are not adequate evidence when evaluating whether marijuana has a currently accepted medical use.

In summary, marijuana contains some 483 natural constituents and exists in several forms, including dried leaves and flowering

tops, hashish and hashish oil. It is generally smoked as a cigarette. Research with marijuana is being conducted in humans in the United States under FDA-authorized IND applications, and using marijuana cigarettes provided by NIDA. Adequate studies have not been published to support the safety and efficacy of marijuana as a medicine. No NDA for marijuana has been submitted to the FDA for any indication and thus no medicinal product containing botanical cannabis has been approved for marketing. DEA notes that state laws do not establish a currently accepted medical use under federal law. Furthermore, DEA previously ruled that anecdotal self-reported effects by patients are not adequate evidence of a currently accepted medical use under federal law. A material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts. At present, there is no consensus of medical opinion concerning medical applications of marijuana. In short, the limited number of clinical trials involving marijuana that have been conducted to date—none of which have progressed beyond phase 1 of the three phases needed to demonstrate safety and efficacy for purposes of FDA approval—fails by a large measure to provide a basis for any alteration of the prior conclusions made by HHS and DEA (in 1992 and in 2001) that marijuana has no currently accepted medical use in treatment in the United States.

FACTOR 4: ITS HISTORY AND CURRENT PATTERN OF ABUSE

Marijuana use has been relatively stable from 2002 to 2009, and it continues to be the most widely used illicit drug. According to the NSDUH, there were 2.4 million new users (6,000 initiates per day) in 2009 and 16.7 million current (past month) users of marijuana aged 12 and older. Past month use of marijuana was statistically significantly higher in 2009 (16.7 million) than in 2008 (15.2 million), according to NSDUH. An estimated 104.4 million Americans age 12 or older had used marijuana or hashish in their lifetime and 28.5 million had used it in the past year. In 2008, most (62.2 percent) of the 2.2 million new users were less than 18 years of age. In 2008, marijuana was used by 75.7 percent of current illicit drug users and was the only drug used by 57.3 percent of these users. In 2008, among past year marijuana users aged 12 or older, 15.0 percent used marijuana on 300 or more days within the previous 12 months. This translates into 3.9 million people using marijuana on a daily or almost daily basis over a 12-month period. In 2008, among past month marijuana users, 35.7 percent (5.4 million) used the drug on 20 or more days in the past month.

Marijuana is also the illicit drug with the highest rate of past year dependence or abuse. According to the 2009 NSDUH report, 4.3 million persons were classified with marijuana dependence or abuse based on criteria specified in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM–IV).

According to the 2010 Monitoring the Future (MTF) survey, marijuana is used by a large percentage of American youths. Among students surveyed in 2010, 17.3 percent of eighth graders, 33.4 percent of tenth graders, and 43.8 percent of twelfth graders reported lifetime use (i.e., any use in their lifetime) of marijuana. In addition, 13.7, 27.5 and 34.8 percent of eighth, tenth and twelfth graders, respectively, reported using marijuana in the past year. A number of high-schoolers reported daily use in the past month, including 1.2, 3.3 and 6.1 percent of eighth, tenth and twelfth graders, respectively.

The prevalence of marijuana use and abuse is also indicated by criminal investigations for which drug evidences were analyzed in DEA and state laboratories. The National Forensic Laboratory System (NFLIS), which compiles information on exhibits analyzed in state and local law enforcement laboratories, showed that marijuana was the most frequently identified drug from January 2001 through December 2010: In 2010, marijuana accounted for 36.3 percent (464,059) of all drug exhibits in NFLIS. Similar findings were reported by the System to Retrieve Information from Drug Evidence (STRIDE), a DEA database which compiles information on exhibits analyzed in DEA laboratories, for the same reporting period. From January 2001 through December 2010, marijuana was the most frequently identified drug. In 2010, there were 11,293 marijuana exhibits associated with 7,158 law enforcement cases representing 16.7 percent of all exhibits in STRIDE.

The high consumption of marijuana is being fueled by increasing amounts of domestically grown marijuana as well as increased amounts of foreign source marijuana being illicitly smuggled into the United States. In 2009, the Domestic Cannabis Eradication and Suppression Program (DCE/SP) reported that 9,980,038 plants were eradicated in outdoor cannabis cultivation areas in the United States. Major domestic outdoor cannabis cultivation areas were found in California, Kentucky, Tennessee and Hawaii. Significant quantities of marijuana were also eradicated from indoor cultivation operations. There were 414,604 indoor plants eradicated in 2009 compared to 217,105 eradicated in 2000. Most foreign-source marijuana smuggled into the United States enters through or between points of entry at the United States-Mexico border. However, drug seizure data show that the amount of marijuana smuggled into the United States from Canada via the United States-Canada border has risen to a significant level. In 2009, the Federal-wide Drug Seizure System (FDSS) reported seizures of 1,910,600 kg of marijuana.

While most of the marijuana available in the domestic drug markets is lower potency commercial-grade marijuana, usually derived from outdoor cannabis grow sites in Mexico and the United States, an increasing percentage of the available marijuana is high potency marijuana derived from indoor, closely controlled cannabis cultivation in Canada and the United States. The rising prevalence of high potency marijuana is evidenced by a nearly two-fold increase in average potency of tested marijuana samples, from 4.87 percent Δ^9-THC in 2000 to 8.49 percent Δ^9-THC in 2008.

In summary, marijuana is the most commonly used illegal drug in the United States, and it is used by a large percentage of American high-schoolers. Marijuana is the most frequently identified drug in state, local and federal forensic laboratories, with increasing amounts both of domestically grown and of illicitly smuggled marijuana. An observed increase in the potency of seized marijuana also raises concerns.

FACTOR 5: THE SCOPE, DURATION, AND SIGNIFICANCE OF ABUSE

Abuse of marijuana is widespread and significant. DHHS presented data from the NSDUH, and DEA has updated this information. As previously noted, according to the NSDUH, in 2009, an estimated 104.4 million Americans age 12 or older had used marijuana or hashish in their lifetime, 28.5 million had used it in the past year, and 16.7 million (6.6 percent) had used it in the past month. In 2008, an estimated 15.0 percent of past year marijuana users aged 12 or older used marijuana on 300 or more days within the past 12 months. This translates into 3.9 million persons using marijuana on a daily or almost daily basis over a 12-month period. In 2008, an estimated 35.7 percent (5.4 million) of past month marijuana users aged 12 or older used the drug on 20 or more days in the past month (SAMHSA, NSDUH and TEDS). Chronic use of marijuana is associated with a number of health risks (see Factors 2 and 6).

Marijuana's widespread availability is being fueled by increasing marijuana production domestically and increased illicit importation from Mexico and Canada. Domestically both indoor and outdoor grow sites have been encountered. In 2009, nearly 10 million marijuana plants were seized from outdoor grow sites and over 410,000 were seized from indoor sites for a total of over 10 million plants in 2009 compared to about 2.8 million plants in 2000 (Domestic Cannabis Eradication/Suppression Program). An increasing percentage of the available marijuana being trafficked in the United States is higher potency marijuana derived from the indoor, closely controlled cultivation of marijuana plants in both the US and Canada (Domestic Cannabis Eradication/Suppression Program) and the average percentage of Δ^9-THC in seized marijuana increased almost two-fold from 2000 to 2008 (The University of Mississippi Potency Monitoring Project). Additional studies are needed to clarify the impact of greater potency, but DEA notes one study showing that higher levels of Δ^9-THC in the body are associated with greater psychoactive effects (Harder and Rietbrock, 1997), which can be correlated with higher abuse potential (Chait and Burke, 1994).

Data from TEDS show that in 2008, 17.2 percent of all admissions were for primary marijuana abuse. In 2007, more than half of the drug-related treatment admissions involving individuals under the age of 15 (60.8 percent) and more than half of the drug-related treatment admissions involving individuals 15 to 19 years of age (55.9 percent), were for primary marijuana abuse. In 2007, among the marijuana/hashish admissions (286,194), 25.1 percent began using marijuana at age 12 or younger.

In summary, the recent statistics from these various surveys and databases show that

marijuana continues to be the most commonly used illicit drug, with significant rates of heavy use and dependence in teenagers and adults.

The petitioner states, ''The use and abuse of cannabis has been widespread in the United States since national drug use surveys began in the 1970s. A considerable number of cannabis users suffer from problems that meet the criteria for abuse. However, the large majority of cannabis users do not experience any relevant problems related to their use.'' (pg. 4, line 31).

Petitioner acknowledges that a considerable number of cannabis users suffer from problems that meet the criteria for abuse. DEA provides data under this Factor, as well as Factors 1, 2, and 7, that support this undisputed issue. Briefly, current data suggest that marijuana use produces adverse effects on the respiratory system, memory and learning. Marijuana use is associated with dependence and addiction. In addition, large epidemiological studies indicate that marijuana use may exacerbate symptoms in individuals with schizophrenia, and may precipitate schizophrenic disorders in those individuals who are vulnerable to developing psychosis.

FACTOR 6: WHAT, IF ANY, RISK THERE IS TO THE PUBLIC HEALTH

The risk marijuana poses to the public health may manifest itself in many ways. Marijuana use may affect the physical and/or psychological functioning of an individual user, but may also have broader public impacts, for example, from a marijuana-impaired driver. The impacts of marijuana abuse and dependence are more disruptive for an abuser, but also for the abuser's family, friends, work environment, and society in general. Data regarding marijuana health risks are available from many sources, including forensic laboratory analyses, crime laboratories, medical examiners, poison control centers, substance abuse treatment centers, and the scientific and medical literature. Risks have been associated with both acute and chronic marijuana use, including risks for the cardiovascular and respiratory systems, as well as risks for mental health and cognitive function and risks related to prenatal exposure to marijuana. The risks of marijuana use and abuse have previously been discussed in terms of the scientific evidence of its pharmacological effects on physical systems under Factor 2. Below, some of the risks of marijuana use and abuse are discussed in broader terms of the effects on the individual user and the public from acute and chronic use of the drug.

Risks Associated with Acute Use of Marijuana

DHHS states that acute use of marijuana impairs psychomotor performance, including performance of complex tasks, which makes it inadvisable to operate motor vehicles or heavy equipment after using marijuana (Ramaekers *et al.*, 2004). DHHS further describes a study showing that acute administration of smoked marijuana impairs performance on tests of learning, associative processes, and psychomotor behavior (Block *et al.*, 1992). DHHS also describes studies showing that administration to human volunteers of Δ^9-THC in a smoked marijuana cigarette produced impaired perceptual motor speed and accuracy, two skills that are critical to driving ability (Kurzthaler *et al.*, 1999) and produced increases in disequilibrium measures, as well as in the latency in a task of simulated vehicle braking, at a rate comparable to an increase in stopping distance of 5 feet at 60 mph (Liguori *et al.*, 1998).

The petitioner states that (pg., 65, line 10), ''Although the ability to perform complex cognitive operations is assumed to be impaired following acute marijuana smoking, complex cognitive performance after acute marijuana use has not been adequately assessed under experimental conditions.'' As described above, DHHS presents evidence of marijuana's acute effects on complex cognitive tasks.

DHHS states that dysphoria and psychological distress, including prolonged anxiety reactions, are potential responses in a minority of individuals who use marijuana (Haney *et al.*, 1999). DEA notes reviews of studies describing that some users report unpleasant psychological reactions. Acute anxiety reactions to cannabis may include restlessness, depersonalization, derealization, sense of loss of control, fear of dying, panic and paranoid ideas (see reviews by Thomas, 1993 and Weil, 1970).

DEA notes a review of studies showing that the general depressant effect of moderate to high doses of cannabis might contribute to slowed reaction times, inability to maintain concentration and lapses in attention (see review by Chait and Pierri, 1992). The review suggests that fine motor control and manual dexterity are generally adversely affected although simple reaction time may or may not be. DEA also notes studies showing that choice or complex reaction time is more likely to be affected, with reaction time consistently increasing with the difficulty of the task (e.g., Block and Wittenborn, 1985).

DEA also notes additional studies showing marijuana use interferes with the ability to operate motor vehicles. Studies show that marijuana use can cause impairment in driving (Robbe and O'Hanlon, 1999). The National Highway Traffic Safety Administration (NHTSA) conducted a study with the Institute for Human Psychopharmacology at Maastricht University in the Netherlands (Robbe and O'Hanlon, 1999) to evaluate the effects of low and high doses of smoked Δ^9-THC alone and in combination with alcohol on the following tests: 1) the Road Tracking Test, which measures the driver's ability to maintain a constant speed of 62 mph and a steady lateral position between the boundaries of the right traffic lane; and 2) the Car Following Test, which measures a driver's reaction times and ability to maintain distance between vehicles while driving 164 ft behind a vehicle that executes a series of alternating accelerations and decelerations. Mild to moderate impairment of driving was observed in the subjects after treatment with marijuana. The study found that marijuana in combination with alcohol had an additive effect resulting in severe driving impairment.

DEA also notes a study by Bedard and colleagues (2007), which used a cross-sectional, case-control design with drivers aged 20–49 who were involved in a fatal crash in the United States from 1993 to 2003. Drivers were included if they had been tested for the presence of cannabis and had a confirmed blood alcohol concentration of zero. Cases were drivers who had at least one potentially unsafe driving action recorded in relation to the crash (e.g., speeding); controls were drivers who had no such driving action recorded. Authors calculated the crude and adjusted odds ratios (ORs) of any potentially unsafe driving action in drivers who tested positive for cannabis but negative for alcohol consumption. Five percent of drivers tested positive for cannabis. The crude OR of a potentially unsafe action was 1.39 (99 percent CI = 1.21–1.59) for drivers who tested positive for cannabis. Even after controlling for age, sex, and prior driving record, the presence of cannabis remained associated with a higher risk of a potentially unsafe driving action (1.29, 99 percent CI = 1.11–1.50). Authors of the study concluded that cannabis had a negative effect on driving, as predicted from various human performance studies.

In 2001, estimates derived from the United States Census Bureau and Monitoring the Future show that approximately 600,000 of the nearly 4 million United States high-school seniors drive under the influence of marijuana. Approximately 38,000 seniors reported that they had crashed while driving under the influence of marijuana in 2001 (MTF, 2001).

DEA further notes studies suggesting that marijuana can affect the performance of pilots. Yeswavage and colleagues (1985) evaluated the acute and delayed effects of smoking one marijuana cigarette containing 1.9 percent Δ^9-THC (19 mg of Δ^9-THC) on the performance of aircraft pilots. Ten subjects were trained in a flight simulator prior to marijuana exposure. Flight simulator performance was measured by the number of aileron (lateral control) and elevator (vertical control) and throttle changes, the size of these control changes, the distance off the center of the runaway on landing, and the average lateral and vertical deviation from an ideal glideslope and center line over the final mile of the approach. Compared to the baseline performance, significant differences occurred at 4 hours. Most importantly, at 24 hours after a single marijuana cigarette, there were significant impairments in the number and size of aileron changes, size of elevator changes, distance off-center on landing, and vertical and lateral deviations on approach to landing. Interestingly, despite these performance deficits, the pilots reported no significant subjective awareness of their impairments at 24 hours.

DEA notes a review of the contaminants and adulterants that can be found in marijuana (McPartland, 2002). In particular, DEA notes that many studies have reported contamination of both illicit and NIDA-grown marijuana with microbial contaminants, bacterial or fungal (McLaren *et al.*, 2008; McPartland, 1994, 2002; Ungerleider *et al.*, 1982; Taylor *et al.*, 1982; Kurup *et al.*, 1983). In a study by Kagen and

colleagues (1983), fungi was found in 13 of the 14 samples, and evidence of exposure to Aspergillus fungi was found in the majority of marijuana smokers (13 of 23), but only one of the 10 control participants. Aspergillus can cause aspergillosis, a fatal lung disease and DEA notes studies suggesting an association between this disease and cannabis smoking among patients with compromised immune systems (reviewed in McLaren *et al.*, 2008). Other microbial contaminants include bacteria such as *Klebsiella pneumoniae*, *salmonella enteritidis,* and group *D Streptococcus* (Ungerlerder *et al.*, 1982; Kagen *et al.*, 1983; Taylor *et al.*, 1982). DEA notes reports that *Salmonella* outbreaks have been linked to marijuana (Taylor *et al.*, 1982, CDC, 1981).

Risks Associated with Chronic Use of Marijuana

DHHS states that chronic exposure to marijuana smoke is considered to be comparable to tobacco smoke with respect to increased risk of cancer and lung damage. DEA notes studies showing that marijuana smoke contains several of the same carcinogens and co-carcinogens as tobacco smoke and suggesting that pre-cancerous lesions in bronchial epithelium also seem to be caused by long-term marijuana smoking (Roth *et al.*, 1998). DEA also notes the publication of a recent case-control study of lung cancer in adults (Aldington *et al.*, 2008), in which users reporting over 10.5 joint-years of exposure had a significantly increased risk of developing lung cancer, leading the study's authors to conclude that long-term cannabis use increases the risk of lung cancer in young adults. In addition, a distinctive marijuana withdrawal syndrome has been identified, indicating that marijuana produces physical dependence (Budney *et al.*, 2004), as described in Factor 7.

DHHS further quotes the Diagnostic and Statistical Manual (DSM–IV–TR, 2000) of the American Psychiatric Association, which states that the consequences of cannabis abuse are as follows:

[P]eriodic cannabis use and intoxication can interfere with performance at work or school and may be physically hazardous in situations such as driving a car. Legal problems may occur as a consequence of arrests for cannabis possession. There may be arguments with spouses or parents over the possession of cannabis in the home or its use in the presence of children. When psychological or physical problems are associated with cannabis in the context of compulsive use, a diagnosis of Cannabis Dependence, rather than Cannabis Abuse, should be considered.

Individuals with Cannabis Dependence have compulsive use and associated problems. Tolerance to most of the effects of cannabis has been reported in individuals who use cannabis chronically. There have also been some reports of withdrawal symptoms, but their clinical significance is uncertain. There is some evidence that a majority of chronic users of cannabinoids report histories of tolerance or withdrawal and that these individuals evidence more severe drug-related problems overall. Individuals with Cannabis Dependence may use very potent cannabis throughout the day over a period of months or years, and they may spend several hours a day acquiring and using the substance. This often interferes with family, school, work, or recreational activities. Individuals with Cannabis Dependence may also persist in their use despite knowledge of physical problems (e.g., chronic cough related to smoking) or psychological problems (e.g., excessive sedation and a decrease in goal-oriented activities resulting from repeated use of high doses).

In addition, DHHS states that marijuana use produces acute and chronic adverse effects on the respiratory system, memory and learning. Regular marijuana smoking produces a number of long-term pulmonary consequences, including chronic cough and sputum (Adams and Martin, 1996), and histopathologic abnormalities in bronchial epithelium (Adams and Martin, 1996). DEA also notes studies suggesting marijuana use leads to evidence of widespread airway inflammation and injury (Roth *et al.*, 1998, Fligiel *et al.*, 1997) and immunohistochemical evidence of dysregulated growth of respiratory epithelial cells that may be precursors to lung cancer (Baldwin *et al.*, 1997). In addition, very large epidemiological studies indicate that marijuana may increase risk of psychosis in vulnerable populations, i.e., individuals predisposed to develop psychosis (Andreasson *et al.*, 1987) and exacerbate psychotic symptoms in individuals with schizophrenia (Schiffman *et al.*, 2005; Hall *et al.*, 2004; Mathers and Ghodse, 1992; Thornicroft, 1990; see Factor 2).

The petitioner cited ''The Missoula Chronic Clinical Cannabis Use Study'' as evidence that long-term use of marijuana does not cause significant harm in patients (Russo *et al.*, 2002). DEA notes that this article describes the case histories and clinical examination of only four patients that were receiving marijuana cigarettes from the National Institute on Drug Abuse for a variety of medical conditions. The number of patients included in the study is not adequate for this evaluation.

The petitioner states, ''Studies have shown the long-term use of cannabis to be safe. In contrast to many other medicinal drugs, the long-term use of cannabis does not harm stomach, liver, kidneys and heart.'' (Exh. C, Section II (10), pg. 66).

However, DHHS states that marijuana has not been shown to have an accepted level of safety for medical use. There have been no NDA-quality studies that have scientifically assessed the full safety profile of marijuana for any medical condition. DEA notes in addition, as described above, the risks associated with chronic marijuana use, including, as described in Factor 2, risks for the cardiovascular and respiratory systems, as well as risks for mental health and cognitive function and risks related to prenatal exposure to marijuana.

Marijuana as a ''Gateway Drug''

A number of studies have examined the widely held premise that marijuana use leads to subsequent abuse of other illicit drugs, thus functioning as a ''gateway drug.'' DHHS discussed a 25-year study of 1,256 New Zealand children, Fergusson *et al.* (2005), which concluded that the use of marijuana correlates to an increased risk of abuse of other drugs. Other studies, however, do not support a direct causal relationship between regular marijuana use and other illicit drug abuse. DHHS cited the IOM report (1999), which states that marijuana is a ''gateway drug'' in the sense that its use typically precedes rather than follows initiation of other illicit drug use. However, as cited by DHHS, the IOM states that, ''[t]here is no conclusive evidence that the drug effects of marijuana are causally linked to the subsequent abuse of other illicit drugs.'' DHHS noted that for most studies that test the hypothesis that marijuana causes abuse of harder drugs, the determinative measure for testing this hypothesis is whether marijuana leads to ''any drug use'' rather than that marijuana leads to ''drug abuse and dependence'' as defined by DSM–IV criteria.

FACTOR 7: ITS PSYCHIC OR PHYSIOLOGICAL DEPENDENCE LIABILITY

DHHS states that many medications that are not associated with abuse or addiction, such as antidepressants, beta-blockers, and centrally acting antihypertensive drugs, can produce physical dependence and withdrawal symptoms after chronic use. However, psychological and physical dependence of drugs that have abuse potential are important factors contributing to increased or continued drug taking. This section provides scientific evidence that marijuana causes physical and psychological dependence.

Physiological (Physical) Dependence in Humans

Physical dependence is a state of adaptation manifested by a drug class-specific withdrawal syndrome produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist (American Academy of Pain Medicine, American Pain Society and American Society of Addiction Medicine consensus document, 2001).

DHHS states that long-term, regular use of marijuana can lead to physical dependence and withdrawal following discontinuation as well as psychic addiction or dependence. The marijuana withdrawal syndrome consists of symptoms such as restlessness, irritability, mild agitation, insomnia, EEG disturbances, nausea, cramping and decrease in mood and appetite that may resolve after 4 days, and may require in-hospital treatment (Haney *et al.*, 1999). It is distinct and mild compared to the withdrawal syndromes associated with alcohol and heroin use (Budney *et al.*, 1999; Haney *et al.*, 1999). DEA notes that Budney *et al.* (1999) examined the withdrawal symptomatology in 54 chronic marijuana abusers seeking treatment for their dependence. The majority of the subjects (85 percent) reported that they had experienced symptoms of at least moderate severity. Fifty seven percent (57 percent) reported having six or more symptoms of a least moderate severity while 47 percent experienced four or more symptoms rated as severe. The most reported mood symptoms associated with the

withdrawal were irritability, nervousness, depression, and anger. Some of the other behavioral characteristics of the marijuana withdrawal syndrome were craving, restlessness, sleep disruptions, strange dreams, changes in appetite, and violent outbursts.

DHHS discusses a study by Lane and Phillips-Bute (1998) which describes milder cases of dependence including symptoms that are comparable to those from caffeine withdrawal, including decreased vigor, increased fatigue, sleepiness, headache, and reduced ability to work. The marijuana withdrawal syndrome has been reported in adolescents who were admitted for substance abuse treatment or in individuals who had been given marijuana on a daily basis during research conditions. Withdrawal symptoms can also be induced in animals following administration of a cannabinoid antagonist after chronic Δ^9-THC administration (Maldonado, 2002; Breivogel *et al.*, 2003). DHHS also discusses a study comparing marijuana and tobacco withdrawal symptoms in humans (Vandrey *et al.*, 2005) which demonstrated that the magnitude and time course of the two withdrawal syndromes are similar.

DHHS states that a review by Budney and colleagues (2004) of studies of cannabinoid withdrawal, with a particular emphasis on human studies, led to the recommendation that the Diagnostic and Statistical Manual of Mental Disorders (DSM) introduce a listing for cannabis withdrawal. In this listing, common symptoms would include anger or aggression, decreased appetite or weight loss, irritability, nervousness/anxiety, restlessness and sleep difficulties including strange dreams. Less common symptoms/equivocal symptoms would include chills, depressed mood, stomach pain, shakiness and sweating.

Psychological Dependence in Humans

In addition to physical dependence, DHHS states that long-term, regular use of marijuana can lead to psychic addiction or dependence. Psychological dependence on marijuana is defined by the American Psychiatric Association in the DSM–IV and cited by DHHS.

The Diagnostic and Statistical Manual of Mental Disorders (DSM–IV) is published by the American Psychiatric Association (2000), and provides diagnostic criteria to improve the reliability of diagnostic judgment of mental disorders by mental health professionals. DSM–IV currently defines ''Cannabis Dependence'' (DSM–IV diagnostic category 304.30) as follows:

Cannabis dependence: A destructive pattern of cannabis use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring when the cannabis use was at its worst:

1. Cannabis tolerance, as defined by either of the following:

a. A need for markedly increased amounts of cannabis to achieve intoxication,

b. Markedly diminished effect with continued use of the same amount of cannabis.

2. Greater use of cannabis than intended: Cannabis was often taken in larger amounts or over a longer period than was intended.

3. Unsuccessful efforts to cut down or control cannabis use: Persistent desire or unsuccessful efforts to cut down or control cannabis use.

4. Great deal of time spent in using cannabis, or recovering from hangovers.

5. Cannabis caused reduction in social, occupational or recreational activities: Important social, occupational, or recreational activities given up or reduced because of cannabis use.

6. Continued using cannabis despite knowing it caused significant problems: Cannabis use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been worsened by cannabis.

In addition, the DSM–IV added a specifier to this diagnostic by which it can be with or without physiological (physical) dependence.

DEA notes additional clinical studies showing that frequency of Δ^9-THC use (most often as marijuana) escalates over time. Individuals increase the number, doses, and potency of marijuana cigarettes. Several studies have reported that patterns of marijuana smoking and increased quantity of marijuana smoked were related to social context and drug availability (Kelly *et al.*, 1994; Mendelson and Mello, 1984; Mello, 1989).

DEA further notes that Budney *et al.* (1999) reported that 93 percent of marijuana-dependent adults seeking treatment reported experiencing mild craving for marijuana, and 44 percent rated their past craving as severe. Craving for marijuana has also been documented in marijuana users not seeking treatment (Heishman *et al.*, 2001). Two hundred seventeen marijuana users completed a 47-item Marijuana Craving Questionnaire and forms assessing demographics, drug use history, marijuana-quit attempts and current mood. The results indicate that craving for marijuana was characterized by 1) the inability to control marijuana use (compulsivity); 2) the use of marijuana in anticipation of relief from withdrawal or negative mood (emotionality); 3) anticipation of positive outcomes from smoking marijuana (expectancy); and 4) intention and planning to use marijuana for positive outcomes (purposefulness).

In summary, long-term, regular use of marijuana can lead to physical dependence and withdrawal following discontinuation as well as psychic addiction or dependence.

FACTOR 8: WHETHER THE SUBSTANCE IS AN IMMEDIATE PRECURSOR OF A SUBSTANCE ALREADY CONTROLLED UNDER THE CSA

Marijuana is not an immediate precursor of any controlled substance.

DETERMINATION

After consideration of the eight factors discussed above and of DHHS's recommendation, DEA finds that marijuana meets the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(1):

1. Marijuana has a high potential for abuse

Marijuana is the most highly abused and trafficked illicit substance in the United States. Approximately 16.7 million individuals in the United States (6.6 percent of the United States population) used marijuana monthly in 2009. A 2009 national survey that tracks drug use trends among high school students showed that by 12th grade, 32.8 percent of students reported having used marijuana in the past year, 20.6 percent reported using it in the past month, and 5.2 percent reported having used it daily in the past month. Its widespread availability is being fueled by increasing marijuana production domestically and increased trafficking from Mexico and Canada.

Marijuana has dose-dependent reinforcing effects that encourage its abuse. Both clinical and preclinical studies have clearly demonstrated that marijuana and its principle psychoactive constituent, Δ^9-THC, possess the pharmacological attributes associated with drugs of abuse. They function as discriminative stimuli and as positive reinforcers to maintain drug use and drug-seeking behavior.

Significant numbers of chronic users of marijuana seek substance abuse treatment. Compared to all other specific drugs included in the 2008 NSDUH survey, marijuana had the highest levels of past year dependence and abuse.

2. Marijuana has no currently accepted medical use in treatment in the United States

DHHS states that the FDA has not evaluated nor approved an NDA for marijuana. The long-established factors applied by DEA for determining whether a drug has a ''currently accepted medical use'' under the CSA are as follows. A drug will be deemed to have a currently accepted medical use for CSA purposes only if all of the following five elements have been satisfied. As set forth below, none of these elements has been fulfilled:

i. The drug's chemistry must be known and reproducible

Although the structures of many cannabinoids found in marijuana have been characterized, a complete scientific analysis of all the chemical components found in marijuana has not been conducted. Furthermore, many variants of the marijuana plant are found due to its own genetic plasticity and human manipulation.

ii. There must be adequate safety studies

Safety studies for acute or sub-chronic administration of marijuana have been carried out through a limited number of Phase I clinical investigations approved by the FDA, but there have been no NDA-quality studies that have scientifically assessed the full safety profile of marijuana for any medical condition. Large, controlled studies have not been conducted to evaluate the risk-benefit ratio of marijuana use, and any potential benefits attributed to marijuana use currently do not outweigh the known risks.

iii. There must be adequate and well-controlled studies proving efficacy

DHHS states that there have been no NDA-quality studies that have scientifically assessed the efficacy of marijuana for any medical condition. To establish accepted medical use, the effectiveness of a drug must be established in well-controlled, well-

designed, well-conducted, and well-documented scientific studies, including studies performed in a large number of patients. To date, such studies have not been performed for any indications.

Small clinical trial studies with limited patients and short duration are not sufficient to establish medical utility. Studies of longer duration are needed to fully characterize the drug's efficacy and safety profile. Scientific reliability must be established in multiple clinical studies. Anecdotal reports and isolated case reports are not sufficient evidence to support an accepted medical use of marijuana. The evidence from clinical research and reviews of earlier clinical research does not meet the requisite standards.

iv. The drug must be accepted by qualified experts

At this time, it is clear that there is no consensus of opinion among experts concerning medical applications of marijuana. To date, research on the medical use of marijuana has not progressed to the point that marijuana can be considered to have a ''currently accepted medical use'' or a ''currently accepted medical use with severe restrictions.

v. The scientific evidence must be widely available

DHHS states that the scientific evidence regarding the safety and efficacy of marijuana is typically available only in summarized form, such as in a paper published in the medical literature, rather than in a raw data format. In addition, as noted, there have only been a limited number of small clinical trials and no controlled, large scale, clinical trials have been conducted with marijuana on its efficacy for any indications or its safety.

3. There is a lack of accepted safety for use of marijuana under medical supervision

At present, there are no FDA-approved marijuana products, nor is marijuana under NDA evaluation at the FDA for any indication. Marijuana does not have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. The Center for Medicinal Cannabis Research in California, among others, is conducting research with marijuana at the IND level, but these studies have not yet progressed to the stage of submitting an NDA. Current data suggest that marijuana use produces adverse effects on the respiratory system, memory and learning. Marijuana use is associated with dependence and addiction. In addition, very large epidemiological studies indicate that marijuana use may be a causal factor for the development of psychosis in individuals predisposed to develop psychosis and may exacerbate psychotic symptoms in individuals with schizophrenia. Thus, at this time, the known risks of marijuana use have not been shown to be outweighed by specific benefits in well-controlled clinical trials that scientifically evaluate safety and efficacy. In sum, at present, marijuana lacks an acceptable level of safety even under medical supervision.

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H.R. 2279/P.L. 112–21

Airport and Airway Extension Act of 2011, Part III (June 29, 2011; 125 Stat. 233)

S. 349/P.L. 112–22

To designate the facility of the United States Postal Service located at 4865 Tallmadge Road in Rootstown, Ohio, as the "Marine Sgt. Jeremy E. Murray Post Office". (June 29, 2011; 125 Stat. 236)

S. 655/P.L. 112–23

To designate the facility of the United States Postal Service located at 95 Dogwood Street in Cary, Mississippi, as the "Spencer Byrd Powers, Jr. Post Office". (June 29, 2011; 125 Stat. 237)

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